Filed Pursuant to Rule 424(b)(4)
Registration Nos. 333-229590
333-230110

5,700,000 Shares

Common Stock

This is the initial public offering of shares of common stock of ShockWave Medical, Inc.

We are offering 5,700,000 shares of our common stock. Prior to this offering, there has been no public market for our common stock. The initial public offering price of our common stock is $17.00 per share. We have been approved to list our common stock on the Nasdaq Global Select Market under the symbol â€œSWAV.â€

We are an emerging growth company under the federal securities laws and will be subject to reduced public company reporting requirements. See â€œProspectus Summaryâ€”Implications of Being an Emerging Growth Company.â€

Investing in our common stock involves a high degree of risk. See â€˜â€˜Risk Factorsâ€™â€™ beginning on page 14.

	Per Share	Total
Initial public offering price	$17.00	$96,900,000
Underwriting discounts and commissions(1)	$ 1.19	$ 6,783,000
Proceeds, before expenses, to us	$15.81	$90,117,000

(1) See â€œUnderwritingâ€ for additional disclosure regarding the underwriting discounts and commissions and estimated offering expenses.

On the date of this prospectus, one of our existing investors, Abiomed, Inc., exercised its option to purchase up to an aggregate of approximately $10.0 million in our common stock in a concurrent private placement at a price per share equal to $17.00. The sale of shares in the concurrent private placement will not be registered under the Securities Act of 1933, as amended. The closing of this offering is not conditioned upon the closing of the concurrent private placement. The shares of common stock purchased in the concurrent private placement will not be subject to any underwriting discounts or commissions.

We have granted the underwriters the right to purchase up to an additional 855,000 shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver the shares against payment in New York, New York on March 11, 2019.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

Morgan Stanley **BofA Merrill Lynch**

Wells Fargo Securities **Canaccord Genuity**

March 6, 2019

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We and the underwriters have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may provide you. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock.

This prospectus includes industry and market data that we obtained from periodic industry publications, third-party studies and surveys, filings of public companies in our industry and internal company surveys. These sources may include government and industry sources. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. Although we believe the industry and market data to be reliable as of the date of this prospectus, this information could prove to be inaccurate. Industry and market data could be wrong because of the method by which sources obtained their data and because information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties. In addition, we do not know all of the assumptions regarding general economic conditions or growth that were used in preparing the forecasts from the sources relied upon or cited herein.

Certain market and industry data used in this document, where noted, is attributable to Millennium Research Group, Inc. (â€œMRGâ€). MRG asserts copyright protection over the use of such information and reserves all rights with respect to its use. This information has been reprinted with MRGâ€™s permission and the reproduction, distribution, transmission or publication of such information is prohibited without its consent.

Until March 31, 2019 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealersâ€™ obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary may not contain all of the information that you should consider before deciding to invest in our common stock. You should read this entire prospectus carefully, including the â€œRisk Factorsâ€ section and the consolidated financial statements and the notes to those statements. Except as otherwise indicated herein or as the context otherwise requires, â€œShockWave Medical,â€ â€œShockWave Medical, Inc.,â€ the â€œCompany,â€ â€œwe,â€ â€œusâ€ and â€œourâ€ refer to ShockWave Medical, Inc. and its consolidated subsidiary.

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 through our differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which we refer to as intravascular lithotripsy (â€œIVLâ€). Our IVL system (our â€œIVL Systemâ€), which leverages our IVL technology (our â€œIVL Technologyâ€), is a minimally invasive, easy-to-use and safe way to significantly improve patient outcomes. Our Shockwave M5 IVL catheter (â€œM5 catheterâ€) was CE-Marked in April 2018 and cleared by the U.S. Food and Drug Administration (â€œFDAâ€) in July 2018 for use in our IVL System for the treatment of peripheral artery disease (â€œPADâ€). Our Shockwave C2 IVL catheter (â€œC2 catheterâ€), which we are currently marketing in Europe, was CE-Marked in June 2018 for use in our IVL System for the treatment of coronary artery disease (â€œCADâ€). We 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, we are undertaking ongoing clinical trials of our C2 catheter intended to support a pre-market application (â€œPMAâ€) in the United States and a Shonin submission in Japan for the treatment of CAD. We anticipate having final data from these ongoing clinical trials intended to support a U.S. launch of our C2 catheter in the first half of 2021 and a Japan launch in the second half of 2021.

The Opportunity

Atherosclerosis is a common disease of aging in which arteries become narrowed (â€œstenoticâ€) 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 (â€œdeepâ€ or â€œmedialâ€ calcium) and close to the inner surface of the artery (â€œsuperficialâ€ or â€œintimalâ€ 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 Aortic Stenosis (â€œASâ€), a condition in which the heartâ€™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 â€œcalciumâ€ 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 MRG. The most common treatment for patients is percutaneous coronary intervention (â€œPCIâ€). This involves a suite of devices to facilitate successful angioplasty and stenting, the most commonly used device being drug-eluting stents (â€œDESâ€). 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 in which 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 (â€œAVRâ€), the main treatment for AS, is growing rapidly, and is dominated by the emergence of Transcatheter Aortic Valve Replacement (â€œTAVRâ€) devices. 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 (â€œballoonsâ€), drug-coated balloons (â€œDCBâ€), 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

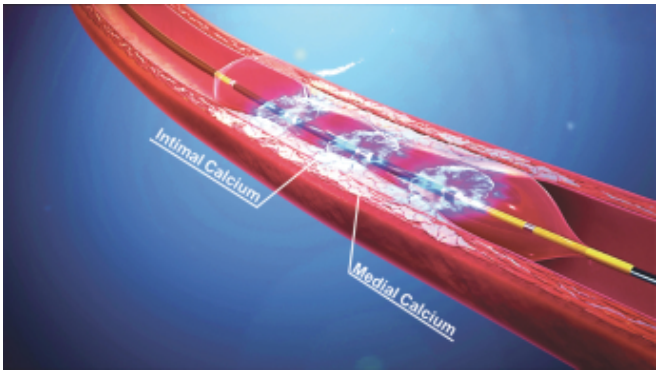
cardiovascular disease, thereby reducing the clinical benefit of angioplasty and stent therapies compared to their use in non-calcified anatomies.

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. 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 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 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 family of IVL catheters designed to treat PAD and CAD. Our IVL System employs our IVL Technology to crack calcium through short 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 (â€œatmâ€) (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.

Our Products and Ongoing Development

The interchangeability of specific catheters enables delivery of IVL therapy of diseased vasculature throughout the body. Our IVL catheters are cleared or approved for use in a number of geographies. Development programs are underway to expand indications and geographies:

- â€¢ M5 catheters (â€œmediumâ€ vessel, five-emitters): for treating above-the-knee PAD in the United States and internationally.
- â€¢ C2 catheters (coronary, two-emitters): for treating CAD in select international markets. We received an investigational device exemption (â€œIDEâ€) to conduct a pivotal global study, which is intended to support U.S. FDA and Japanese Shonin approval of the device. We commenced enrollment of the study in early 2019.
- â€¢ S4 catheter (â€œsmallâ€ vessel, four-emitters): for treating PAD Below-the-Knee (â€œBTKâ€) in the United States, Europe and select international markets. We have 510(k) clearance and CE Mark and we are currently engaged in a limited market evaluation of the product to test its performance in the heavily calcified and challenging BTK environment.

Our IVL catheters resemble in form and function 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.

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 AS.

Since inception, we have focused on generating clinical data to demonstrate the safety and effectiveness of our IVL Technology. These initial studies have consistently delivered 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 demonstrated that our IVL Technology reduces residual stenosis and vascular complications in infrapopliteal and femoropopliteal PAD, with outstanding durability and sustained improvement in functional outcome in 115 patients. Our past studies have also guided optimal IVL procedure technique and informed the design of our IVL System and future products in development. In the treatment of CAD, our past studies have demonstrated both safety and effectiveness of our IVL System in heavily calcified coronary lesions prior to stenting in 60 patients. Feasibility studies have shown the potential of our transcatheter aortic valve lithotripsy system (our â€œTAVL Systemâ€) to safely improve the aortic valve area and reduce transvalvular gradients in AS. We are currently enrolling patients in multiple studies to support applications for and clearances in a variety of indications and geographies, as well as a randomized trial to assess the combination of IVL with DCB for treating PAD.

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, and we have complemented those direct teams with distributors, including in Australia, the Baltics, Canada, Czech Republic, France, Italy, the Netherlands, New Zealand, the Nordic region, Poland, Spain and the United Kingdom. We are actively expanding our international field presence through new distributors, additional sales and clinical personnel, and are adding new U.S. sales territories.

For the treatment of CAD, our C2 catheter has a CE Mark that indicates its use in calcified, stenotic *de novo* coronary arteries prior to stenting. For the treatment of PAD, our M5 and S4 catheters have a CE Mark and have FDA clearances that indicate their use in calcified, stenotic peripheral arteries in patients who are candidates for percutaneous therapy. Our products are not indicated for the treatment of cerebrovascular or carotid arteries; our M5 and S4 catheters are not indicated for the treatment of coronary arteries.

While 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.

Why ShockWave?

Safe - Simple - Effective

- â€¢ Treatment of both superficial and deep calcium.
- â€¢ Improved safety through unique mechanism of action.
- â€¢ Improved efficacy for angioplasty, stents and drug-eluting technologies.
- â€¢ Seamless integration into interventional practice with exceptional ease-of-use.
- â€¢ 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.

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

Recent Developments

There are a number of recent events which we believe will serve as near-term catalysts for our business and position us for long-term success.

- â€¢ We received IDE approval for our DISRUPT CAD III global study, which began enrollment in 2019. This study is designed to support U.S. PMA approval for our C2 catheters.
- â€¢ In December 2018, we entered into a collaboration with Abiomed, a leading global provider of medical devices that provide circulatory support. Pursuant to this collaboration, we will work with Abiomed to integrate our products into Abiomedâ€™s physician training and education programs. In connection with the collaboration, Abiomed purchased shares of our Series D convertible preferred stock.

Risks Associated With Our Business

Our business is subject to numerous risks, as more fully described in the section titled â€œRisk Factorsâ€ immediately following this prospectus summary. You should read these risks before you invest in our common stock. In particular, risks associated with our business include, but are not limited to, the following:

- â€¢ 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.
- â€¢ We currently have limited commercialization, sales or marketing experience. If we are unable to establish effective sales and marketing capabilities or if we are unable to enter into agreements with third parties to commercialize our products, we may not be able to effectively generate product revenue, sustain revenue growth and compete effectively.
- â€¢ 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.
- â€¢ We currently manufacture and sell products used in a limited number of procedures, which could negatively affect our operations and financial condition.
- â€¢ For our company to thrive, we must lead and benefit from a shift in thinking about the role of calcified lesions in our core disease areas.
- â€¢ The continuing development of our products depends upon our maintaining strong working relationships with physicians.
- â€¢ 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.
- â€¢ If we fail to comply with U.S. federal and state 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.
- â€¢ 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.
- â€¢ 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.
- â€¢ 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 our guidance.

Concurrent Private Placement

On March 6, 2019, one of our existing investors, Abiomed, Inc., exercised its option to purchase up to an aggregate of approximately $10.0 million of shares in our common stock (or 588,235 shares) at the initial public offering price of $17.00 per share, in a concurrent private placement (the â€œConcurrent Private Placementâ€). The sale of shares in the Concurrent Private Placement will not be registered under the Securities Act of 1933, as amended (the â€œSecurities Actâ€). The closing of this offering is not conditioned upon the closing of the Concurrent Private Placement. The shares of common stock purchased in the Concurrent Private Placement will not be subject to any underwriting discounts or commissions. The Concurrent Private Placement is expected to close on March 11, 2019.

Reverse Stock Split

Our board of directors and stockholders approved a 12.2-for-one reverse stock split of our common stock and convertible preferred stock, which was effected on February 22, 2019. All references to common stock, convertible preferred stock, warrants to purchase common stock, warrants to purchase convertible preferred stock, options to purchase common stock, early exercised options, share data, per share data and related information have been retrospectively adjusted where applicable in this prospectus to reflect the reverse stock split of our capital stock as if it had occurred at the beginning of the earliest period presented.

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 prospectus. We have included our website address as an inactive textual reference only.

We use â€œShockwave,â€ â€œShockwave M5,â€ â€œShockwave C2,â€ â€œShockwave S4â€ and other marks as trademarks in the United States and other countries. This prospectus 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 prospectus, including logos, artwork, and other visual displays, may appear without the Â® or â„¢ 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 entitiesâ€™ trade names, trademarks, or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Implications of Being an Emerging Growth Company

We are an â€œemerging growth company,â€ as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earliest to occur of: the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; the date we qualify as a â€œlarge accelerated filer,â€ with at least $700 million of equity securities held by non-affiliates; the issuance, in any three-year period, by us of more than $1 billion in non-convertible debt securities; and the last day of the fiscal year ending after the fifth anniversary of our initial public offering. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the â€œJOBS Act,â€ and any reference herein to â€œemerging growth companyâ€ has the meaning ascribed to it in the JOBS Act.

An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- â€¢ being permitted to present only two years of audited financial statements and only two years of related Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- â€¢ not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- â€¢ reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- â€¢ exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and may elect to take advantage of other reduced reporting requirements in our future filings with the U.S. Securities and Exchange Commission (the â€œSECâ€). As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

THE OFFERING

Common stock offered by us	5,700,000 shares.
Underwritersâ€™ over-allotment option	855,000 shares.
Common stock to be outstanding immediately after this offering	26,906,762 shares (or 27,761,762 shares, if the underwriters exercise their over-allotment option in full), which includes 588,235 shares to be issued in the Concurrent Private Placement.
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $86.9 million, or approximately $100.4 million if the underwriters exercise their over-allotment option in full, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We expect to use the net proceeds from this offering for sales and marketing activities to support the ongoing commercialization of our IVL System, including, but not limited to, the expansion of our sales force, additional medical affairs and educational efforts and the expansion of our international sales presence, for research and development and clinical studies and for working capital and general corporate purposes. We may also use a portion of the net proceeds of this offering for acquisitions or strategic transactions, though we have not entered into any agreements or commitments with respect to any specific transactions and have no understandings or agreements with respect to any such transactions at this time. See the section titled â€œUse of Proceedsâ€ for additional information. The foregoing use of proceeds discussion excludes the anticipated net proceeds from the Concurrent Private Placement. We estimate that the net proceeds from the Concurrent Private Placement will be an aggregate of approximately $10.0 million. We intend to use the net proceeds from the Concurrent Private Placement for working capital and general corporate purposes. The sale of shares in the Concurrent Private Placement will not be registered under the Securities Act. The closing of this offering is not conditioned upon the closing of the Concurrent Private Placement. The Concurrent Private Placement is expected to close on March 11, 2019.
Directed share program	At our request, the underwriters have reserved for sale at the initial public offering price, up to 3% of the shares offered hereby for our directors, officers and certain employees and other persons with whom we

	have a relationship. See â€œUnderwritingâ€ for more information.
Concurrent Private Placement	Our Series D convertible preferred stockholder, Abiomed Inc., exercised its option to purchase up to $10.0 million of shares in our common stock (or 588,235 shares) at $17.00 per share in the Concurrent Private Placement. Northgate Technologies, Inc. (together with its affiliates, â€œNorthgateâ€) waived its right to participate in the Concurrent Private Placement pursuant to our Exclusive License Agreement with Northgate dated as of June 23, 2011 (the â€œLicense Agreementâ€). The sale of shares in the Concurrent Private Placement will not be registered in this offering. The closing of this offering is not conditioned upon the closing of the Concurrent Private Placement. The shares of common stock purchased in the Concurrent Private Placement will not be subject to any underwriting discounts or commissions. The Concurrent Private Placement is expected to close on March 11, 2019.
Risk factors	You should read the section titled â€œRisk Factorsâ€ in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Nasdaq Global Select Market symbol	â€œSWAV.â€

The number of shares of common stock to be outstanding immediately after this offering is based upon 20,618,527 shares (including our convertible preferred stock on an as-converted basis and net exercise of certain outstanding warrants) outstanding as of December 31, 2018, which excludes:

- â€¢ 3,636,224 shares of our common stock issuable upon the exercise of options outstanding as of December 31, 2018, with a weighted-average exercise price of $3.50 per share;
- â€¢ 119,667 shares of our common stock issuable upon the exercise of options granted after December 31, 2018, with an exercise price of $6.59 per share;
- â€¢ 54,903 shares of our Series A-1 convertible preferred stock issuable upon the exercise of our Series A-1 convertible preferred stock warrant outstanding as of December 31, 2018, with an exercise price of $3.09636 per share;
- â€¢ 34,440 shares of our common stock issuable upon the exercise of our common stock warrants outstanding as of December 31, 2018, with an exercise price of $4.026 per share;
- â€¢ 22,216 shares of our common stock issued upon the net exercise of preferred stock warrants;
- â€¢ 588,235 shares of our common stock issuable in the Concurrent Private Placement;
- â€¢ 306,316 shares of our common stock issuable upon the exercise of options that we granted under our 2019 Equity Incentive Plan upon the pricing of this offering to our directors, executive officers and certain other employees at an exercise price equal to the initial public offering price of this offering;
- â€¢ 1,694,114 additional shares of our common stock reserved for future issuance under our 2019 Equity Incentive Plan, which became effective as of the date of the effectiveness of the registration statement

of which this prospectus forms a part, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to this plan; and

- 300,650 shares of our common stock initially reserved for issuance under our Employee Stock Purchase Plan (the â€œESPPâ€), which became effective as of the date of the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to this plan.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- the automatic conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 18,670,259 shares of our common stock immediately prior to the completion of this offering;
- outstanding shares include 13,421 shares of our common stock issued upon the early exercise of stock options and subject to repurchase;
- the automatic conversion of our outstanding Series A-1 convertible preferred stock warrant into a warrant to purchase 54,903 shares of our common stock upon the completion of this offering, with an exercise price of $3.09636 per share;
- the net exercise of outstanding warrants to purchase 141,777 shares of our common stock immediately prior to the completion of this offering that would otherwise expire upon completion of this offering, with an exercise price of $2.196 per share, which will result in the issuance of 123,461 shares of our common stock based on the initial public offering price of $17.00 per share;
- no exercise of outstanding options or warrants, other than as described in the fourth bullet above;
- no exercise by the underwriters of their over-allotment option;
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws immediately upon the completion of this offering; and
- a 12.2-for-one reverse stock split of our common stock and convertible preferred stock, which was effected on February 22, 2019.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables summarize our consolidated financial data. We have derived the summary consolidated statements of operations data for the years ended December 31, 2017 and 2018 from our audited consolidated financial statements included elsewhere in this prospectus. We have derived our balance sheet data as of December 31, 2017 and 2018 from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The following summary consolidated financial data should be read in conjunction with the section titled â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€ and our consolidated financial statements and related notes included elsewhere in this prospectus.

	Years Ended December 31,	
	2017	2018
	(in thousands, except share and per share data)	
Consolidated Statements of Operations Data:		
Product revenue	$ 1,719	$ 12,263
Operating expenses:		
Cost of product revenue	2,836	7,250
Research and development	17,963	22,698
Sales and marketing	6,363	17,536
General and administrative	5,422	5,979
Total operating expenses	32,584	53,463
Loss from operations	(30,865)	(41,200)
Interest and other income, net	276	136
Net loss before taxes	(30,589)	(41,064)
Income tax provision	26	38
Net loss	(30,615)	(41,102)
Net loss per share, basic and diluted(1)	$ (19.71)	$ (23.39)
Weighted-average shares used in computing net loss per share, basic and diluted(1)	1,553,365	1,757,102
Pro forma net loss per share, basic and diluted (unaudited)(1)		$ (2.10)
Weighted-average shares used in computing pro forma net loss per share, basic and diluted (unaudited) (1)		19,528,258

(1) See Notes 2 and 12 to our audited consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share and unaudited pro forma net loss per share and the weighted-average number of shares used in the computation of the per share amounts.

	As of December 31, 2018		
	Actual	Pro Forma(1)	Pro Forma as Adjusted(2)
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 39,643	$ 39,643	$ 137,200
Working capital	39,365	39,365	137,815
Total assets	53,421	53,421	149,459
Long-term debt, current and non-current	15,050	15,050	15,050
Convertible preferred stock warrant liability	313	â€”	â€”
Convertible preferred stock	152,806	â€”	â€”
Accumulated deficit	(126,865)	(126,865)	(126,865)
Total stockholdersâ€™ (deficit) equity	(122,588)	30,531	127,462

(1) The pro forma consolidated balance sheet data gives effect to: (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of December 31, 2018 into an aggregate of 18,670,259 shares of our common stock immediately prior to the completion of this offering; (ii) the issuance of 123,461 shares of our common stock, based on the initial public offering price of $17.00 per share upon the net exercise of warrants outstanding as of December 31, 2018 for the purchase of 141,777 shares of our common stock that would otherwise expire upon the completion of this offering; (iii) the filing and effectiveness of our amended and restated certificate of incorporation and the retirement of our authorized convertible preferred stock that will convert to common stock as set forth in clause (i); and (iv) the reclassification of the convertible preferred stock warrant liability to additional paid-in capital, a component of total stockholdersâ€™ (deficit) equity, due to our convertible preferred stock warrant converting to a warrant to purchase our common stock immediately prior to the completion of this offering.

(2) The pro forma as adjusted balance sheet data gives effect to: (i) the pro forma adjustments set forth in footnote (1) above; (ii) the issuance and sale of shares of our common stock in this offering at the initial public offering price of $17.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us; (iii) the issuance and sale of our common stock in the Concurrent Private Placement at the initial public offering price of $17.00 per share; and (iv) the reclassification of $1.5 million of deferred offering costs recorded in other assets on the consolidated balance sheet as of December 31, 2018 to additional paid-in capital, a component of total stockholdersâ€™ (deficit) equity. The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as all of the other information contained in this prospectus, 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. If any of the following risks materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to Our Business and Products

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. We have reported net losses of $30.6 million and $41.1 million for the years ended December 31, 2017 and 2018, respectively. As a result of these losses, as of December 31, 2018, we had an accumulated deficit of approximately $126.9 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 our general and administrative expenses to increase following this offering due to the additional costs 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.

We have a limited commercialization experience.

We were incorporated in 2009 and began commercializing our Shockwave M5 IVL catheter (â€œM5 catheterâ€) for treating peripheral artery disease (â€œPADâ€) in the United States and Europe in 2018 and our Shockwave C2 IVL catheter (â€œC2 catheterâ€) for treating coronary artery disease (â€œCADâ€) in Europe in 2018. Our C2 catheter has not yet been approved or cleared for the treatment of CAD in the United States. 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 successfully complete our Disrupt PAD III, Disrupt CAD II, Disrupt CAD III, Disrupt CAD IV and Transcatheter Aortic Valve Lithotripsy (â€œTAVRâ€) feasibility clinical trials and obtain U.S. Food and Drug Administration (â€œFDAâ€) pre-market approval for, and successfully commercialize, our C2 catheter for the treatment of CAD in the United States or 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.

Our success depends in large part on our intravascular lithotripsy technology (our â€œIVL Technologyâ€). 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:

- â€¢ the actual and perceived effectiveness and reliability of our products, especially relative to alternative products;
- â€¢ the prevalence and severity of any adverse patient events involving our products;
- â€¢ the results of clinical trials relating to the use of our products;
- â€¢ our ability to obtain regulatory approval to market our planned or future products for use in treating PAD, CAD and aortic stenosis (â€œASâ€) in the United States;
- â€¢ the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for conditions treated by our products;
- â€¢ the degree to which treatments using our products are covered and receive adequate reimbursement from third-party payors, including governmental and private insurers;
- â€¢ the degree to which physicians adopt our products;
- â€¢ 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;
- â€¢ achieving and maintaining compliance with all regulatory requirements applicable to our products;
- â€¢ 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;
- â€¢ the strength of our marketing and distribution infrastructure;
- â€¢ the effectiveness of our and our distributorsâ€™ marketing and sales efforts in the United States and abroad, including our efforts to build out our sales team;
- â€¢ the level of education and awareness among physicians and hospitals concerning our products;
- â€¢ our reputation among physicians and hospitals;
- â€¢ our ability to continue to develop, validate and maintain a commercially viable manufacturing process that is compliant with current Good Manufacturing Practices (â€œcGMPâ€) and Quality Systems Regulations (â€œQSRâ€); and
- â€¢ 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 currently manufacture and sell products that are used in a limited number of procedures, which could negatively affect our operations and financial condition.

Currently, our products consist primarily of our IVL System using M5 catheters for the treatment of above-the-knee PAD in the United States and internationally and C2 catheters for the treatment of CAD internationally. 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.

For our company to thrive, we must lead and benefit from a shift in thinking about the role of calcified lesions in our core disease areas.

A shift in thinking in the treatment of our core disease areas is needed for the successful market acceptance of our products. We will need 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.

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 industryâ€™s relationship with physicians is under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General (the â€œOIGâ€), the U.S. Department of Justice (the â€œDOJâ€), the state attorney generals and other foreign and domestic government agencies. Our failure to comply with requirements governing the industryâ€™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 â€œRisks Related to Government Regulation and Our Industry.â€

We currently have limited sales or marketing capabilities. If we are unable to establish effective sales and marketing capabilities or if we are unable to enter into agreements with third parties to commercialize our products, we may not be able to effectively generate product revenue, sustain revenue growth and compete effectively.

We currently have limited sales or marketing capabilities. Our sales were $1.72 million and $12.3 million for the years ended December 31, 2017 and 2018, respectively. 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 we expect to launch our C2 catheters for the treatment of CAD in the United States in the first half of 2021, subject to FDA approval. Building the requisite sales, marketing or distribution capabilities will be expensive and time-consuming and will require significant attention from our leadership team to manage. Any failure or delay in the development of our sales, marketing or distribution capabilities would adversely impact the commercialization of our products. 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. Additionally, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties on the commercialization of our products. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our products.

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.

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

The medical device industry is characterized by rapid and significant 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.

The commercial success of our products will depend upon attaining significant market acceptance of these 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. 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. Healthcare providers must believe that our products offer benefits over alternative treatment methods. The degree of market acceptance of any of our products will depend on a number of factors, including:

- â€¢ whether physicians and others in the medical community consider our products to be safe and cost effective treatment methods;
- â€¢ the potential and perceived advantages of our products over alternative treatment methods;
- â€¢ the prevalence and severity of any side effects associated with using our products;

- â€¢ product labeling or product insert requirements by the FDA or other regulatory authorities;
- â€¢ limitations or warnings contained in the labeling cleared or approved by the FDA or other authorities;
- â€¢ the cost of treatment in relation to alternative treatments methods;
- â€¢ the convenience and ease of use of our products relative to alternative treatment methods;
- â€¢ pricing pressure, including from group purchasing organizations (â€œGPOsâ€), seeking to obtain discounts on our products based on the collective buying power of the GPO members;
- â€¢ a substantial shift in the number of PAD procedures that are performed in office-based labs (â€œOBLsâ€) compared to those performed in a hospital as OBLs tend to have higher price sensitivity than hospitals;
- â€¢ the availability of coverage and adequate reimbursement for procedures using our products from third-party payors, including government authorities;
- â€¢ the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors, including government authorities;
- â€¢ 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
- â€¢ 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 Shockwave S4 IVL catheters (â€œS4 catheterâ€) after seeing a higher instance of leaks in the balloon, which prevented the balloon from staying inflated at 4 atmospheres (â€œatmâ€) 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 productâ€™s launch can have lasting negative impact on our ability to sell such product.

In addition, 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.

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 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 have limited experience in commercially manufacturing our products and no experience manufacturing 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 substantially 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 competitorsâ€™ products, which would have a material adverse effect on our business, financial condition and results of operations.

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

There are numerous approved products for treating vascular diseases in the indications in which we have received clearance or approval and those that we are pursuing or may pursue in the future. Many of these cleared or approved products are well-established and are widely accepted by physicians, patients and third-party payors. Third-party payors may encourage the use of competitorsâ€™ 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. Our most notable competitors in the highly competitive cardiovascular field include 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:

- â€¢ significantly greater name recognition;
- â€¢ broader or deeper relations with healthcare professionals, customers and third-party payors;

- â€¢ more established distribution networks;
- â€¢ 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;
- â€¢ greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- â€¢ 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:

- â€¢ develop innovative, proprietary products that can cost-effectively address significant clinical needs;
- â€¢ continue to innovate and develop scientifically advanced technology;
- â€¢ obtain and maintain regulatory clearances or approvals;
- â€¢ demonstrate efficacy in our sponsored and third-party clinical trials and studies;
- â€¢ apply our technology across product lines and markets;
- â€¢ attract and retain skilled research and development and sales personnel; and
- â€¢ 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.

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:

- â€¢ the level of demand for our products and any approved products, which may vary significantly;
- â€¢ expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- â€¢ the timing and cost of obtaining regulatory approvals or clearances for planned or future products or indications;
- â€¢ 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;

- â€¢ 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;
- â€¢ coverage and reimbursement policies with respect to our products, if approved, and potential future products that compete with our products;
- â€¢ the timing and success or failure of preclinical studies or clinical trials for our products or any future products we develop or competing products;
- â€¢ 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;
- â€¢ 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 to become more pronounced in the future as our business grows;
- â€¢ 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;
- â€¢ 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
- â€¢ 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.

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.

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

We currently market and sell our M5 catheters for the treatment of calcified plaque in patients with PAD in the United States and international markets and our C2 catheters for the treatment of calcified plaque in patients with CAD in Europe. However, our strategy is to market and sell our products for the treatment of CAD in the United States, upon approval or clearance from the FDA, and also to pursue additional vascular indications for our products. Conducting clinical studies to obtain data for new or additional indications may require substantial additional funding beyond the net proceeds of this offering. 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.

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 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. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching an agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board approval at each site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials.

We cannot provide any assurance that we will successfully, or in a timely manner, enroll our clinical trials, that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities.

We may experience numerous unforeseen events during, or because of, the 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:

- â€¢ enrollment in our clinical trials may be slower than we anticipate, or we may experience high screen failure rates in our clinical trials, resulting in significant delays;
- â€¢ 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;
- â€¢ trial results may not meet the level of statistical significance required by the FDA or other regulatory authorities;
- â€¢ the FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans;
- â€¢ the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;
- â€¢ there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities;
- â€¢ there may be delays in obtaining institutional review board approvals or governmental approvals to conduct clinical trials at prospective sites;
- â€¢ the FDA or similar foreign regulatory authorities may find our or our suppliersâ€™ manufacturing processes or facilities unsatisfactory;
- â€¢ the FDA or similar foreign regulatory authorities may change their review policies or adopt new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications;
- â€¢ we may have trouble in managing multiple clinical sites;
- â€¢ we may have trouble finding patients to enroll in our trials;
- â€¢ we may experience delays in agreeing on acceptable terms with third-party research organizations and trial sites that may help us conduct the clinical trials; and
- â€¢ we, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks.

Failures or perceived failures in our clinical trials will delay and may prevent our product development and regulatory approval process, damage our business prospects and negatively affect our reputation and competitive position.

Clinical trials may be delayed, suspended or terminated for many reasons, which will increase our expenses and delay the time it takes to develop new products or seek new indications.

We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate

number of patients on time or be completed on schedule, if at all. The commencement and completion of clinical trials for future products or indications may be delayed, suspended or terminated as a result of many factors, including:

- â€¢ the FDA or other regulators disagreeing as to the design, protocol or implementation of our clinical trials;
- â€¢ the delay or refusal of regulators or institutional review boards (â€œIRBsâ€) to authorize us to commence a clinical trial at a prospective trial site;
- â€¢ changes in regulatory requirements, policies and guidelines;
- â€¢ delays or failure to reach agreement on acceptable terms with prospective clinical research organizations (â€œCROsâ€) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- â€¢ delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- â€¢ the inability to enroll a sufficient number of patients in trials to observe statistically significant treatment effects in the trial;
- â€¢ having clinical sites deviate from the trial protocol or dropping out of a trial;
- â€¢ negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we expect to be promising;
- â€¢ safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- â€¢ reports from preclinical or clinical testing of other similar therapies that raise safety or efficacy concerns;
- â€¢ regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- â€¢ lower than anticipated retention rates of patients and volunteers in clinical trials;
- â€¢ our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- â€¢ delays relating to adding new clinical trial sites;
- â€¢ difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- â€¢ the quality of the products falling below acceptable standards;
- â€¢ the inability to manufacture sufficient quantities of our products to commence or complete clinical trials; and
- â€¢ exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or the Ethics Committees of institutions at which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, including the FDAâ€™s current Good Clinical Practice (â€œGCPâ€), regulations, or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate safety and effectiveness, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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.

If we experience delays in the commencement or completion of any clinical trial of our products, or if any of our clinical trials are terminated, the commercial prospects of our products may be harmed, and our ability to generate revenue from sales may be delayed or materially diminished.

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. 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.

We may be required to suspend or discontinue clinical trials due to side effects or other safety risks that could preclude approval of our products.

Our clinical trials may be suspended at any time for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to participants.

Our ability to market our current products is limited to the treatment of PAD in the United States and internationally and limited to the treatment in CAD in certain countries outside of the United States. If we want to market our products for further uses in the United States, we will need to file for FDA clearances or approvals and may need to conduct trials in addition to our existing trials to support expanded use, which would be expensive and time-consuming and may not be successful. 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 current products are cleared in the United States solely for the treatment of PAD and in certain non-U.S. jurisdictions solely for the treatment of PAD and CAD. This prohibits our ability to market or advertise our products for any other indication, which restricts our ability to sell these products and could affect 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 â€œoff-labelâ€ use. We cannot prevent a physician from using our products for off-label use, as the FDA does not restrict or regulate a physicianâ€™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 or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, disgorgement of profits, a civil fine 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 uncleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. 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 a civil fine 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 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.

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.

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 inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. Since our inception, our operations have been financed primarily by net proceeds from the sale of our convertible preferred stock, indebtedness and, to a lesser extent, product revenue. As of December 31, 2018, we had $39.6 million in cash and cash equivalents, and an accumulated deficit of $126.9 million. Based on our current planned operations, we expect our cash and cash equivalents, together with available borrowings under our current revolving line of credit from our Loan and Security Agreement with Silicon Valley Bank (the â€œ2018 Loan and Security Agreementâ€) and the proceeds from this offering, 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 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 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 incur additional 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:

- â€¢ the cost, timing and results of our clinical trials and regulatory reviews;
- â€¢ the cost and timing of establishing sales, marketing and distribution capabilities;
- â€¢ the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- â€¢ the timing, receipt and amount of sales from our current and potential products;
- â€¢ the degree of success we experience in commercializing our products;
- â€¢ the emergence of competing or complementary technologies;
- â€¢ the cost of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights; and
- â€¢ 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 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 stockholdersâ€™ 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.

The terms of the 2018 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.

The 2018 Loan and Security Agreement, entered into in February 2018, provides for a $2.0 million revolving line of credit and a $15.0 million term loan. The loan is secured by all our assets, excluding intellectual property and certain other assets. Subject to the terms of the 2018 Loan and Security Agreement, amounts borrowed under the revolving line and term loan can be repaid at any time, subject to certain penalty payments, prior to the February 26, 2021 maturity date and December 1, 2021 maturity date, respectively, at which time all amounts borrowed will be due and payable. In connection with the 2018 Loan and Security Agreement, Silicon Valley Bank was concurrently issued a common stock warrant that entitles 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. The 2018 Loan and Security Agreement contains a number of restrictive covenants, and the terms 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 â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€”Liquidity and Capital Resourcesâ€”Debt obligations.â€

The 2018 Loan and Security Agreement contains 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 does not include any financial covenants. If we fail to

comply with the covenants or payments specified in the 2018 Loan and Security Agreement, 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. If the debt under the 2018 Loan and Security Agreement were accelerated, we may not have sufficient cash or be able to sell sufficient assets to repay this debt, which would harm our business and financial condition.

The report of our independent registered public accounting firm includes a â€œgoing concernâ€ explanatory paragraph.

The report of our independent registered public accounting firm on our consolidated financial statements as of and for the year ended December 31, 2018 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. If we are unable to raise sufficient capital in this offering or otherwise when needed, our business, financial condition and results of operations will be materially and adversely affected, and we will need to significantly modify our operational plans to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The inclusion of a going concern explanatory paragraph by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

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 â€œkey manâ€ 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, 2018, we had 162 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:

- â€¢ identifying, recruiting, integrating, maintaining and motivating additional employees;
- â€¢ managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- â€¢ 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 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.

If we fail to grow our sales and marketing capabilities and develop widespread brand awareness cost effectively, our growth will be impeded and our business may suffer.

We are actively expanding our international field presence through new distributors, additional sales and clinical personnel and are adding new U.S. sales territories. We plan to continue to expand and optimize our sales infrastructure in order to grow our customer base and our business. Identifying and recruiting qualified personnel and training them on the use of our products, on applicable federal and state laws and regulations and on our internal policies and procedures, require significant time, expense and attention. It can take significant time before our sales representatives are fully trained and productive. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenue. In particular, if we are unable to hire, develop and retain talented sales personnel or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenue.

Our ability to increase our customer base and achieve broader market acceptance of our products will depend to a significant extent on our ability to expand our marketing operations. We plan to dedicate significant financial and other resources to our marketing programs. Our business would be harmed if our marketing efforts and expenditures do not generate an increase in revenue.

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.

We intend 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.

While most of our revenue has been in the United States, our current products are cleared in certain international markets for the treatment of PAD and CAD, and international sales comprised 43% of our revenue for the year ended December 31, 2018. We intend to increase our sales outside the United States, and our C2 catheters are currently only available outside the United States. 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:

- â€¢ differing regulatory requirements in foreign countries;
- â€¢ differing reimbursement regimes in foreign countries, including price controls;
- â€¢ unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- â€¢ economic weakness, including inflation, or political instability in particular foreign economies and markets;
- â€¢ compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- â€¢ foreign taxes, including withholding of payroll taxes;
- â€¢ foreign currency fluctuations, which could result in increased operating expenses, reduced revenue and other obligations incident to doing business in another country;
- â€¢ difficulties staffing and managing foreign operations;
- â€¢ workforce uncertainty in countries where labor unrest is more common than in the United States;
- â€¢ potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended (the â€œFCPAâ€), or comparable foreign regulations;
- â€¢ 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;
- â€¢ product shortages resulting from any events affecting raw material or finished good supply or distribution or manufacturing capabilities abroad; and
- â€¢ 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:

- â€¢ different regulatory requirements for approval of medical devices in foreign countries;
- â€¢ reduced protection for intellectual property rights;
- â€¢ the existence of additional third-party patent rights of potential relevance to our business;
- â€¢ unexpected changes in tariffs, trade barriers and regulatory requirements;
- â€¢ economic weakness, including inflation or political instability in particular foreign economies and markets;
- â€¢ compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- â€¢ foreign currency fluctuations, which could result in increased operating expenses, reduced revenue and other obligations incident to doing business in another country;
- â€¢ foreign reimbursement, pricing and insurance regimes;
- â€¢ workforce uncertainty in countries where labor unrest is common;
- â€¢ production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- â€¢ 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, in 2018 we sold to distributors located in Europe, Canada, Australia and New Zealand. For the year ended December 31, 2018, approximately 43% 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 the FCPA, the United Kingdom Bribery Act 2010 (the â€œU.K. Bribery Actâ€) or similar laws, 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.

Technological change may adversely affect sales of our products and may cause our products to become obsolete.

The medical device market is characterized by extensive research and development and rapid technological change. Technological progress or new developments in our industry could adversely affect sales of our products. Our products could be rendered obsolete because of future innovations by our competitors or others in the treatment of vascular diseases, which would have a material adverse effect on our business, financial condition and results of operations.

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.

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:

- â€¢ decreased demand for our products;
- â€¢ injury to our reputation;
- â€¢ initiation of investigations by regulators;
- â€¢ costs to defend the related litigation;
- â€¢ a diversion of managementâ€™s time and our resources;
- â€¢ substantial monetary awards to trial participants or patients;
- â€¢ product recalls, withdrawals or labeling, marketing or promotional restrictions;
- â€¢ loss of revenue;
- â€¢ exhaustion of any available insurance and our capital resources; and
- â€¢ 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 customersâ€™ confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

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. We do not have redundant information technology systems at this time. 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 customersâ€™ 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 consumersâ€™ personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g. the Health Insurance Portability and Accountability Act (â€œHIPAAâ€) and the Health Information Technology for Economic and Clinical Health Act (â€œHITECH Actâ€)) and international law (e.g. the European Unionâ€™s General Data Protection Regulation (â€œGDPRâ€)). 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.

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.

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 2018 Loan and Security Agreement. The 2018 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.

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 suppliersâ€™ ability to provide us with materials and components, which could have a material adverse effect on our business, financial condition and results of operations.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce our products. Our ability to obtain clinical supplies of our products could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in Santa Clara, California, near major earthquake faults and fire zones, and the ultimate impact on us for being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Risks Related to Government Regulation and Our Industry

If we fail to comply with U.S. federal and state 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 (â€œAnti-Kickback Statuteâ€) and federal civil False Claims Act. There are similar laws in other countries. Our relationships and our distributorsâ€™ relationships with physicians, other health care professionals and hospitals are subject to scrutiny under these laws.

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:

- â€¢ 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 â€œremunerationâ€ 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 is 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.

- â€¢ federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, 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 â€œrelatorsâ€ or, more commonly, as â€œwhistleblowers,â€ 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 without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings.

- â€¢ 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;

- â€¢ HIPAA, as amended by HITECH Act, and their implementing regulations, also impose obligations, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services for them or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We believe we are not a covered entity for purposes of HIPAA, and we believe that we generally do not conduct our business in a manner that would cause us to be a business associate under HIPAA;

- â€¢ the federal Physician Payment 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 Childrenâ€™s Health Insurance Program to report annually, with certain exceptions to the Centers for Medicare & Medicaid Services (â€œCMSâ€), information related to payments or other â€œtransfers of valueâ€ 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

- â€¢ analogous state and foreign law equivalents of each of the above 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 industryâ€™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. Most recently, the Bipartisan Budget Act of 2018 (â€œBBAâ€) increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. 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 HIPAAâ€™s healthcare fraud and privacy provisions.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including certain sales and

marketing practices of our marketed IVL System, including the IVL generator, connector cable and catheter, 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, in many instances we generally 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 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 customersâ€™ facilities, these arrangements will likely 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 managementâ€™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.

We are subject to numerous laws and regulations related to anti-bribery and anti-corruption laws, 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 similarly subject to various heavily-enforced anti-bribery and anti-corruption laws, such as the FCPA, U.K. Bribery Act 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 managementâ€™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.

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 pre-marketing approval from the FDA, unless an exemption applies.

FDA regulations and regulations of similar agencies are wide-ranging and include, among other things, oversight of:

- â€¢ product design, development, manufacture (including suppliers) and testing;
- â€¢ laboratory, preclinical and clinical studies;
- â€¢ product safety and effectiveness;
- â€¢ product labeling;
- â€¢ product storage and shipping;
- â€¢ record keeping;
- â€¢ pre-market clearance or approval;
- â€¢ marketing, advertising and promotion;
- â€¢ product sales and distribution;
- â€¢ product changes;
- â€¢ product recalls; and
- â€¢ 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:

- â€¢ untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- â€¢ unanticipated expenditures to address or defend such actions;
- â€¢ customer notifications for repair, replacement or refunds;
- â€¢ recall, detention or seizure of our products;
- â€¢ operating restrictions or partial suspension or total shutdown of production;
- â€¢ refusing or delaying our requests for 510(k) clearance or PMA approval of new products or modified products;
- â€¢ operating restrictions;
- â€¢ withdrawing 510(k) clearances or PMA approvals that have already been granted;
- â€¢ refusal to grant export approval for our products; or
- â€¢ 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 â€œgeneral controlsâ€ 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 â€œ510(k)-exemptâ€ devices can be marketed without prior marketing-clearance or approval from the FDA. In addition to the â€œgeneral controls,â€ some Class II medical devices are also subject to â€œspecial controls,â€ including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510(k) clearance, most Class III devices are subject to PMA. Our C2 catheters 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 managementâ€™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.

Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, Open Payments requires us to annually report to CMS payments and other transfers of value to all U.S. physicians and U.S. teaching hospitals, with the reported information made publicly available on a searchable website. 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.

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 the 510(k) process. Unlike a 510(k) review, which determines â€œsubstantial equivalence,â€ 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 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 manufacturerâ€™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.

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

Although our M5 catheters for the treatment of PAD have obtained regulatory clearance in the United States, and our M5 catheters for the treatment of PAD and C2 catheters for the treatment of CAD in certain non-U.S. jurisdictions have obtained applicable regulatory approvals, 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) 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 productsâ€™ 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 product, including certain changes to product labeling, the holder of a cleared 510(k) application may be required to submit a new application and obtain clearance. We will train our marketing and sales force against promoting our product candidates for uses outside of the cleared or approved indications for use, known as â€œoff-label uses.â€ However, physicians may use our products for off-label purposes and are allowed to do so when in the physicianâ€™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:

- â€¢ subject our facility to an adverse inspectional finding or Form 483, or other compliance or enforcement notice, communication or correspondence;
- â€¢ issue warning or untitled letters that would result in adverse publicity or may require corrective advertising;
- â€¢ impose civil or criminal penalties;
- â€¢ suspend or withdraw regulatory clearances or approvals;
- â€¢ refuse to clear or approve pending applications or supplements to approved applications submitted by us;
- â€¢ impose restrictions on our operations, including closing our sub-assembly suppliersâ€™ facilities;
- â€¢ seize or detain products; or
- â€¢ require a product recall.

In addition, violations of the Federal Food, Drug and Cosmetic Act (â€œFD&C Actâ€), 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 S^4 catheters after seeing a higher instance of leaks in the balloon, which prevented the balloon from staying inflated at 4 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 FDAâ€™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 FDAâ€™s Quality System Regulation or any applicable state 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 FDAâ€™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 (â€œCDHSâ€). We anticipate that we and certain of our third-party component suppliers will be subject to FDA and CDHS inspections.

We produce substantially all of our IVL catheters in-house at our facilities in Fremont, California which, together with our research and development, controlled environment room and office space, currently totals 12,000 square feet. We plan to move our production of IVL catheters to our new 35,000 square foot facility in Santa Clara, California in 2019. Our Santa Clara facility has not been inspected by the FDA to date. Our most recent audit by the British Standards Institution (â€œBSIâ€) was held in 2018. There was one minor non-conformance and no major non-conformances. We can provide no assurance that we will continue to remain in compliance with QSR. If our facilities are found to be in noncompliance or 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 customersâ€™ 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 FDAâ€™s and other comparable non-U.S. regulatory agenciesâ€™ 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 managementâ€™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 medical device reporting regulations (â€œMDR regulationsâ€), medical device manufacturers are required to report to the FDA information 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 to the FDA within the required timeframes, or at all, the FDA 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 (â€œACAâ€), 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. Implementation of the ACA will impact existing government healthcare programs and will result in the development of new programs. For example, the ACA, among other things, imposes a deductible excise tax of 2.3% on the sale of most medical devices, including ours, and any failure to pay this amount could result in the imposition of an injunction on the sale of our products, fines and penalties.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA, and we expect such challenges and amendments to continue. For example, since January 2017, President Trump has signed two 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. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 (â€œTCJAâ€) 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 â€œindividual mandate.â€ On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 (the â€œ2018 Continuing Resolutionâ€), that delayed the implementation of certain ACA-mandated fees, including the 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices through December 31, 2019. Further, the 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 â€œdonut hole.â€ In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the â€œindividual mandateâ€ was repealed by Congress as part of the TCJA. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and 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 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 2027 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 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:

- â€¢ our ability to set a price that we believe is fair for our products;
- â€¢ our ability to generate revenue and achieve or maintain profitability; and
- â€¢ 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. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control product costs. 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.

Our financial performance may be adversely affected by medical device tax provisions in the healthcare reform legislation.

The imposition of the 2.3% medical device excise tax enacted as part of the ACA could adversely affect our financial results. Although the suspension of the excise tax was extended to the end of 2019 by the 2018 Continuing Resolution, we do not know whether the suspension will continue beyond 2019. We may not be able to pass along the cost of the tax to our customers or offset the cost of the tax through higher sales volumes resulting from the expansion of health insurance coverage. Ongoing implementation of this legislation could have a material adverse effect on our business, financial condition and results of operations.

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 manufacturerâ€™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.

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.

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 suppliersâ€™ 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.

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 participantsâ€™ 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 usersâ€™ accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and may use such access to obtain usersâ€™ 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 California Consumer Privacy Act of 2018, which will come into effect beginning in January 2020. The GDPR became effective in May 2018. The GDPR 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 pseudonymised (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 (â€œEUâ€) 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 â‚¬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. 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 (â€œEEAâ€). 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.

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.

Moreover, the policies of the Trump Administration and their impact on the regulation of our products in the United States remain uncertain. The outcome of the 2016 election and the 2018 Congressional mid-term elections resulting in a split in majority control between the House of Representatives and the Senate could result in significant legislative and regulatory reforms impacting the FDAâ€™s regulation of our products. 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.

In the EU, on May 25, 2017 the new Medical Devices Regulation (â€œ2017/745â€ or â€œMDRâ€) was adopted. Following its entry into application on May 26, 2020, 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.

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-ownersâ€™ 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 â€œUSPTOâ€), or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, 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 *inter partes* review of U.S. Pat. Nos. 9,642,673, 8,956,371 and 8,728,091 (the â€œIPR Patentsâ€), which are three of our issued U.S. patents that relate to our current IVL Technology, were filed in December 2018 at the USPTOâ€™s Patent Trial and Appeal Board (the â€œPTABâ€) by Cardiovascular Systems, Inc., one of our competitors. Our preliminary responses to these petitions are due by April 2019, and the PTAB is expected to decide whether or not to institute the *inter partes* reviews by July 2019. If the PTAB decides to institute an *inter partes* review with respect to one or more of the IPR Patents, it could result in the loss or narrowing in scope of such 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, *inter partes* review, 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 â€œAmerica Invents Actâ€), 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, *inter partes* review 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 collaboratorsâ€™ 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 (â€œNPEsâ€), 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 attorneysâ€™ 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-ownersâ€™ 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 â€œopen sourceâ€ 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 â€œopen sourceâ€ 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:

- â€¢ 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;
- â€¢ 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;
- â€¢ we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- â€¢ others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- â€¢ it is possible that our current or future pending patent applications will not lead to issued patents;
- â€¢ 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;
- â€¢ 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;
- â€¢ we may not develop additional proprietary technologies that are patentable;
- â€¢ the patents of others may harm our business; and
- â€¢ 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 Our Reliance on Third Parties

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

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:

- â€¢ reliance on the third party for regulatory compliance and quality assurance;
- â€¢ the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and
- â€¢ 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 to establish an alternative source of supply for our products and to have any such new source approved by the FDA.

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 supplierâ€™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 (â€œISOâ€) 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 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 Inc., pursuant to which we will work with Abiomed to integrate our products into Abiomedâ€™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.

Risks Related to This Offering and Ownership of Our Common Stock

An active, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock at or above the public offering price. The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the initial public offering price.

Prior to this offering, there has not been a public market for our common stock. We cannot assure you that an active trading market for our common stock will develop following this offering. You may not be able to sell

your shares quickly or at the market price if trading in our common stock is not active. The initial public offering price for the shares was determined by negotiations between us and the representatives.

The trading price of our common stock is likely 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, including:

- â€¢ our failure to increase the sales of our products;
- â€¢ 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;
- â€¢ unanticipated serious safety concerns related to the use of our products;
- â€¢ introduction of new products or services offered by us or our competitors;
- â€¢ announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- â€¢ announcements of technological or medical innovations for the treatment of vascular disease;
- â€¢ our ability to effectively manage our growth;
- â€¢ the size and growth of our target markets;
- â€¢ actual or anticipated quarterly variations in our or our competitorsâ€™ results of operations;
- â€¢ failure to meet estimates or recommendations by securities analysts who cover our stock;
- â€¢ failure to meet our own financial estimates;
- â€¢ accusations that we have violated a law or regulation;
- â€¢ recalls of our products;
- â€¢ 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;
- â€¢ significant litigation, including stockholder litigation or litigation related to intellectual property;
- â€¢ our cash position;
- â€¢ 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 authorityâ€™s review of such products;
- â€¢ 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;
- â€¢ changes in laws or regulations applicable to our products;
- â€¢ adverse developments concerning our suppliers or distributors;
- â€¢ our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices;
- â€¢ our inability to establish and maintain collaborations if needed;
- â€¢ changes in the market valuations of similar companies;
- â€¢ overall performance of the equity markets;
- â€¢ sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;

- â€¢ trading volume of our common stock;
- â€¢ additions or departures of key scientific or management personnel;
- â€¢ changes in accounting principles;
- â€¢ ineffectiveness of our internal controls;
- â€¢ actual or anticipated changes in healthcare policy and reimbursement levels;
- â€¢ general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors; and
- â€¢ 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 managementâ€™s attention and resources, which could materially adversely affect our business, financial condition and results of operations.

We do not intend to pay dividends on our common stock, so any returns will be limited to increases, if any, in our stockâ€™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, 2018, we had net operating loss (â€œNOLâ€) carryforwards of approximately $119.5 million for federal income tax purposes, and $56.7 million for state income tax purposes. These federal (generated prior to 2018) and 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 â€œCodeâ€), and corresponding provisions of state law, if a corporation undergoes an â€œownership change,â€ 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 corporationâ€™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, including this offering, 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, the consequences of which have not yet been fully determined. 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 other 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 newly enacted federal tax legislation.

After this offering, our principal stockholders and management will 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, 2018, our executive officers, directors and 5% stockholders beneficially owned approximately 67% of the outstanding shares of capital stock, and, upon the closing of this offering, that same group will hold approximately 53.7% of our outstanding shares of common stock (assuming no exercise of the underwritersâ€™ over-allotment option). In addition, as of December 31, 2018, our officers and directors held options to purchase an aggregate of 1,863,190 shares of our common stock at a weighted-average exercise price of $3.35 per share; and (ii) 41,115 warrants to purchase shares of our common stock, which would give our officers and directors ownership of approximately 27.1% of our outstanding common stock following this offering if such awards are fully vested and are exercised in full (assuming no exercise of the underwritersâ€™ over-allotment option). Therefore, even after this offering, these stockholders will have the ability to influence us through this ownership position.

A significant portion of our outstanding shares of common stock is restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to the 180-day lock-up periods under the lock-up agreements and market standoff provisions described in the sections of this prospectus titled â€œShares Eligible for Future Saleâ€ and â€œUnderwriting.â€ These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of December 31, 2018, our directors, executive officers and holders of 5% or more of our outstanding stock beneficially owned approximately 67% of our outstanding stock in the aggregate. If one or more of them were to sell a substantial portion of the shares they hold, it could cause our stock price to decline. Furthermore, the lock-up agreements mentioned above may be waived by the underwriters at any time which could lead to these shares being sold in the market prior to the expiration of this 180-day lock-up period.

In addition, as of December 31, 2018, there were 3,636,224 shares of our common stock subject to outstanding options that will become eligible for sale in the public market upon exercise of such options to the extent permitted by any applicable vesting requirements, the lock-up agreements, market standoff provisions and Rules 144 and 701 under the Securities Act of 1933, as amended (the â€œSecurities Actâ€). Moreover, after this offering, holders of an aggregate of 18,670,259 shares of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

We also registered all 2,301,080 shares of our common stock that will be initially reserved for issuance under our 2019 Equity Incentive Plan and our ESPP. Once we register these shares, they can be freely sold in the public market upon issuance and once vested and exercised, as applicable, subject to the 180-day lock-up periods under the lock-up agreements described in the section of this prospectus titled â€œUnderwriting.â€

Sales of our common stock as restrictions end or pursuant to registration rights may make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. These sales also could cause the price of our common stock to fall and make it more difficult for you to sell shares of our common stock.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the â€œJOBS Actâ€). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we complete this offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the â€œExchange Actâ€), which will require, 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 â€œSarbanes-Oxley Actâ€), 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, beginning with our annual report for the year ending December 31, 2020, which must be attested to by our independent registered public accounting firm to the extent we are no longer an â€œemerging growth company,â€ as defined by the JOBS Act, or a smaller reporting company under the Securities Act. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the â€œDodd-Frank Actâ€), 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 â€œsay on payâ€ and proxy access. Emerging growth companies are permitted to implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend to take advantage of this legislation but cannot guarantee that we will not be required to implement these requirements sooner than anticipated or planned and thereby incur unexpected expenses. 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.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities 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. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or

increase the prices of our products or services. 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 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. Until such time as we are no longer an â€œemerging growth company,â€ our auditors will not be required to attest as to our internal control over financial reporting. 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.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares. You will likely experience further dilution if we issue shares in future financing transactions or upon exercise of options or warrants.

The initial public offering price is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $12.26 per share. Further, investors purchasing common stock in this offering will contribute approximately 37.2% of the total amount invested by stockholders since our inception, but will own only approximately 21.2% of the shares of common stock outstanding after giving effect to this offering.

This dilution is due to our investors who purchased shares prior to this offering having paid substantially less when they purchased their shares than the price offered to the public in this offering. To the extent outstanding options or warrants are exercised, there will be further dilution to new investors. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see section titled â€œDilution.â€

If we raise additional funds by issuing additional common stock, or securities convertible into or exchangeable or exercisable for common stock, our stockholders will experience additional dilution, and new investors could have rights superior to existing stockholders.

Pursuant to our 2019 Equity Incentive Plan, our management is authorized to grant stock options to our employees, directors and consultants. In addition, we also have warrants outstanding to purchase shares of our common stock. You will incur dilution upon exercise of any outstanding stock options or warrants.

We have broad discretion to use the net proceeds from this offering and our investment of these proceeds may not yield a favorable return.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled â€œUse of Proceeds,â€ and you will not have the

opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. We expect to use the net proceeds from this offering to expand our direct sales force and marketing of our products, to support clinical studies for new products and product enhancements, including expanded indications, and to support other research and development activities, working capital and general corporate purposes. We may also use a portion of the net proceeds of this offering for acquisitions or strategic transactions. We have not entered into any agreements or commitments with respect to any specific transactions and have no understandings or agreements with respect to any such transactions at this time. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade or interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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 managementâ€™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.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our amended and 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 amended and 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:

- â€¢ authorizing the issuance of â€œblank checkâ€ preferred stock without any need for action by stockholders;
- â€¢ requiring supermajority stockholder voting to effect certain amendments to our amended and restated certificate of incorporation and amended and restated bylaws;
- â€¢ eliminating the ability of stockholders to call and bring business before special meetings of stockholders;
- â€¢ prohibiting stockholder action by written consent;

- â€¢ 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;
- â€¢ 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
- â€¢ 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 stockholdersâ€™ best interests and could also affect the price that some investors are willing to pay for our common stock. See the section titled â€œDescription of Capital Stock.â€

Our amended and restated certificate of incorporation will provide 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 stockholdersâ€™ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and 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 amended and 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 stockholderâ€™s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our amended and restated 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 Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

We have made statements under the captions â€œProspectus Summary,â€ â€œRisk Factors,â€ â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operations,â€ â€œBusinessâ€ and in other sections of this prospectus that are forward-looking statements. In some cases, you can identify these statements by forward-looking words such as â€œmay,â€ â€œmight,â€ â€œwill,â€ â€œshould,â€ â€œexpects,â€ â€œplans,â€ â€œanticipates,â€ â€œbelieves,â€ â€œestimates,â€ â€œpredicts,â€ â€œpotentialâ€ or â€œcontinue,â€ the negative of these terms and other comparable terminology. These forward-looking statements, which are subject to risks, uncertainties and assumptions about us, may include projections of our future financial performance, our anticipated growth strategies and anticipated trends in our business. Forward-looking statements contained in this prospectus include, but are not limited to statements about:

- â€¢ our ability to design, develop, manufacture and market innovative products to treat patients with challenging medical conditions, particularly in PAD, CAD and AS;
- â€¢ our expected future growth, including growth in international sales;
- â€¢ the size and growth potential of the markets for our products, and our ability to serve those markets;
- â€¢ the rate and degree of market acceptance of our products;
- â€¢ coverage and reimbursement for procedures performed using our products;
- â€¢ the performance of third parties in connection with the development of our products, including third-party suppliers;
- â€¢ regulatory developments in the United States and foreign countries;
- â€¢ our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines;
- â€¢ our plans to research, develop and commercialize our products and any other approved or cleared product;
- â€¢ our ability to scale our organizational culture of cooperative product development and commercial execution;
- â€¢ the development, regulatory approval, efficacy and commercialization of competing products;
- â€¢ the loss of key scientific or management personnel;
- â€¢ our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- â€¢ our ability to develop and maintain our corporate infrastructure, including our internal controls;
- â€¢ our use of the proceeds from this offering;
- â€¢ our financial performance and capital requirements; and
- â€¢ 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 statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements, including those factors discussed in the section titled â€œRisk Factors.â€ You should specifically consider the numerous risks outlined under â€œRisk Factors.â€

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. We undertake no obligation to update any of these forward-looking statements after the date of this prospectus to conform our prior statements to actual results or revised expectations.

MARKET, INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the market in which we operate, including our general expectations and market position, market opportunity and market size, is based on information from various third-party industry and research sources, on assumptions that we have made based on that data and other similar sources, and on our knowledge of the markets for our current and planned or future products. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

Certain market and industry data used in this document, where noted, is attributable to Millennium Research Group, Inc. (â€œMRGâ€). MRG asserts copyright protection over the use of such information and reserves all rights with respect to its use. This information has been reprinted with MRGâ€™s permission and the reproduction, distribution, transmission or publication of such information is prohibited without its consent.

In addition, industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although we do not guarantee the accuracy or completeness of such information. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled â€œRisk Factorsâ€ and elsewhere in this prospectus. These and other factors could cause our actual results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $86.9 million, or approximately $100.4 million if the underwriters exercise their over-allotment option in full, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds of this offering, together with our existing cash and cash equivalents, as follows:

- approximately $32.6 million for sales and marketing activities to support the ongoing commercialization of our IVL System, including, but not limited to, the expansion of our sales force, additional medical affairs and educational efforts and the expansion of our international sales presence;
- approximately $15.5 million for research and development and clinical studies; and
- the remainder for working capital and general corporate purposes.

Our ongoing clinical programs are intended to allow us to expand commercialization of our products into new geographies and indications. Our Disrupt PAD III clinical study, Disrupt PAD III observational study, Disrupt CAD II clinical study, Disrupt CAD III clinical study and TAVL Chronic Feasibility clinical study are currently enrolling, with enrollment expected to be completed in the second half of 2019 for the Disrupt PAD III clinical study and Disrupt PAD III observational study, the first half of 2019 for the Disrupt CAD II clinical study, the second half of 2020 for the Disrupt CAD III clinical study and the first half of 2019 for the TAVL Chronic Feasibility clinical study. Our Disrupt CAD IV clinical study is currently in the early planning phase with Japanâ€™s Pharmaceuticals and Medical Devices Agency. See â€œBusinessâ€”Our Productsâ€ and â€œBusinessâ€”Clinical Studiesâ€”Ongoing and Planned Clinical Studiesâ€ for further information on the status of our clinical studies and current and planned products.

We believe that our existing cash and cash equivalents, together with available borrowing under our current revolving line of credit from the 2018 Loan and Security Agreement and the net proceeds from this offering, will be sufficient to fund our planned operations for at least the next 12 months. However, following this offering, we will require additional capital in order to achieve our goals. For additional information regarding our potential additional capital requirements, see â€œRisk Factorsâ€”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.â€

The foregoing use of proceeds discussion excludes the Concurrent Private Placement. We estimate that the net proceeds from the Concurrent Private Placement will be an aggregate of approximately $10.0 million. We intend to use the net proceeds from the Concurrent Private Placement for working capital and general corporate purposes. The sale of shares in the Concurrent Private Placement will not be registered under the Securities Act. The closing of this offering is not conditioned upon the closing of the Concurrent Private Placement. We expect the Concurrent Private Placement to close on March 11, 2019.

We cannot specify with certainty the particular uses of the net proceeds that we will receive from this offering and the Concurrent Private Placement. Accordingly, we will have broad discretion in using these proceeds. Pending the use of proceeds from this offering and the Concurrent Private Placement as described above, we plan to invest the net proceeds that we receive in this offering and the Concurrent Private Placement in short-term and long-term interest-bearing obligations, including government and investment-grade debt securities and money market funds.

DIVIDEND POLICY

We have never paid any dividends on our common shares or any of our other securities. We currently anticipate that we will retain all available funds for use in the operation and expansion of our business, and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our board of directors and will be dependent upon our financial condition, results of operations, capital requirements, restrictions under any future indebtedness and other factors the board of directors deems relevant. In addition, the terms of our 2018 Loan and Security Agreement with Silicon Valley Bank restrict our ability to pay dividends to limited circumstances.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2018:

- â€¢ on an actual basis;
- â€¢ on a pro forma basis, giving effect to: (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of December 31, 2018 into an aggregate of 18,670,259 shares of our common stock immediately prior to the completion of this offering, as if such conversion had occurred on December 31, 2018; (ii) the issuance of 123,461 shares of our common stock, based on the initial public offering price of $17.00 per share upon the net exercise of warrants outstanding as of December 31, 2018 for the purchase of 141,777 shares of our common stock that would otherwise expire upon the completion of this offering; (iii) the filing and effectiveness of our amended and restated certificate of incorporation and the retirement of our authorized convertible preferred stock that will convert to common stock as set forth in clause (i); and (iv) the reclassification of the convertible preferred stock warrant liability to additional paid-in capital, a component of total stockholdersâ€™ (deficit) equity, due to our convertible preferred stock warrant converting to a warrant to purchase our common stock immediately prior to the completion of this offering; and
- â€¢ on a pro forma as adjusted basis to give further effect to (i) the sale by us of 5,700,000 shares of our common stock in this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us; (ii) the sale by us of 588,235 shares of our common stock in the Concurrent Private Placement at the initial public offering price of $17.00 per share; and (iii) the reclassification of $1.5 million of deferred offering costs recorded in other assets on the consolidated balance sheet as of December 31, 2018 to additional paid-in capital, a component of total stockholdersâ€™ (deficit) equity.

This table should be read in conjunction with the section titled â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€ and the consolidated financial statements and the related notes appearing elsewhere in this prospectus.

	December 31, 2018 (in thousands, except share and per share data)		
	Actual	Pro Forma	Pro Forma as Adjusted
Cash and cash equivalents	$ 39,643	$ 39,643	$ 137,200
Long-term debt, current and non-current	$ 15,050	$ 15,050	$ 15,050
Convertible preferred stock warrant liability	313	â€”	â€”
Convertible preferred stock, $0.001 par value per share; 229,098,987 shares authorized, 18,670,259 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	152,806	â€”	â€”
Stockholdersâ€™ (deficit) equity:			
Preferred stock, $0.001 par value per share; no shares authorized, issued or outstanding, actual; 5,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	â€”	â€”	â€”
Common stock, $0.001 par value per share, 325,000,000 shares authorized, 1,824,807 shares issued and outstanding, actual, 281,274,838 shares authorized, 20,618,527 issued and outstanding, pro forma; 281,274,838 shares authorized, 26,906,762 shares issued and outstanding, pro forma as adjusted	2	21	27
Additional paid-in capital	4,275	157,375	254,300
Accumulated deficit	(126,865)	(126,865)	(126,865)
Total stockholdersâ€™ (deficit) equity	$ (122,588)	$ 30,531	$ 127,462
Total capitalization	$ 45,581	$ 45,581	$ 142,512

If the underwritersâ€™ over-allotment option were exercised in full, pro forma as adjusted cash and cash equivalents, additional paid-in capital and stockholdersâ€™ (deficit) equity as of December 31, 2018, would be $150.7 million, $267.8 million and $141.0 million, respectively.

The number of shares of our common stock issued and outstanding actual, pro forma and pro forma as adjusted in the table above is based on 20,618,527 shares (including our convertible preferred stock on an as-converted basis and net exercise of certain outstanding warrants) outstanding as of December 31, 2018, which excludes:

- â€¢ 3,636,224 shares of our common stock issuable upon the exercise of options outstanding as of December 31, 2018, with a weighted-average exercise price of $3.50 per share;
- â€¢ 119,667 shares of our common stock issuable upon the exercise of options granted after December 31, 2018, with an exercise price of $6.59 per share;
- â€¢ 54,903 shares of our Series A-1 convertible preferred stock issuable upon the exercise of our Series A-1 convertible preferred stock warrant outstanding as of December 31, 2018, with an exercise price of $3.09636 per share;
- â€¢ 34,440 shares of our common stock issuable upon the exercise of our common stock warrants outstanding as of December 31, 2018, with an exercise price of $4.026 per share;
- â€¢ 22,216 shares of our common stock issued upon the net exercise of preferred stock warrants;
- â€¢ 588,235 shares of our common stock issuable in the Concurrent Private Placement;
- â€¢ 306,316 shares of our common stock issuable upon the exercise of options that we granted under our 2019 Equity Incentive Plan upon the pricing of this offering to our directors, executive officers and certain other employees at an exercise price equal to the initial public offering price of this offering;
- â€¢ 1,694,114 additional shares of our common stock reserved for future issuance under our 2019 Equity Incentive Plan, which became effective as of the date of the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to this plan; and
- â€¢ 300,650 shares of our common stock initially reserved for issuance under our ESPP, which became effective as of the date of the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to this plan.

DILUTION

If you invest in our common stock you will experience immediate and substantial dilution in the pro forma net tangible book value of your shares of common stock. Dilution in pro forma net tangible book value represents the difference between the public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock.

As of December 31, 2018, we had a historical net tangible book deficit of $(122.6) million, or $(67.18) per share of common stock, based on 1,824,807 shares of our common stock outstanding. Our historical net tangible book value per share represents the amount of our tangible assets, less liabilities and convertible preferred stock, divided by the total number of shares of our common stock outstanding at December 31, 2018.

Our pro forma net tangible book value as of December 31, 2018, was $30.5 million, or $1.48 per share of common stock. Pro forma net tangible book value per share represents our historical net tangible book value per share, after giving effect to: (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of December 31, 2018 into an aggregate of 18,670,259 shares of our common stock immediately prior to the completion of this offering, (ii) the issuance of 123,461 shares of our common stock, based upon the initial public offering price of $17.00 per share, upon the net exercise of warrants outstanding as of December 31, 2018 for the purchase of 141,777 shares of our common stock that would otherwise expire upon completion of this offering; (iii) the reclassification of the convertible preferred stock warrant liability to additional paid-in capital, a component of total stockholdersâ€™ (deficit) equity, due to our convertible preferred stock warrant converting to a warrant to purchase our common stock immediately prior to the completion of this offering; and (iv) the filing and effectiveness of our amended and restated certificate of incorporation, which will be in effect immediately upon the completion of this offering.

After giving further effect to (i) the sale and issuance by us of the 5,700,000 shares of our common stock in this offering and the receipt and application of the net proceeds; (ii) the sale and issuance of 588,235 shares of our common stock in the Concurrent Private Placement and the receipt of the net proceeds; and (iii) the reclassification of $1.5 million of deferred offering costs recorded in other assets on the consolidated balance sheet as of December 31, 2018 to additional paid-in capital, a component of total stockholdersâ€™ (deficit) equity, our pro forma as adjusted net tangible book value as of December 31, 2018 would be $127.5 million, or $4.74 per share. This represents an immediate increase in pro forma net tangible book value to our existing stockholders of $3.26 per share and an immediate dilution to new investors of $12.26 per share. Dilution per share to new investors represents the difference between the price per share to be paid by new investors for the shares of common stock sold in this offering and the pro forma as adjusted net tangible book value per share immediately after this offering. The following table illustrates this per share dilution:

Initial public offering price per share		$17.00
Historical net tangible book deficit per share as of December 31, 2018	$(67.18)	
Pro forma increase in historical net tangible book value per share as of December 31, 2018	68.66	
Pro forma net tangible book value per share as of December 31, 2018	1.48	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	$ 3.26	
Pro forma as adjusted net tangible book value per share		$ 4.74
Dilution per share to new investors participating in this offering		$12.26

If the underwritersâ€™ over-allotment option is exercised in full, the pro forma as adjusted net tangible book value per share of our common stock would be $5.08 per share, and the dilution in pro forma net tangible book value per share to new investors in this offering would be $11.92 per share.

The following table sets forth, on a pro forma as adjusted basis, as of December 31, 2018, the number of shares of common stock purchased from us, the total consideration paid, or to be paid, and the average price per share paid, or to be paid, by existing stockholders and by the new investors, at the initial public offering price of $17.00 per share, before deducting the underwriting discounts and commissions and offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	20,618,527	76.6%	$153,495,036	59.0%	$ 7.44
Concurrent Private Placement investor	588,235	2.2	9,999,995	3.8	$17.00
New public investors	5,700,000	21.2	96,900,000	37.2	$17.00
Total	26,906,762	100%	$260,395,031	100%	

The above table assumes no exercise of the underwritersâ€™ over-allotment option. If the underwritersâ€™ over-allotment option were exercised in full, our existing stockholders and the Concurrent Private Placement investor would own 76.4% and our new investors would own 23.6% of the total number of shares of our common stock outstanding upon completion of this offering. Additionally, the cash consideration paid to us by existing stockholders and the Concurrent Private Placement investor would be $163.5 million, or approximately 59.5% of the total cash consideration, and the cash consideration paid to us by new investors purchasing shares in this offering would be $111.4 million, or approximately 40.5% of the total cash consideration.

The foregoing tables and calculations assume no exercise of outstanding options or warrants. If all of our outstanding options and warrants were exercised in full, (i) existing stockholders and the Concurrent Private Placement investor would own 81.4% and our new investors in this offering would own 18.6% of the total number of shares of our common stock outstanding upon the completion of this offering and (ii) the cash consideration paid to us by existing stockholders and the Concurrent Private Placement investor would be $176.5 million, or approximately 64.6% of the total cash consideration, and the cash consideration paid to us by new investors purchasing shares in this offering would be $96.9 million, or approximately 35.4% of the total cash consideration. The average price per share paid to us by existing stockholders and the Concurrent Private Placement investor would be $7.08 and the average price per share paid to us by new investors purchasing shares in this offering would be $17.00.

The foregoing tables and calculations (other than the historical net tangible book value calculation) are based on 20,618,527 shares (including our convertible preferred stock on an as-converted basis and net exercise of certain outstanding warrants) outstanding as of December 31, 2018, which excludes:

- â€¢ 3,636,224 shares of our common stock issuable upon the exercise of options outstanding as of December 31, 2018, with a weighted-average exercise price of $3.50 per share;
- â€¢ 119,667 shares of our common stock issuable upon the exercise of options granted after December 31, 2018, with an exercise price of $6.59 per share;
- â€¢ 54,903 shares of our Series A-1 convertible preferred stock issuable upon the exercise of our Series A-1 convertible preferred stock warrant outstanding as of December 31, 2018, with an exercise price of $3.09636 per share;
- â€¢ 34,440 shares of our common stock issuable upon the exercise of our common stock warrants outstanding as of December 31, 2018, with an exercise price of $4.026 per share;
- â€¢ 22,216 shares of our common stock issued upon the exercise of preferred stock warrants;
- â€¢ 588,235 share of our common stock issuable in the Concurrent Private Placement;
- â€¢ 306,316 shares of our common stock issuable upon the exercise of options that we granted under our 2019 Equity Incentive Plan upon the pricing of this offering to our directors, executive officers and certain other employees at an exercise price equal to the initial public offering price of this offering;
- â€¢ 1,694,114 additional shares of our common stock reserved for future issuance under our 2019 Equity Incentive Plan, which became effective as of the date of the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to this plan; and
- â€¢ 300,650 shares of our common stock initially reserved for issuance under our ESPP, which became effective as of the date of the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to this plan.

To the extent that any outstanding options or warrants are exercised, new investors will experience further dilution.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables summarize our consolidated financial data. We have derived the summary consolidated statements of operations data for the years ended December 31, 2017 and 2018 from our audited consolidated financial statements included elsewhere in this prospectus. We have derived our balance sheet data as of December 31, 2017 and 2018 from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The following summary consolidated financial data should be read in conjunction with the section titled â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€ and our consolidated financial statements and related notes included elsewhere in this prospectus.

	Years Ended December 31,	
	2017	2018
	(in thousands, except share and per share data)	
Consolidated Statements of Operations Data:		
Product revenue	$ 1,719	$ 12,263
Operating expenses:		
Cost of product revenue	2,836	7,250
Research and development	17,963	22,698
Sales and marketing	6,363	17,536
General and administrative	5,422	5,979
Total operating expenses	32,584	53,463
Loss from operations	(30,865)	(41,200)
Interest and other income, net	276	136
Net loss before taxes	(30,589)	(41,064)
Income tax provision	26	38
Net loss	(30,615)	(41,102)
Net loss per share, basic and diluted(1)	$ (19.71)	$ (23.39)
Weighted-average shares used in computing net loss per share, basic and diluted(1)	1,553,365	1,757,102
Pro forma net loss per share, basic and diluted (unaudited)(1)		$ (2.10)
Weighted-average shares used in computing pro forma net loss per share, basic and diluted (unaudited)(1)		19,528,258

(1) See Notes 2 and 12 to our audited consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share and unaudited pro forma net loss per share and the weighted-average number of shares used in the computation of the per share amounts and unaudited pro forma information.

	As of December 31,	
	2017	2018
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 53,729	$ 39,643
Working capital	53,318	39,365
Total assets	59,304	53,421
Long-term debt, current and non-current	â€”	15,050
Convertible preferred stock warrant liability	577	313
Convertible preferred stock	137,469	152,806
Accumulated deficit	(85,763)	(126,865)
Total stockholdersâ€™ (deficit) equity	(83,292)	(122,588)

MANAGEMENTâ€™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 appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks, uncertainties and assumptions. You should read the â€œSpecial Notes Regarding Forward-Looking Statementsâ€ and â€œRisk Factorsâ€ sections of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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 through our differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which we refer to as IVL. Our IVL System, which leverages our IVL Technology, is a minimally invasive, easy-to-use and safe way to significantly improve patient outcomes. Our M5 catheter was CE-Marked in April 2018 and cleared by the FDA in July 2018 for use in our IVL System for the treatment of PAD. Our C2 catheter, which we are currently marketing in Europe, was CE-Marked in June 2018 for use in our IVL System for the treatment of CAD. We 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, we are undertaking ongoing clinical trials of our C2 catheter intended to support a PMA within the United States and a Shonin submission in Japan for the treatment of CAD. We anticipate having final data from these ongoing clinical trials intended to support a U.S. launch of our C2 catheter in the first half of 2021.

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 AS, a condition where the heartâ€™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 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 includes a generator, connector cable and a family of IVL catheters designed to treat PAD and CAD.

We have completed five clinical studies with a total of 179 patients, across 22 centers in multiple countries, for peripheral and coronary artery and cardiac valve diseases. We are currently conducting or planning five other studies, involving nearly 2,000 patients in up to 190 centers in the United States and internationally.

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, including in Australia, the Baltics, Canada, Czech Republic, France, Italy, the Netherlands, New Zealand, the Nordic region, Poland, Spain and the United Kingdom. We are actively expanding our international field presence through new distributors, additional sales and clinical personnel and are adding new U.S. sales territories.

We produce substantially all of our IVL catheters in-house at our facilities in Fremont, California which, together with our research and development, controlled environment room and office space, currently totals 12,000 square feet. We stock inventory of raw materials, components and finished goods at our facilities in Fremont and with our direct sales representatives, who travel to our hospital customersâ€™ locations as part of their sales efforts. Our electronics (*i.e.*, our generators and connector cables) are produced by original equipment manufacturing (â€œOEMâ€) partners using our design specifications. We plan to move our production of IVL catheters to our new 35,000 square foot facility in Santa Clara, California in 2019. 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 Fremont to our hospital customers in the United States on a consignment basis, 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. Internationally, we ship our IVL products from Fremont 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 Fremont 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.

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 customerâ€™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. Currently, our product sales consist predominantly of sales of our M^5 catheters and our C^2 catheters, as we generally loan our generator kits, which include a generator and a connector cable, to our customers without charge to facilitate the use of our IVL catheters.

In 2018, we generated product revenue of $12.3 million, which represents a 613% increase over 2017, and a $41.2 million loss from operations as compared to a loss from operations of $30.9 million in 2017. In 2018, 43% 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. Since our inception, our operations have been financed primarily by net proceeds from the sale of our convertible preferred stock, indebtedness, and, to a lesser extent, product revenue. As of December 31, 2018, we had $39.6 million in cash and cash equivalents, and an accumulated deficit of $126.9 million.

We have a number of on-going 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 as well as broaden awareness of our products to new hospital accounts. We also expect to continue to make investments in research and development, regulatory affairs and clinical studies to develop future generations of products based on our IVL Technology, support regulatory submissions and demonstrate the clinical efficacy of our products. Moreover, we expect to incur additional 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. In addition, 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.

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:

- â€¢ ***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.

- â€¢ ***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 receive FDA approval for the use of our C2 catheters in our IVL System for the treatment of CAD in the United States, and will 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.

- â€¢ ***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.

- â€¢ ***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 competitorsâ€™ existing and future products and related pricing and their resources to successfully market to the physicians who use our products.

- â€¢ ***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.

- â€¢ ***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.
- â€¢ ***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.
- â€¢ ***Seasonality***. We expect to experience a 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 around the winter holidays. In addition, 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 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. See the section titled â€œRisk Factorsâ€ for more information.

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 customerâ€™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.

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 depreciation relating to the equipment used in our IVL System that we loan to our hospital customers without charge 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 (â€œR&Dâ€) expenses consist of applicable personnel, consulting, materials and clinical trial expenses. R&D expenses include:

- â€¢ certain personnel-related expenses, including salaries, benefits, bonus, travel and stock-based compensation;
- â€¢ cost of clinical studies to support new products and product enhancements, including expenses for clinical research organizations (â€œCROsâ€) and site payments;
- â€¢ materials and supplies used for internal R&D and clinical activities;
- â€¢ allocated overhead including facilities and information technology expenses; and
- â€¢ 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. As a result, we expect sales and marketing expenses to increase in absolute dollars in future periods.

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. As a result, we expect general and administrative expenses to increase in absolute dollars in future periods.

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 as described in Note 7 to our consolidated financial statements appearing elsewhere in this prospectus (the â€œ2018 Loan and Security Agreementâ€). In June 2018 and December 2018, we drew an aggregate

of $15.0 million in borrowings under the term loan facility. As a result, we expect interest expense to increase in absolute dollars in future periods. As of December 31, 2018, we had $2.0 million available on the revolving line of credit.

Change in fair value of warrant liability

We have accounted for our freestanding warrants to purchase shares of our convertible preferred stock as liabilities at fair value primarily because the shares underlying the warrants contain contingent redemption features outside our control. The warrants are subject to re-measurement at each balance sheet date with gains and losses reported through our consolidated statements of operations and comprehensive loss.

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, 2017 and 2018

The following table shows our results of operations for the years ended December 31, 2017 and 2018:

	Year Ended December 31,		Change	Change
	2017	2018	$	%
	(in thousands)			
Revenue:				
Product revenue	$ 1,719	$ 12,263	$ 10,544	613%
Operating expenses:				
Cost of product revenue	2,836	7,250	4,414	156%
Research and development	17,963	22,698	4,735	26%
Sales and marketing	6,363	17,536	11,173	176%
General and administrative	5,422	5,979	557	10%
Total operating expenses	32,584	53,463	20,879	64%
Loss from operations	(30,865)	(41,200)	(10,335)	33%
Interest expense	(58)	(401)	(343)	591%
Change in fair value of warrant liability	(32)	(52)	(20)	63%
Other income, net	366	589	223	61%
Net loss before taxes	(30,589)	(41,064)	(10,475)	34%
Income tax provision	26	38	12	46%
Net loss	$(30,615)	$(41,102)	$(10,487)	34%

Product revenue

Product revenue increased by $10.5 million, or 613%, from $1.7 million in 2017 to $12.3 million in 2018. The increase was primarily due to an increase in the number of customers and an increase in purchase volume of our products per customer both within the United States and internationally.

Product revenue consisted primarily of the sale of our IVL catheters. Product revenue, classified by the major geographic areas in which our products are shipped, was $1.0 million within the United States and $0.7 million for all other countries in 2017 and $7.0 million within the United States and $5.3 million for all other countries in 2018.

Cost of product revenue and gross margin percentage

Cost of product revenue increased by $4.4 million, or 156%, from $2.8 million in 2017 to $7.3 million in 2018. The increase was primarily due to growth in sales volume. Gross margin percentage was negative 65% for the year ended December 31, 2017. Gross margin percentage improved to 41% for the year ended December 31, 2018. This change in gross margin percentage was primarily due to increased sales volume of our catheters.

Research and development expenses

The following table summarizes our R&D expenses incurred during the periods presented:

	Year Ended December 31,	
	2017	2018
	(in thousands)	
Compensation and related personnel costs	$ 10,263	$ 10,580
Clinical-related costs	3,358	5,626
Materials and supplies	1,805	2,541
Facilities and other allocated costs	1,153	1,560
Outside consultants	788	1,360
Other research and development costs	596	1,031
Total research and development expenses	$ 17,963	$ 22,698

R&D expenses increased by $4.7 million, or 26%, from $18.0 million in 2017 to $22.7 million in 2018. The increase was primarily due to a $2.3 million increase in clinical-related costs and a $0.6 million increase in costs associated with outside consultants to support clinical trials. There was also a $0.7 million increase in materials and supplies for R&D and a $0.4 million increase in facilities and other allocated costs due to higher rent and building expenditures.

Sales and marketing expenses

Sales and marketing expenses increased by $11.2 million, or 176%, from $6.4 million in 2017 to $17.5 million in 2018. The increase was primarily due to a $9.5 million increase in compensation and related personnel costs, which includes a $3.1 million increase in commission expense, as a result of increased headcount and increased business development related activities to expand the domestic and international customer base. Marketing and promotional expenses increased by $0.8 million to support the commercialization of our products.

General and administrative expenses

General and administrative expenses increased by $0.6 million, or 10%, from $5.4 million in 2017 to $6.0 million in 2018. The increase was primarily due to a $0.8 million increase in professional services and general corporate expenses incurred in connection with our preparation to become a public company, partially offset by a $0.3 million decrease in recruiting and training expenses.

Interest expense

Interest expense increased by $0.3 million, or 591%, from $0.1 million in 2017 to $0.4 million in 2018. The increase in interest expense was attributable to us entering into the 2018 Loan and Security Agreement and

drawing down on the first tranche of the term loan in June 2018 of $10.0 million and the second tranche of the term loan in December 2018 of $5.0 million.

Change in fair value of warrant liability

The change in fair value of warrant liability was $32,000 in 2017 and $0.1 million in 2018, reflecting an increase in the convertible preferred stock warrant liability of $0.2 million from changes to the Black-Scholes option pricing model assumptions used to value the warrant liability, partially offset by a decrease in the convertible preferred stock warrant liability of $0.1 million related to the expiration of 46,102 of our Series A-1 convertible preferred stock warrants in 2018.

Other income, net

Other income, net increased by $0.2 million, or 61%, from $0.4 million in 2017 to $0.6 million in 2018. The increase was primarily due to a $0.3 million increase in interest income on our cash and cash equivalents and short-term investments due to increases in interest rates on balances held in interest-earning instruments, partially offset by a $0.1 million increase in other expenses.

Income tax provision

Income tax provision increased by $12,000, or 46%, from $26,000 in 2017 to $38,000 in 2018. This increase was primarily due to an increase in foreign income tax expense.

Liquidity and Capital Resources

Sources of liquidity

Since our inception through December 31, 2018, our operations have been financed primarily by net proceeds from the sale of our convertible preferred stock, indebtedness and, to a lesser extent, product revenue. As of December 31, 2018, we had $39.6 million in cash and cash equivalents and an accumulated deficit of $126.9 million.

In December 2018, we received $15.0 million in gross proceeds from the sale of our Series D convertible preferred stock.

Debt obligations

2018 Loan and Security Agreement

In February 2018, we entered into the 2018 Loan and Security Agreement. The terms of the 2018 Loan and Security Agreement include a term loan of $15.0 million and a revolving line of credit of $2.0 million. The term loan is 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.

The term loan matures in December 2021, with interest-only monthly payments until September 2019. The interest-only period will extend through December 2019 if certain financing milestones are met. The term loan accrues interest at a floating per annum rate equal to the greater of the Wall Street Journal prime rate minus 1.75% and 2.75% (3.75% as of December 31, 2018). There is a final payment equal to 6.75% of the original aggregate principal amount, or $1.0 million, of the term loan advances. The line of credit accrues interest at the Wall Street Journal prime rate.

The revolving line of credit matures in February 2021 and accrues interest at the Wall Street Journal prime rate. As of December 31, 2018, we have $2.0 million available on our revolving line of credit. In connection with the execution of the 2018 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.

The term loan is secured by all our assets, excluding intellectual property and certain other assets. The loan contains 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 and merge or consolidate with any other person or engage in transactions with our affiliates, but does not include any financial covenants.

Funding requirements

Based on our planned operations, we do not expect that our current cash and cash equivalents, together with available borrowings under our revolving line of credit from our 2018 Loan and Security Agreement, will be sufficient to fund our operations for at least 12 months after the date our most recent consolidated financial statements were issued without raising additional capital through equity or debt financing. These conditions raise substantial doubt about our ability to continue as a going concern for a period of one year from the date of the issuance of our most recent consolidated financial statements. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations. However, based on our planned operations, we expect our cash and cash equivalents, together with available borrowings under our revolving line of credit and the proceeds from this offering, will be sufficient to fund our operating expenses for at least the next 12 months.

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 as well as broaden awareness of our products to new hospitals. We also expect to continue to make investments in research and development, regulatory affairs and clinical studies to develop future generations of products based on our IVL Technology, support regulatory submissions and demonstrate the clinical efficacy of our products. Moreover, we expect to incur additional 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:

- â€¢ the cost, timing and results of our clinical trials and regulatory reviews;
- â€¢ the cost and timing of establishing sales, marketing and distribution capabilities;
- â€¢ the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- â€¢ the timing, receipt and amount of sales from our current and potential products;
- â€¢ the degree of success we experience in commercializing our products;
- â€¢ the emergence of competing or complementary technologies;
- â€¢ the cost of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights; and
- â€¢ 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 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 at all. If adequate funds are not available on

acceptable terms when needed, we may be required to significantly reduce operating activities, 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 existing stockholdersâ€™ 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.

Cash Flows

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

	Year Ended December 31,	
	2017	2018
	(in thousands)	
Net cash used in operating activities	$ (30,347)	$ (41,465)
Net cash used in investing activities	(2,232)	(174)
Net cash provided by financing activities	33,687	29,809
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 1,108	$ (11,830)

Operating activities

In 2018, cash used in operating activities was $41.5 million, attributable to a net loss of $41.1 million and a net change in our net operating assets and liabilities of $2.6 million, partially offset by non-cash charges of $2.3 million. Non-cash charges primarily consisted of $1.3 million in stock-based compensation, $0.7 million in depreciation and amortization and $0.2 million in amortization of debt issuance costs. The change in our net operating assets and liabilities was primarily due to a $2.6 million increase in inventory and $2.2 million increase in accounts receivable due to an increase in sales, and a $0.9 million increase in other assets from deferred offering costs. These changes were partially offset by a $3.1 million increase in accrued and other current liabilities and accounts payable resulting primarily from increases in our operating activities and accrued professional services fees.

In 2017, cash used in operating activities was $30.3 million, attributable to a net loss of $30.6 million and a net change in our net operating assets and liabilities of $1.3 million, partially offset by non-cash charges of $1.5 million. Non-cash charges primarily consisted of $1.0 million in stock-based compensation and $0.5 million in depreciation. The change in our net operating assets and liabilities was primarily due to a $1.9 million increase in inventory for anticipated growth in our business, a $0.6 million increase in accounts receivable due to increase in sales, and a $0.4 million increase in prepaid expenses and other current assets. These changes were partially offset by a $1.6 million increase in accrued and other current liabilities and accounts payable resulting primarily from increases in our operating activities.

Investing activities

In 2018, cash used in investing activities was $0.2 million, attributable to the purchase of property and equipment of $2.0 million, partially offset by the maturity of available-for-sale investments of $1.8 million.

In 2017, cash used in investing activities was $2.2 million, attributable to purchases of investments of $17.7 million and purchase of property and equipment of $0.4 million, partially offset by maturity of available-for-sale investments of $15.9 million.

Financing activities

In 2018, cash provided by financing activities was $29.8 million, attributable to proceeds of $15.0 million from borrowings on the 2018 Loan and Security Agreement, net proceeds of $14.9 million from the issuance of our Series D convertible preferred stock and proceeds from stock option exercises and warrant exercises of $0.5 million, partially offset by deferred offering cost payments of $0.6 million.

In 2017, cash provided by financing activities was $33.7 million, attributable to net proceeds of $34.9 million from the issuance of our Series C convertible preferred stock and proceeds from stock option exercises and warrant exercises of $0.3 million, partially offset by the principal payment of our term loan of $1.6 million.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2018:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Operating lease obligations	$3,207	$940	$1,685	$ 582	$ â€”
Debt, principal and interest(1)	17,138	2,243	14,895	â€”	â€”
Total	$20,345	$ 3,183	$16,580	$ 582	$ â€”

(1) In June 2018 and December 2018, we borrowed $10.0 and $5.0 million, respectively, pursuant to a term loan under the 2018 Loan and Security Agreement. The term loan matures in December 2021. Principal payments associated with the term loan are included in the above table. Interest expense incurred on the term loan is included in the above table based on obligations outstanding and rates effective as of December 31, 2018, including a final one-time payment of $1.0 million in December 2021.

In addition, we enter into agreements in the normal course of business with contract research organizations for clinical trials and with vendors for preclinical studies and other services and products for operating purposes which are cancelable at any time by us, generally upon 30 days prior written notice. These payments are not included in this table of contractual obligations.

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

Managementâ€™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 (â€œGAAPâ€). 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 consolidated financial statements appearing elsewhere in this prospectus, 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 adopted Accounting Standards Codification (â€œASCâ€) 606, *Revenue from Contracts with Customers*, effective January 1, 2018 using the modified retrospective method. The adoption of ASC 606 did not have a material effect on our 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 customerâ€™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 generally 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 daysâ€™ notice.

Convertible preferred stock warrant liability

We have accounted for our freestanding warrants to purchase shares of our convertible preferred stock as liabilities at fair value upon issuance primarily because the shares underlying the warrants contain contingent redemption features outside our control. The warrants are subject to re-measurement at each balance sheet date and any change in fair value is recognized as the change in fair value of warrant liability. We will continue to adjust the carrying value of the warrants until such time as these instruments are exercised, expire or convert into warrants to purchase shares of our common stock. At that time, the liabilities will be reclassified to additional paid-in capital, a component of stockholdersâ€™ equity (deficit). The consummation of this offering will result in this reclassification.

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.

Stock-based compensation

We account 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. We account for forfeitures as they occur.

The fair value of each stock option grant was determined using the methods and assumptions discussed below (see â€œâ€”Fair value of common stockâ€). Each of these inputs is subjective and generally requires significant judgment and estimation by management.

- *Expected Term*â€”The expected term represents the period that stock-based awards are expected to be outstanding. Our historical share option exercise information is limited due to a lack of sufficient data points and does 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*â€”The expected volatility was derived from the historical stock volatilities of comparable peer public companies within our industry that are considered to be comparable to our business over a period equivalent to the expected term of the stock-based awards, since there has been no trading history of our common stock.
- *Risk-Free Interest Rate*â€”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 awardsâ€™ expected term.
- *Expected Dividend Yield*â€”The expected dividend yield is zero as we have not paid nor do we anticipate paying any dividends on our common stock in the foreseeable future.

During the years ended December 31, 2017 and 2018, stock-based compensation was $1.0 million and $1.3 million, respectively. As of December 31, 2018, we had $3.8 million of total unrecognized stock-based compensation, which we expect to recognize over a weighted-average period of 2.72 years. Based upon the initial public offering price of $17.00 per share, the aggregate intrinsic value of options outstanding as of December 31, 2018 was $49.1 million, of which $22.8 million related to vested options and $26.3 million related to unvested options.

Fair value of common stock

Historically, for all periods prior to this initial public offering, the fair values of the shares of our common stock underlying our share-based awards were estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, valuations of our common stock prepared by an independent third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

For our valuations performed prior to December 31, 2017, the fair value of our common stock was estimated using the option pricing model (â€œOPMâ€) with a backsolve method based on precedent transactions. The backsolve method for inferring the equity value implied by a recent financing transaction involves making assumptions for the expected time to liquidity, volatility and risk-free rate and then solving for the value of equity such that value for the most recent financing equals the amount paid. This method was selected as management concluded that the contemporaneous financing transaction was an armâ€™s-length transaction. Furthermore, as of each of the valuation dates prior to December 31, 2017, we were at an early stage of development and future liquidity events were difficult to forecast. The stock options granted from January 2018 through July 2018 were issued with an exercise price based on the then most recent valuation determined by our board of directors as of September 2017. This valuation was prepared using the OPM valuation with a backsolve based on the Series C convertible preferred stock financing in September 2017. The Series C convertible preferred stock was issued at $12.32 per share and the common stock value was estimated to be $4.03 per share at the time of grant. Subsequently, for accounting purposes, we determined the common stock fair value to be $4.51 per share and we used this higher valuation for the purposes of recording share based compensation

expense in our consolidated financial statements. From January 2018 through July 2018, options to purchase approximately 571,000 shares of common stock were issued with an exercise price of $4.03 per share.

In August 2018, we considered a near-term initial public offering to be more likely, and no new stock options were issued in August or September 2018 until a new third-party valuation report was prepared. In October 2018, our board of directors made a new valuation determination in which the fair value of our common stock was estimated using a hybrid Probability Weighted Expected Return Model (â€œPWERMâ€) that incorporated aspects of the market and income approaches. The hybrid method applied the PWERM for the going public and mergers and acquisitions transaction scenarios and applied an OPM in the stay-private scenario. The hybrid method was used because of a near-term potential initial public offering scenario that also factored in the inherent uncertainty associated with being able to complete an initial public offering. In October and November 2018, options to purchase a total of approximately 445,000 shares of common stock were issued with an exercise price of $6.71 per share. No stock options were issued in December 2018. The increase in the estimated fair value of our common stock during 2018 is primarily attributed to our board of directorsâ€™ assessment of an increased probability of an initial public offering in the near term. An initial public offering scenario contemplates that the preferred stock will convert to common stock and that the preferred stock will lose its liquidation preference, thereby decreasing the difference in valuation between preferred stock and common stock. Also, the incorporation of a near-term liquidity event, such as an initial public offering, reduces the period of discount for the lack of marketability of the common stock and further increases the value of the common stock. We issued Series D convertible preferred stock in December 2018 at $13.75 per share, representing a 12% increase in the preferred stock valuation compared to the Series C round. The overall increase in the preferred stock valuation reflected the continued progress by us in developing our products and continued trends of increasing revenues. The valuation of the common stock increased 49% during 2018, incorporating the increased probability of a near-term initial public offering in addition to the overall increase in the valuation of the Company.

Given the absence of a public trading market for our common stock, our board of directors exercised their judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including valuations performed by an independent third party, developments in our operations, sales of preferred stock, the prices, rights, preferences and privileges of our preferred stock relative to the common stock, actual operating results and financial performance and capital resources, the conditions in the medical device industry and the economy and capital markets in general, the stock price performance and volatility of comparable public companies, the likelihood of achieving a liquidity event for shares of our common stock underlying these stock options, such as an initial public offering or sale of our company, and the lack of liquidity of our common stock, among other factors. After the closing of this offering, our board of directors will determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of the grant. Our board of directors intended all options granted to be exercisable at a price per share not less than the per share fair value of our common stock underlying those options on the grant date.

Emerging Growth Company Status

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an â€œemerging growth companyâ€ may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Therefore, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included elsewhere in this prospectus for more information.

Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk

Our cash and cash equivalents as of December 31, 2018 consisted of $39.6 million in bank deposits and money market funds. 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 and cash equivalents.

As of December 31, 2018, we had $15.0 million in variable rate debt outstanding. The 2018 Loan and Security Agreement matures in December 2021, with interest-only monthly payments until September 2019. The term loan accrues interest at a floating per annum rate equal to the greater of the Wall Street Journal prime rate minus 1.75% and 2.75% (3.75% as of December 31, 2018).

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, 2017 and 2018, approximately 43% and 26% of our product revenue, respectively, was denominated in Euros. Our expenses are generally denominated in the currencies in which our 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 $0.2 million in cash and accounts receivable in 2018. 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.

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 through our differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which we refer to as intravascular lithotripsy (â€œIVLâ€). Our IVL system (our â€œIVL Systemâ€), which leverages our IVL technology (our â€œIVL Technologyâ€), is a minimally invasive, easy-to-use and safe way to significantly improve patient outcomes. Our Shockwave M^5 IVL catheter (â€œM^5 catheterâ€) was CE-Marked in April 2018 and cleared by the U.S. Food and Drug Administration (â€œFDAâ€) in July 2018 for use in our IVL System for the treatment of peripheral artery disease (â€œPADâ€). Our Shockwave C^2 IVL catheter (â€œC^2 catheterâ€), which we are currently marketing in Europe, was CE-Marked in June 2018 for use in our IVL System for the treatment of coronary artery disease (â€œCADâ€). We 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, we are undertaking ongoing clinical trials of our C^2 catheter intended to support a pre-market application (â€œPMAâ€) in the United States and a Shonin submission in Japan for the treatment of CAD. We anticipate having final data from these ongoing clinical trials intended to support a U.S. launch of our C^2 catheter in the first half of 2021 and a Japan launch in the second half of 2021.

The Opportunity

Atherosclerosis is a common disease of aging in which arteries become narrowed (â€œstenoticâ€) 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 (â€œdeepâ€ or â€œmedialâ€ calcium) and close to the inner surface of the artery (â€œsuperficialâ€ or â€œintimalâ€ 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 Aortic Stenosis (â€œASâ€), a condition in which the heartâ€™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 â€œcalciumâ€ 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. (â€œMRGâ€). The most common treatment for patients is percutaneous coronary intervention (â€œPCIâ€). This involves a suite of devices to facilitate successful angioplasty and stenting, the most commonly used device being drug-eluting stents (â€œDESâ€). 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 C2 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 (â€œAVRâ€), the main treatment for AS, is growing rapidly, and is dominated by the emergence of Transcatheter Aortic Valve Replacement (â€œTAVRâ€) 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 (â€œballoonsâ€), drug-coated balloons (â€œDCBâ€), 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.

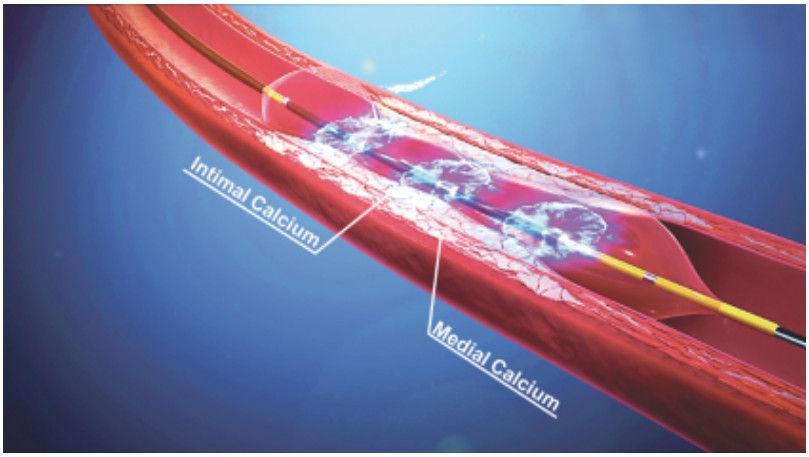
Our Solution

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 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 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 (â€œatmâ€) (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.



Our IVL System *delivers lithotripsy directly to the calcified vessels using a standard interventional balloon catheter delivery system that is able to make contact with the vessel wall and transmit energy efficiently.*

In addition to the treatment of PAD and CAD, we believe our IVL Technology has the potential to improve the care of patients with AS. AVR is the standard of care for patients suffering from symptomatic severe AS, performed either by surgery (â€œsurgical aortic valve replacementâ€ or â€œSAVRâ€) or through a less-invasive TAVR approach. Currently, our M5 catheters are used in our IVL System to enable transfemoral access above-the-knee in patients for whom severely stenotic and calcified ilio-femoral disease puts them at risk for cardiovascular complications associated with TAVR devices. We believe that increasing the number of patients who can have TAVR performed via transfemoral access, the preferred delivery pathway for TAVR, will help reduce complications associated with the procedure. We are also evaluating the use of our IVL Technology to directly treat patients with symptomatic severe AS in clinical feasibility trials as an alternative to AVR. Our transcatheter aortic valve lithotripsy system (our â€œTAVL Systemâ€) is designed to safely crack calcium in the aortic valve

leaflets, thereby improving leaflet mobility and reducing the severity of AS. The prospect of being able to offer an alternative that either delays or obviates the need for AVR in some patients represents a substantial opportunity to provide a meaningfully safer and less invasive approach to treating AS.

Since inception, we have focused on generating clinical data to demonstrate the safety and effectiveness of our IVL Technology. These initial studies have consistently delivered 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 demonstrated that our IVL Technology reduces residual stenosis and vascular complications in infrapopliteal and femoropopliteal PAD, with outstanding durability and sustained improvement in functional outcome in 115 patients. Our past studies have also guided optimal IVL procedure technique and informed the design of our IVL System and future products in development. In the treatment of CAD, our past studies have demonstrated both safety and effectiveness of our IVL System in heavily calcified coronary lesions prior to stenting in 60 patients. Feasibility studies have shown the potential of our TAVL System to safely improve the aortic valve area and reduce transvalvular gradients in AS. We are currently enrolling patients in multiple studies to support applications for approvals and clearances in a variety of indications and geographies, as well as a randomized trial to assess the combination of IVL with DCB for treating PAD.

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, and we have complemented those direct teams with distributors, including in Australia, the Baltics, Canada, Czech Republic, France, Italy, the Netherlands, New Zealand, the Nordic region, Poland, Spain and the United Kingdom. We are actively expanding our international field presence through new distributors, additional sales and clinical personnel, and are adding new U.S. sales territories.

We are headquartered in Santa Clara, California, and we have additional operations and facilities in Fremont, California. We currently manufacture our IVL catheters in Fremont, California. As of December 31, 2018, we had 162 full-time employees. Our revenue was $1.7 million and $12.3 million for the years ended December 31, 2017 and 2018, respectively, and we incurred a net loss of $30.6 million and $41.1 million for those same periods, respectively.

For the treatment of CAD, our C^2 catheter has a CE Mark that indicates its use in calcified, stenotic *de novo* coronary arteries prior to stenting. For the treatment of PAD, our M^5 and S^4 catheters have a CE Mark and have FDA clearances that indicate their use in calcified, stenotic peripheral arteries in patients who are candidates for percutaneous therapy. Our products are not indicated for the treatment of cerebrovascular or carotid arteries; our M^5 and S^4 catheters are not indicated for the treatment of coronary arteries.

While 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, conduct clinical trials on our existing and 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.

Why ShockWave? Safe â€“ Simple â€“ Effective

- â€¢ **Treatment of both superficial and deep calcium.** Our IVL System employs our IVL Technology to create shockwaves that penetrate 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. We believe our IVL System is the only available cardiovascular therapy able to safely and effectively treat medial calcium, which is highly prevalent and for which other existing therapies have limited utility.
- â€¢ **Improved safety through unique mechanism of action.** By relying on locally delivered sonic pressure, our IVL System safely modifies both intimal and medial calcium without causing perforations, distal embolization or damage to the vasculature and surrounding tissues. We believe that by reducing complications, physicians will also be able to reduce the number of additional devices required to successfully complete the treatment of the patient.
- â€¢ **Improved efficacy for angioplasty, stents and drug-eluting therapies.** We believe our IVL System enables better interventions in complex calcified lesions by improving the likelihood of the procedureâ€™s success and facilitating optimal outcomes in conjunction with other therapies, including stents, drug-eluting technologies and structural heart interventions.
- â€¢ **Seamless integration into interventional practice with exceptional ease-of-use.** Our IVL System is portable and easy to install and set-up. There are no special facility requirements, no external connections and no settings to adjust. Physicians prepare and deliver our IVL catheters just as they would a standard angioplasty catheter, and they maintain the ability to use guidewires and other interventional tools of their choice.
- â€¢ **Expanded access to interventional techniques for patients.** The ability to treat complex calcium effectively and with low safety risk may enable endovascular therapy in multiple underserved patient cohorts, including: common femoral artery stenosis cases currently avoided due to the risk of stenting; critical limb ischemia (â€œCLIâ€) patients scheduled for bypass or amputation; transfemoral access instead of alternate access or surgical cut-down for TAVR, Endovascular Aneurysm Repair (â€œEVARâ€) and Thoracic Endovascular Aneurysm Repair (â€œTEVARâ€) procedures; and PCI in patients who may otherwise need a surgical coronary bypass procedure.
- â€¢ **Cost-saving potential of our IVL System.** We believe that our IVL System will provide economic value to the healthcare system. Multiple value streams can result in cost saving benefits:
  - â€¢ reduced time required by physicians to understand and adopt our IVL System relative to other therapies;
  - â€¢ reduced expense to train and support physicians compared to the burdensome and expensive physician certification programs required by manufacturers of some atherectomy devices;
  - â€¢ reduced cost to hospitals to treat complex calcified disease due to lower risk of complications, less lab time and lower equipment costs per case than other commercially available options; and
  - â€¢ reduced need for complex, risky and expensive alternative procedures, such as surgery or surgical access for TAVR, EVAR and TEVAR.

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.

- â€¢ **Address unmet clinical needs in multiple large markets.** Calcified cardiovascular disease is a growing treatment challenge that is not safely and effectively treated by existing therapies. Treatment of this disease represents a large, growing total addressable market opportunity across multiple

indications. Patients with calcified arteries are typically excluded from clinical trials and are often referred to highly specialized hospitals and physicians for treatment. This habitual avoidance of complex calcium cases is due to the difficulty in using, and high complication rates associated with, existing therapies. Our IVL System is safe, easy to use and effective for its approved indications. We are targeting PAD and CAD as our first two indications, which represent an existing combined global medical device market of nearly $13 billion as of 2018, according to MRG. Calcified vascular disease represents an immediate total addressable market opportunity of over $3.5 billion for our IVL Technology. We believe treating AS, our third target indication which is currently being developed, represents a potential $3 billion total addressable market opportunity.

- **Advance our IVL System as a common treatment for calcified PAD and CAD.** Our clinical studies demonstrate our IVL Systemâ€™s safety and effectiveness in treating calcified cardiovascular disease. In addition, our IVL System is as familiar and easy to use as a standard angioplasty catheter, making it an attractive option for physicians. Procedures using our IVL System are generally reimbursed by public and private insurers, and there is potential to improve the existing reimbursement profile in the future. To grow our business, we plan to continue to establish and strengthen our clinical evidence and commercial presence in our first two target indications, PAD and CAD.

- **Grow our specialized sales force across indications and geographies to foster deep relationships with physicians and drive revenue growth.** We sell our IVL System through our direct sales organization in the United States, Germany, Austria and Switzerland, and through distribution partners in other geographies. We have assembled a team with in-depth knowledge of the target markets in which we compete and seek to compete. We have also collaborated with many of the physician thought leaders in the interventional cardiology, interventional radiology and vascular surgery communities; they have helped us deliver new and improved products that meet their clinical needs and inform our product pipeline. We intend to grow our sales organization meaningfully as we launch new products, expand our indications and enter new geographies.

- **Execute on our clinical program to expand indications and build a robust body of clinical evidence.** Our clinical and regulatory strategies are designed to gain approval for new products in new indications and new geographies, including our Shockwave S4 IVL catheter (â€œS4 catheterâ€) and our TAVL System, among others. They are also designed to demonstrate the benefits of our IVL Technology when combined with existing therapies. We are currently enrolling patients in Disrupt PAD III, a study designed to demonstrate the benefit of combining our IVL Technology with DCB as an alternative to standalone DCB in severely calcified femoropopliteal lesions. CAD III, a study designed to demonstrate the safety and efficacy of our IVL Technology when combined with DES in the treatment of severely calcified CAD, began enrolling patients in early 2019. If successful, we expect the data from CAD III will support the approval of our C2 catheter to be used in our IVL System for the treatment of CAD in the United States in the first half of 2021 and Japan in the second half of 2021.

- **Leverage our IVL Technology to develop new products that satisfy significant unmet clinical needs.** For its approved uses, our IVL System has been shown to be safe, effective and easy to use. We see a significant opportunity for the expansion of our IVL Technology beyond our current indications, and we have robust research and development capabilities and a growing intellectual property portfolio to support such expansion. We believe our ability to rapidly and cost-effectively develop innovative products is in large part attributable to our fully integrated product development process. Ultimately, our plan is to have a family of IVL catheters that can be used in our IVL System to treat calcium-related vascular disease throughout the body.

- **Drive profitability by scaling our business operations to achieve cost and production efficiencies.** We plan to drive profitability by expanding the scale and improve the efficiency of our manufacturing process with the goal of lowering our costs and having enough supply to meet demand as we grow our business. We intend to move our production to our new facility in Santa Clara, California in 2019,

which we expect to provide us enough manufacturing space to support our business for the foreseeable future. In the future we intend to lower our cost of goods sold through productivity improvements, the implementation of lean manufacturing and fixed cost absorption as we grow volume.

The Market

Occlusive Calcified Cardiovascular Disease (Atherosclerosis)

Atherosclerosis is a common disease associated with aging in which arteries become narrowed 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 can be present in multiple layers of the artery. Primarily, it is found in the intimal layer and the medial layer. None of the commercially available technologies, other than our IVL System, are able to adequately target both the intimal and medial layers of calcium.

The first two indications which we have sought to develop our IVL Technology to treat atherosclerotic occlusive PAD and CAD. These diseases decrease the diameter of the blood vessel which impedes the heartâ€™s ability to pump oxygenated blood throughout the body and can lead to heart attacks, organ failure, claudication (severe leg pain), tissue loss (including amputation) and ultimately death. In the future, we see a significant opportunity for the use of our IVL Technology in the potential paradigm shifting treatment of AS, a disease characterized by calcification of the aortic valve, which can also lead to death if left untreated.

As of 2018, the global market opportunities for medical devices that treat occlusive PAD and CAD are approximately $2.9 billion and $10 billion, respectively, according to MRG. Within these segments, the presence of calcified disease is as high as 30% to 75% of procedures, representing a combined, immediately total addressable market opportunity of over $3.5 billion for our IVL System. Likewise, our TAVL System could potentially have a total addressable opportunity of over $3 billion if it is determined to be safe and effective for treating the aortic valve and we are able to obtain relevant regulatory approvals or clearances. We expect these markets to grow significantly due to the following trends:

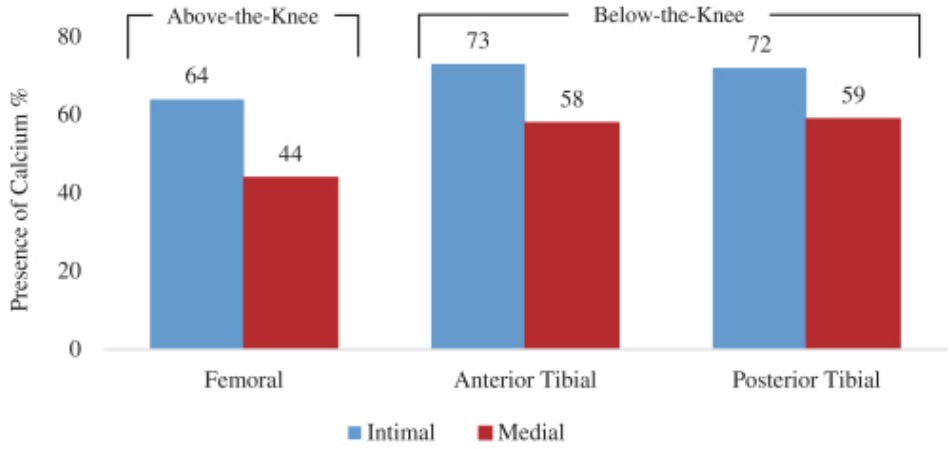
- â€¢ global, aging population;
- â€¢ meaningful increase in the number of diabetic patients;
- â€¢ additional clinical evidence that supports endovascular treatment of cardiovascular disease;
- â€¢ improvement of technologies to enable safer and more effective endovascular treatment;
- â€¢ growing evidence of the complications and costs associated with surgical treatment of cardiovascular disease;
- â€¢ continued support and education of the growing number of physicians who treat cardiovascular disease; and
- â€¢ increasing patient awareness and physician adoption of less invasive endovascular treatment options.

Peripheral Artery Disease (PAD)

PAD is the narrowing or blockage of vessels that carry blood from the heart to the extremities, caused by the buildup of plaque within the walls of arteries. It is a common, under-diagnosed and under-treated disease whose global patient population, estimated at more than 200 million in 2010 by a paper published in *The Lancet*, is driven by an aging population and increased rates of diabetes, among other causes. The most common symptom of PAD in the lower extremities is claudication and painful muscle cramping in the hips, thighs or calves when walking, climbing stairs or exercising. The more advanced form of PAD, CLI, is characterized by resting pain and sores or wounds that heal slowly and, if not resolved, can lead to amputation of a limb. The PAD population in the United States is estimated to be at least eight million people. Calcium is a prevalent problem and the â€œcalciumâ€ segment of the PAD market is a relatively high percentage of the current commercial market.

Moderate-to-severe calcium can occur in different parts of the peripheral vasculature, including:

- **Femoropopliteal:** Over 325,000 estimated worldwide cases of heavily calcified procedures annually, representing a nearly $700 million total addressable market opportunity for our IVL System.
- **Common Femoral Artery, Iliac Artery:** Over 300,000 estimated worldwide cases of heavily calcified procedures annually, representing a $600 million total addressable market opportunity for our IVL System.
- **Infrapopliteal (Below-the-Knee (BTK)):** Over 180,000 estimated worldwide cases of heavily calcified procedures annually, representing a nearly $400 million total addressable market opportunity for our IVL System.



***Medial Calcification Prevalence** is higher in PAD below-the-knee than above-the-knee, creating additional challenges for effective treatment and the potential for complications increasing the risk of amputation. Soor, et al, Pathology, June 2008; from ScienceDirect.*

There are expected to be nearly 750,000 PAD endovascular procedures performed in the United States and an additional 500,000 PAD endovascular procedures performed in other developed international markets to treat occlusive disease in 2018, according to MRG. A significant portion of these procedures involves moderate-to-severe calcium, which varies in intensity between vessels. In 2018, the total market for endovascular devices used to treat occlusive PAD was estimated to be approximately $2 billion and $950 million in the United States and international markets, respectively, as reported by MRG. Of this, the plaque modification market for PAD is estimated to be over $600 million annually, nearly all of which is in the United States.

Vessel(s)	Region	Endovascular Procedure Volume(1)	% Calcification(2)
Femoropopliteal (includes superficial femoral artery (SFA))	United States	339,000	50%
	International	337,000	
Iliac	United States	212,000	70%
	International	182,000	
Infrapopliteal (BTK)	United States	152,000	65%
	International	133,000	
TAVR Access	United States	55,000	15%
	International	70,000	
EVAR / TEVAR Access	United States	53,000	15%
	International	107,000	
Common Femoral (Surgical Endarterectomy (CFE) + Endovascular)	United States	50,000	75%

(1) *Annual procedures in the United States and internationally (nine European countries and Japan), according to MRG, an article published in the* Journal of Thoracic Disease *in June 2017 and Company estimates.*
(2) *Proportion of annual procedures associated with calcified disease, according to Yost, M. L., Prevalence and Significance of Calcium, Vulnerable Plaque and Plaque Morphology in Peripheral Artery Disease (PAD). Beaufort, SC: THE SAGE GROUP; 2016 (for femoropopliteal, BTK, TAVR and common femoral) and Company estimates based on multiple occlusive disease studies (for iliac and EVAR / TEVAR).*

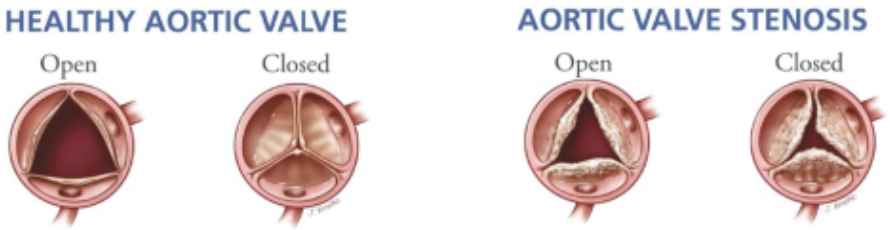
Coronary Artery Disease (CAD)

CAD is the narrowing or blockage of the arteries that supply blood to the heart, caused by the buildup and rupture of plaque within the walls of arteries. As with PAD, its growing prevalence is driven by an aging population and increased rates of diabetes, among others. According to the American Heart Association, approximately 15.5 million people in the United States suffered from CAD in 2016. Patients are treated for CAD following either a heart attack or after presenting symptoms, such as angina, which is an acute pain in the chest. As is the case with PAD, the primary goal of treatment of CAD is to re-open the coronary artery in order to restore adequate blood flow to the heart muscle.

Plaque modification devices for treating CAD are under-penetrated in the market due to a number of reasons, including the difficulty to use available devices, their limited effectiveness in some cases and the potential for serious complications to the patient. Despite these significant limitations, they still represent a market of nearly $100 million in 2018 in the United States and Japan alone, according to MRG, an amount we believe is significantly larger globally. Moreover, due to increasing prevalence of calcified disease, we believe that our safe, simple and effective solution in approved indications can increase the utilization of IVL Technology beyond the existing market for plaque modification devices.

Aortic Stenosis (AS)

AS is a condition where the heartâ€™s aortic valve, which regulates oxygenated blood flow from the heart to the rest of the body, becomes increasingly calcified with age. As the calcium burden on the valve increases, the valve narrows and stiffens, reducing the ability to pump blood from the heart to the rest of the body. Patients who become symptomatic and/or are diagnosed with severe AS are treated by surgically replacing the aortic valve. Historically, this procedure, SAVR, was a highly invasive surgical procedure. Over the last decade, a new class of devices known as TAVR has enabled interventional cardiologists to replace the valve through a less invasive, catheter-based endovascular approach. According to an article published in the *Journal of Thoracic Disease* in 2017, the global market for TAVR is estimated to be over 125,000 procedures performed worldwide in 2018 and is expected to grow to nearly 300,000 by 2025.



***AS** results from calcification that inhibits the aortic valve from opening and closing effectively.*

Current Treatments & Limitations

Occlusive Calcified Cardiovascular Disease (Atherosclerosis)

The primary approaches to treat occlusive cardiovascular disease are balloons, DCB, stents and DES. The drug-eluting technologies were designed to reduce restenosis rates associated with balloons and bare metal stents.

The application of medical therapy via balloons or stents targets the inflammatory response caused by the use of devices, to reduce the risk of restenosis. The delivery of drugs in conjunction with vessel dilation has been shown to improve long-term results in atherosclerotic disease. Treatment with balloons and stents is often suboptimal because calcified vessels fail to expand under pressure. This in turn can lead to acute failure, damage to the intimal layer leading to restenosis or acute complications requiring adjunctive tools or conversion to bypass surgery.

Plaque modification devices have also meaningfully contributed to the advancement in the treatment of cardiovascular disease. These devices are designed to improve the outcomes of angioplasty and stenting by modifying the calcium, thus improving the ability of the vessels to expand. Some of these devices are incremental, such as specialty angioplasty balloons, and others are more paradigm-shifting, such as atherectomy. The 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. The atherectomy devices vary in function with mechanisms, including carving, â€œsandingâ€, high-pressure mechanical disruption, focused dissection and laser ablation of the plaque and surrounding tissue.

In patients with moderate and severe calcium, the complications associated with endovascular treatment are significantly increased. Particularly in cases where there is medial calcium, where existing plaque modification devices cannot effectively modify the calcium without damaging the surrounding tissue. These severe complications commonly include:

- â€¢ **Dissections**: The abnormal, and usually abrupt, formation of a tear along the inside wall of an artery. If the tear is large enough, blood can accumulate behind the tear creating blood clots or the tear itself can block the flow of blood. Treatment options for managing a dissection include additional balloons, stenting or for PAD, implantation of a covered stent.
- â€¢ **Embolization**: Particles that travel down the bloodstream and occlude the artery as it narrows. These particles can be blood clots, thrombus, vascular tissue or calcium. While embolization is inherently a risk with all procedures, the use of cutting or sanding tools increases the risk of creating these particles as part of the procedure to occlude blood flow.
- â€¢ **Restenosis:** Re-occlusion of the vessel following endovascular treatment, leading to the need for one or more repeat treatments.
- â€¢ **Vessel Perforations**: A hole or break in the vessel wall. Depending on where the perforations occur in the vasculature, this could be a life-threatening event. Treatment is usually implantation of a covered stent.
- â€¢ **Vessel Recoil**: After expansion is created by ballooning or stenting, the vessel does not maintain its larger diameter and recoils to a smaller diameter which continues to inhibit blood flow. With balloons, this may mean insufficient lumen gain. With stenting, this may result in an under-expanded stent, which is a serious complication that may require surgery to repair.

Advances in technologies have addressed many of the challenges associated with non-calcified lesions. However, these advancements do not adequately address the challenges posed by calcified lesions. For example, DCB and DES have generally been studied in patients without severe calcification. In the limited PAD clinical trials where DCB have been evaluated in severely calcified arteries, their effectiveness was significantly lower than in non-calcified arteries and not noticeably different than other treatment modalities, according to a study published in *CardioVascular and Interventional Radiology* in May 2014.

Plaque modification devices were initially considered the advancement needed to effectively treat all lesion types, including calcified lesions. However, due to the nature of how these devices modify the vessel, their use can create additional complications, including severe dissection, perforation and distal embolism. Furthermore, because these devices can cause damage to the surrounding healthy artery, they may increase the risk of restenosis, which would put the patient at an increased risk of requiring a repeat procedure.

We believe that by successfully addressing cardiovascular calcification and by enabling safer and more effective treatment of the disease, the use of our IVL Technology delivered through our IVL System will lead to an increase in the number of patients who receive endovascular treatment for calcified cardiovascular disease rather than surgery in approved indications.

Peripheral Artery Disease (PAD)

Initial treatment for PAD is through medication and lifestyle adjustments. More advanced cases are treated using invasive CFE (surgical removal of the inside of the blood vessel), surgical bypass or minimally invasive interventional procedures. The primary goal of interventional therapy is to re-open the peripheral artery to restore adequate blood flow, thereby eliminating leg pain or supporting wound healing.

Percutaneous Balloon Angioplasty (â€œPTAâ€) is a catheter-based procedure that uses a balloon to open a blood vessel. It is the most common tool for PAD due to its simplicity and low cost. However, balloons often fail to open the vessel due to vessel recoil, which occurs when the diseased vessel fails to stay open immediately after the PTA procedure. PTA procedures also use high pressure which can cause vessel injury, and which is associated with poor long-term outcomes. When PTA fails, stent implantation can help improve acute outcomes and has better long-term outcomes than PTA. But in many cases, stent implantation is not preferred because it leaves metal in the peripheral arteries reducing future treatment options. Considerations for selecting a device to treat PAD include planning for the best acute outcome, choosing a therapy that may provide good long-term outcomes and the eventual likelihood of re-intervention or intervention in another part of the vasculature.

Moderate-to-severe calcium poses different challenges and an unmet need in various parts of the peripheral vasculature. The use of high-pressure balloons and stents can result in dissection, perforation and barotrauma, which result in restenosis. The use of atherectomy devices damages the vessel and can cause embolization. Further, heavy calcium can prevent full stent expansion and can also cause vessel recoil after angioplasty due to the stiffness of the vessel.

- â€¢ **Femoropopliteal:** Endovascular intervention is the most common treatment for occlusive disease in the femoropopliteal arteries, principally via atherectomy, PTA and stenting. While endovascular procedures are generally profitable for hospitals, treating complex lesions is much more resource intensive, and treatment of these types of patients can be unprofitable for hospitals.
- â€¢ **Common Femoral Artery:** The common femoral artery is found at the junction between the SFA and the iliac arteries. Occlusive disease in this location is typically treated by CFE. Recent studies, however, have shown that CFE is not a benign procedure and not all patients are good candidates for this therapy. CFE can lead to complications such as infection and an increased length of hospital stay for the patient. Endovascular treatment has not been considered a primary treatment option previously due to calcium-related risks, such as embolization and dissection, which is subsequently treated with stenting and risks blocking blood flow.
- â€¢ **Infrapopliteal (BTK):** BTK lesions are more commonly found in patients with the more advanced CLI. The most common clinical treatment approach is PTA. Failure of PTA, including balloon rupture, is more common in BTK lesions because medial calcification is most prevalent in these vessels and because the vessels are smaller and more tortuous. Reinterventions due to failed treatment are also more common, as they are required to ensure adequate blood flow for ongoing wound healing. Importantly, calcium has been shown to be an independent predictor of poor wound healing and increased amputation risk in patients with CLI. Further, distal emboli can be a severe complication in patients with CLI.
- â€¢ **Iliac Artery:** Stenting is considered the standard of care for symptomatic iliac disease with good acute diameter gain and long-term outcomes. Though calcium is common in the iliac arteries, modifying calcium in these vessels has not previously been an option because of the large diameter and potentially catastrophic outcome if the iliac is ruptured during treatment. As a result, atherectomy devices are not approved for use in the iliac arteries.

Calcified iliac and femoral arteries can hinder the delivery of large endovascular devices for other catheter-based procedures, including those that treat aortic aneurysms (EVAR and TEVAR), severe aortic stenosis treated with TAVR and cardiac support devices for high-risk PCI (e.g. Abiomedâ€™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 due to the extent of vascular calcification, according to a 2018 study in the *Journal of the American College of Cardiology*.

With increasing frequency, our IVL System using our M5 catheters is being used to crack the ilio-femoral calcium prior to insertion of devices that are delivered via large-diameter catheters. Treating these arteries with our IVL System makes them more pliable and enables them to stretch and bend, thus accommodating the large-diameter catheters required for TAVR, EVAR, TEVAR and Impella. We have observed that many of the cardiologists using TAVR and Impella in Europe also perform PCI in the same interventional lab. Introducing physicians in the United States to our IVL System for large bore access can be beneficial in terms of building awareness and access to our IVL Technology in advance of the regulatory approval or clearance of our C2 catheters in the United States.

In December 2018, we entered into a collaboration with Abiomed, a leading global provider of medical devices that provide circulatory support. Pursuant to this collaboration, we will work with Abiomed to integrate our products into Abiomedâ€™s physician training and education programs. In connection with the collaboration, Abiomed purchased shares of our Series D convertible preferred stock.

There are multiple treatment options for PAD across the different vessel types throughout the vascular system. Each treatment type presents different limitations and safety issues, which restrict their use by physicians. The following table summarizes the treatment options for each vessel type, their frequency of use and the challenges calcium poses for each treatment option.

Vessels	Endovascular Treatment	Frequency of Use	Challenges Associated with Use in Calcified Lesions
Femoropopliteal & Common Femoral	PTA & DCB	Moderate	â€¢â€‚â€‚Perforation, Dissection, Recoil â€¢â€‚â€‚Limited Drug Uptake (DCB) â€¢â€‚â€‚Crushed Stents
	Stents & DES	Moderate	
	Plaque Modification	Moderate	â€¢â€‚â€‚Perforation, Dissection, Recoil â€¢â€‚â€‚Lack of efficacy in medial calcium â€¢â€‚â€‚Difficulty of use and procedure time
Iliac	PTA	Moderate	â€¢â€‚â€‚Dissection â€¢â€‚â€‚Perforation â€¢â€‚â€‚Recoil â€¢â€‚â€‚Catastrophic perforation â€¢â€‚â€‚Large vessel size â€¢â€‚â€‚Embolization
	Stents/covered stents	High	
	Plaque Modification	Low	
Infrapopliteal (BTK)	Angioplasty	High	â€¢â€‚â€‚Perforation, Dissection, Recoil â€¢â€‚â€‚High restenosis rates â€¢â€‚â€‚Increases complexity of reintervention
	Stents	Low	
	Plaque Modification	Moderate	â€¢â€‚â€‚Embolization â€¢â€‚â€‚Lack of efficacy in medial calcium

Coronary Artery Disease (CAD)

The most common treatment for patients with CAD is PCI. This involves a suite of devices to facilitate successful angioplasty and stenting (most commonly DES) of the culprit artery or arteries. According to MRG, there are nearly 4 million PCI procedures performed globally every year, and the growth in PCI procedures is more than 5% annually. A study published in the *American Journal of Cardiology* in 2014 demonstrated that more than 30% of patients undergoing PCI have calcified lesions and that this percentage is growing. Calcium can impair the ability to deliver and expand coronary stents. The complication rates for patients undergoing PCI increase significantly with a greater calcium burden. Further, the long-term outcomes in patients who have increased calcium are worse, including increased risk of death and increased need for target lesion revascularization. Due to the demographic changes discussed earlier, the percentage of PCI cases that include moderate-to-severe calcium are increasing at a faster rate than the growth of non-calcified PCI cases. There is an unmet need for tools to safely and effectively treat calcified CAD, which is increasing.

As with PAD treatment, plaque modification devices are used to facilitate PCI in patients with moderate-to-severe calcium. This class includes atherectomy devices and specialty angioplasty balloons. The most common mechanism in coronary atherectomy is to â€œsandâ€ the calcium with miniature, high-speed, drill-like catheters known as either â€œrotationalâ€ or â€œorbitalâ€ atherectomy. Physicians typically use these devices in conjunction with, and in preparation for, stents and balloons. When there is significant calcium present and plaque modification devices are not used successfully, however, it is difficult to fully expand the stent due to the under-treated calcium, and when stents are under-expanded there is an increased risk of stent thrombosis, creating an increased risk that the patient suffers from chest pain or a future heart attack.

Due to the risk of complications and complexity of the anatomy, coronary atherectomy devices are difficult to use. They necessitate specialized training, physician certification and significant support from manufacturers. Use of these devices can cause severe complications and damage to healthy tissue due to the high-speed rotation of atherectomy and the high-pressure mechanical trauma of specialty balloons. These complications include severe dissection, perforation and distal embolism. When these complications occur during treatment of a coronary artery, the patient may experience major adverse events (â€œMAEâ€), including greater damage to the heart (myocardial infarction) and even death. Because these devices can damage the surrounding healthy artery, they may increase the risk of future restenosis, which puts the patient at risk of a heart attack or the need for a repeat procedure. Specialty balloon devices also 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.

For many interventional cardiologists and treatment centers, the burden of training and certification, the increased time and complexity in using plaque modification devices and the risk of serious procedural complications limit the use of such devices. This has led to a low penetration in cases with significant calcium burden.

Device Type	Device Utilization in Calcified Cases	Challenges
Atherectomy	**Low**	â€¢â€ŠEase of Use â€¢â€ŠDissections & Perforations â€¢â€ŠDistal Embolism â€¢â€ŠBifurcated lesions â€¢â€ŠLarge vessels (i.e., Left Main Artery) â€¢â€ŠDamage to healthy vessel â€¢â€ŠTortuous vessels
Specialty Balloon	**Low**	â€¢â€ŠEfficacy in severe, diffuse calcium â€¢â€ŠDissections & Perforations â€¢â€ŠDamage to healthy vessel

Aortic Stenosis (AS)

Patients who become symptomatic and/or are diagnosed with severe AS are treated by replacing the aortic valve. Historically, this procedure was a highly invasive surgical procedure. Over the last decade, however, TAVR has enabled interventional cardiologists to replace the valve through a less invasive, catheter-based endovascular approach. The introduction of TAVR has led to a paradigm shift in treating patients with severe AS and has enabled access to a life-saving therapy for severe AS patients who otherwise would generally have no safe and effective option. TAVR has also led to an increasing diagnosis of patients with symptomatic severe AS. TAVR, however, introduces the potential for certain significant complications, including risk of ischemic stroke and cardiovascular complications associated with the delivery of the catheter. In patients with severely stenotic and calcified iliofemoral disease, the large diameter catheters required to deliver TAVR devices can create severe cardiovascular complications or even necessitate the use of alternative access routes, such as the subclavian, direct aortic, transcaval and transapical approaches. Furthermore, TAVR outcomes can be compromised or can be prohibitive in patients with poor ventricular function or other co-morbidities that preclude safe administration of the pharmaceutical regimen required after the TAVR procedure. We believe there is significant potential for our IVL Technology to be used as a synergistic procedure to facilitate TAVR access and thus avoid a potentially more invasive procedure. Additionally, we are evaluating the use of our IVL Technology to directly treat patients with symptomatic severe AS in clinical feasibility trials as an alternative to aortic valve replacement. Our TAVL System is designed to safely crack calcium in the aortic valve leaflets, thereby improving leaflet mobility and reducing the severity of AS.

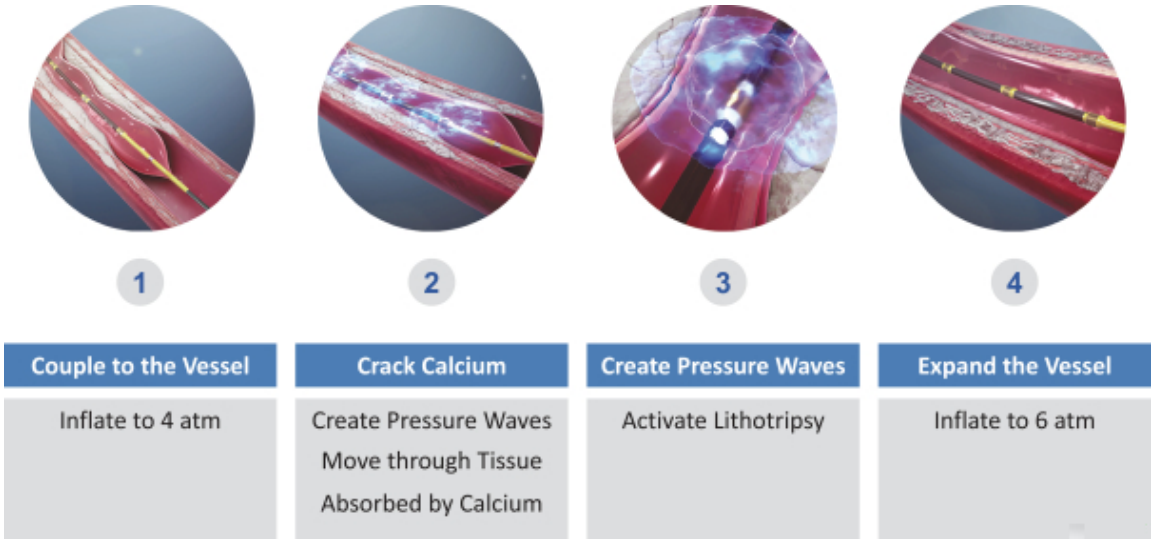
Our Approach

Our IVL System utilizes a generator, connector cable and IVL catheter to create short bursts of sonic pressure waves that travel through the diseased vessel. These pressure waves crack calcium with an effective pressure of up to 50 atm without harming the soft tissue of the vessel. The IVL catheter consists of a semi-compliant balloon catheter integrated with multiple lithotripsy emitters specific to each region of the body.

During the procedure, the IVL catheter is advanced to the target lesion, and the integrated balloon is inflated with fluid at a low pressure so the balloon is able to make contact with the artery wall and facilitate efficient energy transfer. IVL is then activated with the touch of a button on the connector cable, creating a small bubble that rapidly expands and collapses within the catheter balloon. The expansion and collapse of this bubble creates sonic pressure waves that pass through the artery and cracks both intimal and medial calcium, making the artery more compliant, enabling it to be dilated by the balloon at very low pressures. This minimizes injury inherent with traditional high-pressure balloon dilations or atherectomy devices typically used to treat calcified lesions.

After cracking the calcium with IVL, the physician may decide to perform additional endovascular treatments, depending on the location and type of lesion. IVL enables more effective delivery and expansion of stents or balloons at lower pressure. When followed by an anti-proliferative therapy such as DCB or DES, the micro-fractures may enable better drug penetration into the arterial wall and improved drug uptake, thereby improving the effectiveness of the combined treatment.

The IVL Procedure



We believe there is significant opportunity to apply our IVL Technology as a platform to treat a broad scope of vasculature, and therefore a broad scope of indications. The interchangeability of specific catheters enables delivery of IVL therapy across diseased vasculature throughout the body. Ultimately, our plan is to have a family of IVL catheters that can treat calcium-related vascular disease.

ShockWave IVL System Components

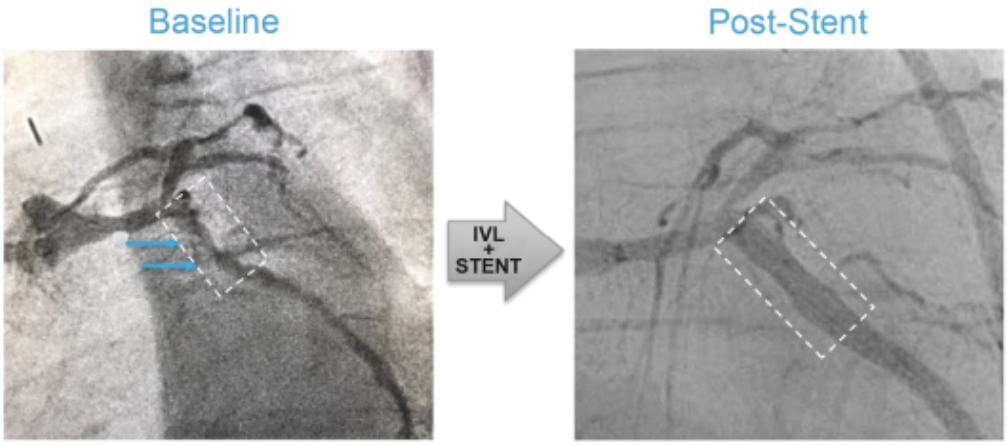
ShockWave IVL Catheters: Our IVL catheters are prepared in the interventional lab and delivered through the blood vessel, just like traditional balloon angioplasty devices. Our IVL catheters incorporate proximal and distal radiopaque markers for visibility under fluoroscopy. At the touch of a button, miniaturized lithotripsy emitters create high-pressure sonic waves through a conversion of electrical energy into mechanical energy. These pressure waves are created along the length of the balloon at a frequency of one per second and propagate spherically from the emitters to impact calcium in all directions.

IVL Connector Cable: Our IVL catheters attach to our IVL connector cable through a magnetic plug designed to provide a simple and secure connection. The physician activates the lithotripsy by pushing a button on the IVL connector cable.

IVL Generator: Our compact, battery-powered, rechargeable IVL generator is linked to the balloon catheter via the IVL connector cable. By design, the IVL generator recognizes which type of IVL catheter is connected and the generator software then determines how much power and how many pulses to deliver.

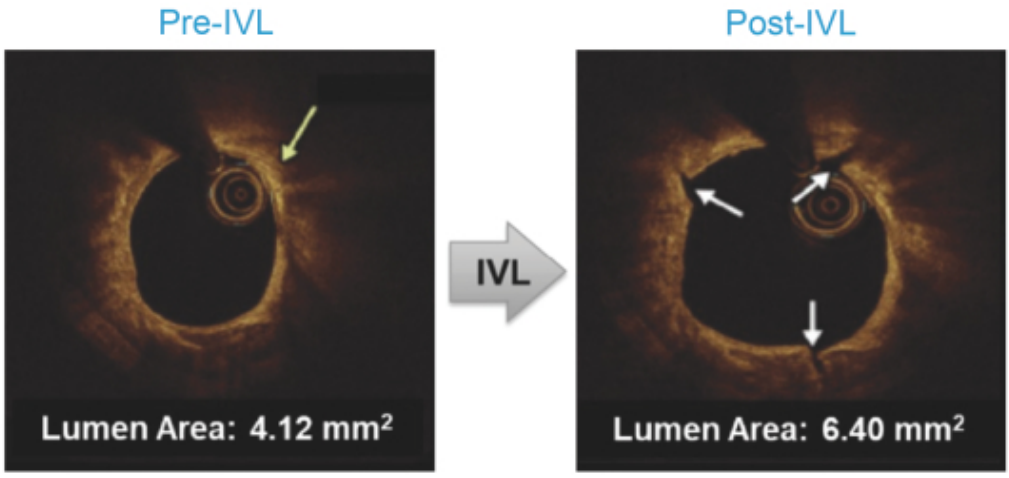
Angiographic Images of Calcified Coronary Lesion Prior to IVL, Post-IVL and Post-Stent

The angiogram images below show the treatment of a heavily calcified left anterior descending artery in the heart. Baseline imaging shows a calcified stenosis, to which IVL is delivered at a balloon pressure of only 4 atm. With subsequent pulses and without increasing the balloon pressure, the balloon expands, demonstrating IVLâ€™s efficacy in cracking calcium and making the artery more compliant. The final angiogram shows a widely patent vessel after stent implantation.



OCT Images of Calcified Coronary Lesion Prior to IVL and After IVL

Below, optical coherence tomography (â€œOCTâ€) imaging shows on the left, stenotic vessel with circumferential calcium prior to treatment by IVL and on the right, cracks in the calcium and luminal diameter gain (from 4.1 mm^2 to 6.4 mm^2) following IVL.



Broad Anatomical Applications

Below is a summary of the vasculature in which IVL can be used and what we believe are its benefits:

Patient Segment		Expected IVL Advantages
PAD	Femoropopliteal (including SFA)	â€¢â€‚â€ŠImproves ease of use â€¢â€‚â€ŠReduces procedure time â€¢â€‚â€ŠLowers complications â€¢â€‚â€ŠHelps with cost containment â€¢â€‚â€ŠAddresses medial calcium
	Iliac Occlusive Disease	â€¢â€‚â€ŠReduces risk of complications (e.g. dissection, rupture) â€¢â€‚â€ŠEnables stent delivery and full expansion â€¢â€‚â€ŠAvoids embolic debris in the profunda artery
	Common Femoral	â€¢â€‚â€ŠEnables safe endovascular treatment options â€¢â€‚â€ŠAvoids risks associated with surgical endarterectomy â€¢â€‚â€ŠImproves outcomes
	Infrapopliteal (BTK)	â€¢â€‚â€ŠProvides option for treating the trifurcation â€¢â€‚â€ŠLowers complications vs. atherectomy â€¢â€‚â€ŠReduces recoil â€¢â€‚â€ŠAddresses medial calcium
EVAR & TEVAR	Access	â€¢â€‚â€ŠReduces complications associated with large-diameter delivery systems â€¢â€‚â€ŠEnables transfemoral access and contains costs
	Stent-graft Deployment	â€¢â€‚â€ŠReduces complications associated with under-expanded iliac grafts
CAD	Stable Angina	â€¢â€‚â€ŠImproves ease of use â€¢â€‚â€ŠReduces procedure time â€¢â€‚â€ŠLowers complications â€¢â€‚â€ŠImproves outcomes
	Acute Coronary Syndromes (unstable/emergency patients)	â€¢â€‚â€ŠLowers complications vs. direct stenting â€¢â€‚â€ŠImproves outcomes vs. direct stenting â€¢â€‚â€ŠReduces hospitalization time vs. staged procedures
AS	TAVR Access	â€¢â€‚â€ŠReduces complications â€¢â€‚â€ŠEnables transfemoral access â€¢â€‚â€ŠReduces costs associated with alternate access
	Primary Therapy	â€¢â€‚â€ŠStabilizes patients to improve future treatment options â€¢â€‚â€ŠAvoids the long-term risks associated with an implant

Our Products

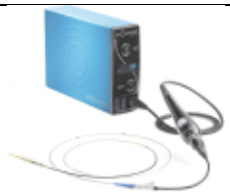
Current Marketed Products

We are marketing our IVL System using M5 catheters (â€œmediumâ€ vessel, five-emitters) for treating PAD in the United States and internationally. We are marketing our IVL System using C2 catheters (coronary, two-emitters) for treating CAD in select international markets. We received an investigational device exemption (â€œIDEâ€) to conduct our pivotal global study for our IVL System using our C2 catheters, which is intended to support U.S. FDA and Japanese Shonin approval of the device. We commenced enrollment of the study in early 2019. Our IVL catheters resemble in form and function 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.

Our IVL catheters are single-use and are powered in our IVL System by our non-disposable IVL generator and IVL connector cable.

Disposable Products	Specifications	Indications	Regulatory Status
	â€¢â€‚â€Š3.5 â€“ 7.0 mm diameter â€¢â€‚â€Š60 mm length â€¢â€‚â€Š5 lithotripsy emitters â€¢â€‚â€Š6 & 7 Fr sheath compatible â€¢â€‚â€Š300 pulses (max)	Peripheral vascular use excluding carotid and cerebral vessels	FDA 510(k) clearance and CE Mark in 2018
	â€¢â€‚â€Š2.5 â€“ 4.0 mm diameter â€¢â€‚â€Š12 mm length â€¢â€‚â€Š2 lithotripsy emitters â€¢â€‚â€Š6 Fr guide compatible â€¢â€‚â€Š80 pulses (max)	Calcified *de novo* coronary arteries in CAD	CE Mark in 2018 Ongoing global IDE study. Enrollment began in early 2019.

Reusable Products	Specifications	Indications	Regulatory Status
	â€¢â€‚â€ŠCompact & portable â€¢â€‚â€ŠRechargeable power supply â€¢â€‚â€Š3 kV output at 1 Hz â€¢â€‚â€ŠIntuitive controls â€¢â€‚â€ŠErgonomic handle â€¢â€‚â€ŠReusable	For use with ShockWave Medical IVL catheters	FDA 510(k) in 2016 and CE Mark in 2014

Our Product Pipeline

We believe there is a significant opportunity to apply our IVL Technology to additional cardiovascular indications. Our strategy is to maintain a robust, efficient product development team that will continue to create lithotripsy-based products that meet our customersâ€™ unmet needs. In addition to our pipeline of new products, we will continue to focus on building clinical evidence through both company-sponsored and investigator-sponsored research.

Pipeline Product	Specifications	Indications	Regulatory Status
	â€¢â€‚â€Š2.5 â€“ 4.0 mm diameter â€¢â€‚â€Š40 mm length â€¢â€‚â€Š4 lithotripsy emitters â€¢â€‚â€Š5 Fr sheath compatible â€¢â€‚â€Š160 pulses (max)	Peripheral vascular use excluding carotid and cerebral vessels	FDA 510(k) and CE Mark in 2018

The next product that we plan to broadly commercialize through our IVL System will be our S4 catheter (â€œsmallâ€ vessel, four-emitters) for treating PAD BTK. We have 510(k) clearance and CE Mark for the use of our S4 catheters in our IVL System. Our experience to date suggests the S4 catheter may be effective at modifying the calcium below-the-knee (which includes significant medial calcium) without causing distal embolic clinical events. We are continuing to assess the performance of the product, including its deliverability and durability in long, calcified and stenotic lesions. The S4 catheter is powered by the same generator and connector cable that power the other IVL catheters.

In July 2018, we initiated and subsequently completed a voluntary recall of the S4 catheters based on an inability of the balloon to maintain inflation due to suboptimal balloon wall thickness in some of the sizes. We

are currently engaged in a redesign and a limited market release of the product to test its performance in the heavily calcified and challenging BTK environment and expect to launch the new catheters in the second half of 2019. There were no reports of adverse clinical events related to this issue.

Transcatheter Aortic Valve Lithotripsy (TAVL)

We are also exploring 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 AS. Our IVL Technology can potentially be used to apply lithotripsy directly to the aortic valve leaflets, called transcatheter aortic valve lithotripsy (â€œTAVLâ€). This represents a potentially significant long-term opportunity and is currently in clinical feasibility trials. Our TAVL System is designed to safely crack calcium in the aortic valve leaflets, thereby improving leaflet mobility and reducing the severity of AS. If TAVL-mediated calcium fracture is successful, valve leaflets will be re-mobilized and the valve will open more effectively, allowing increased blood delivery from the heart to the rest of the body. The initial goal of this technology is to safely, and without the associated risks of a prosthetic valve implant, decrease the severity of AS and its associated symptoms. We believe our TAVL System could provide a valuable alternative treatment option for a significant population of patients with AS including those who are:

- â€¢ absolutely contraindicated for SAVR or TAVR;
- â€¢ at higher risk for complications from SAVR or TAVR;
- â€¢ in need of treatment for other conditions prior to receiving TAVR, such as hip or knee replacement, cancer surgery, correction of metabolic or nutritional deficiency;
- â€¢ younger, for whom delaying valve replacement may reduce the likelihood of needing a subsequent valve-in-valve procedure; and
- â€¢ suffering from moderate AS (in whom treatment with our TAVL System could delay the onset of symptomatic severe AS).

Clinical Studies

Overview of Clinical Programs

We are committed to obtaining clinical evidence to support the safety and effectiveness of our products based on our IVL Technology. The data from our clinical studies strengthen our ability to drive the adoption of products based on our IVL Technology across multiple therapies in existing and new market segments. We expect our clinical evidence will support regulatory approvals, provide physicians with safety and efficacy data on the appropriate use of our IVL System and demonstrate the cost effectiveness of our IVL System. A recurring theme across the studies we have conducted is our ability to treat calcified lesions with a strong safety profile.

Investment in clinical evidence is a core strategy of our company. We involve physician advisors who are recognized for excellence in cardiovascular medicine to assist us with clinical study designs. We also seek to ensure rigorous, high-quality data collection and reporting using imaging core laboratories and clinical events committees (â€œCECâ€) for an independent assessment of safety and imaging-based effectiveness endpoints.

We have completed five clinical studies with a total of 179 patients, across 22 centers in multiple countries, for peripheral and coronary artery and cardiac valve diseases. We are currently conducting or planning five other studies, involving nearly 2,000 patients in up to 190 centers in the United States and internationally.

Below is a chart of our completed, ongoing and planned clinical programs:

	Name	Trial	Size	Sites	Product	Geography	Primary Endpoint(s)	Outcome / Conclusion	Enrolled
Peripheral	**Disrupt PAD I**	Pre-market, OUS, single arm	n=35	3	MV60	EU; NZ	Acute; 30d	CE Approval	2014
	Disrupt PAD II	Pre-market, OUS, single arm	n=60	8	MV60	EU; NZ	30d; 12m	510(k) Approval	2015
	Disrupt PAD III	Global, post-market RCT	n=400	60	M5	US; EU; NZ	Acute; 12m	Market adoption	â€”
	Disrupt PAD III Observational Study	Global, post-market registry	n=1,000	60	M5	US; EU	Acute	Market adoption	â€”
	BTK Registry	Post-market, OUS, single arm	n=20	3	MV60	EU; NZ	30d	Support CE Mark and 510(k) for S4	2016/2017
Coronary	**Disrupt CAD I**	Pre-market, OUS, single arm	n=60	7	C2	EU; AUS	30d	CE Approval	2015/2016
	Disrupt CAD II	Post-market, EU, single arm	n=120	15	C2	EU	30d	Post-Market Study	â€”
	Disrupt CAD III	Pre-market, Global, single arm	n=392	50	C2	US; EU	30d	US Coronary PMA Approval	â€”
	Disrupt CAD IV	Pre-market, JP, single arm	n=64	5	C2	JPN	30d	JP Coronary Shonin Approval	â€”
TAVL	**TAVL FIM Study**	First-in-man feasibility study	n=4	1	TAVL	Paraguay	30d	Feasibility	2016
	TAVL Chronic Study	Feasibility study	n=20	3	TAVL	Australia	30d	Safety & Feasibility	2019

Completed Clinical Studies

Clinical Studies to Support Use of our IVL System in the Treatment of PAD to Date

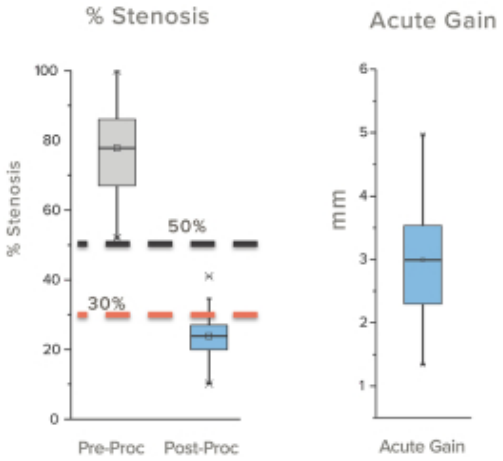
To date, all of our PAD studies were performed using our first generation IVL catheter called MV60. MV60 is identical to our recently introduced M5 catheters in all but two ways. The first difference is that each M5 catheter is able to deliver up to 300 pulses, whereas the MV60 catheter was only able to deliver 180 pulses. The second difference is that each pulse from an M5 catheter delivers approximately 40% more energy than a pulse from the MV60 catheter. These changes have improved the efficacy of our IVL System and helped reduce the overall procedure cost by requiring fewer devices to complete the treatment. In 2019, we expect that all of our M5 catheters will have replaced our MV60 catheters for commercial and clinical trial use.

The Disrupt PAD I study was a prospective, non-randomized, multicenter study to demonstrate the safety and performance of our IVL System using the MV60 catheter in heavily calcified femoropopliteal lesions. This study demonstrated the safety and effectiveness of our IVL System as a standalone treatment in calcified, femoropopliteal PAD up to six months. The study showed 100% procedural results, excellent safety and a low use of adjunctive therapies. The data from this study was supportive of the 510(k) clearance for the use of our M5 catheters in our IVL System.

Between January 2014 and September 2014, 35 patients were enrolled at three centers in Europe and New Zealand. All patients had heavily calcified, femoropopliteal lesions and were treated with standalone IVL System

therapy. Key study endpoints included MAEs at 30 days and six months, procedural success, and vessel patency and freedom from target lesion revascularization (â€œTLRâ€) at 30 days and six months. All results were adjudicated by an independent core lab and CEC.

The delivery of IVL catheters was successful in 100% of patients with minimal pre- or post-dilation (8.6% and 14.3%, respectively) and no stent implants. There were no vascular complications or MAEs. The results showed a significant reduction in percent diameter stenosis, large acute diameter gain and excellent durability of results at 30 days and six months.



High Acute Gain, Low Residual Stenosis, and Minimal Complications

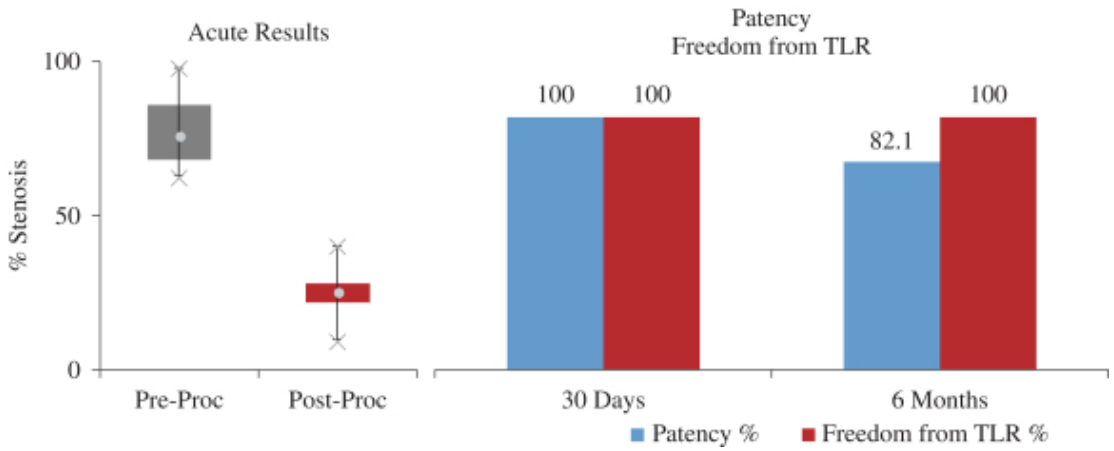
	Post Procedure N=60
Dissections D†/E/F	1.7% (1)
Perforations	0% (0)
Abrupt Closure	0% (0)
Slow/ No Reflow	0% (0)
Thrombosis	0% (0)

(Left) Pre-procedural (Pre-Proc) stenosis (76.3 Â±13.5%) measured at baseline, post-procedural (Post-Proc) (23.4 Â±5.7%) measured post-index procedure. (Right) Patency and freedom from TLR

The Disrupt PAD II study was a prospective, non-randomized, multicenter study to demonstrate the safety and performance of our IVL System using the MV60 catheter in heavily calcified femoropopliteal lesions. This study demonstrated the safety and effectiveness of our IVL System in calcified, femoropopliteal PAD up to 12 months. We believe it is the first and only core lab adjudicated study to exclusively enroll heavily calcified disease. The results demonstrated safety and long-term functional benefit from our IVL System in this challenging patient population.

Between June 2015 and December 2015, 60 patients were enrolled at eight centers in Europe and New Zealand. 85% of patients had heavily calcified, femoropopliteal lesions, and all patients were treated with standalone IVL System therapy. Key study endpoints included MAEs at 30 days, six months and 12 months, procedural success, in addition to vessel patency, freedom from TLR and improvement in functional outcomes at 30 days, six months and 12 months. All results were adjudicated by an independent core lab and CEC, and the study incorporated revised definitions of severe calcification and primary patency as published in the Peripheral Academic Research Consortium (â€œPARCâ€) paper.

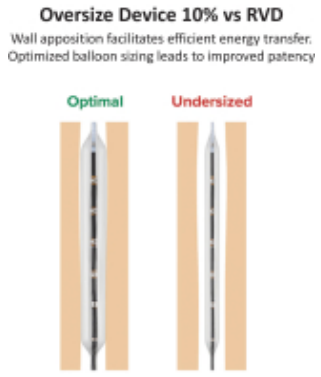
The acute safety and performance results were positive, particularly for a severely calcified patient population. The delivery of IVL catheters was successful in 100% of patients. The original stenosis was 78.2% and the final residual stenosis after IVL System therapy was 24.2%, with an average acute gain of 3.0 mm. The 30-day MAE rate was very low at 1.7%, with a bail-out stenting rate of 1.7% and only one grade D dissection that was resolved following stent placement. There were no instances of vessel perforation, distal embolization, thrombus, abrupt closure and slow flow or no-reflow events.

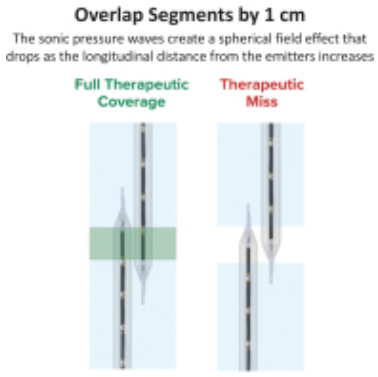


The long-term functional results demonstrated strong durability of our IVL System as a standalone therapy. The safety profile continued to be strong, with no additional MAEs beyond 30 days. Freedom from clinically-driven revascularization at 12 months was 79% and revascularizations were completed using simple, endovascular procedures. Functional outcomes, including patient symptoms measured by Rutherford Category and arterial pulse pressures measured by the ankle-brachial index (â€œABIâ€), showed statistically significant and sustained improvements from baseline.

This study led to an increased understanding of how to teach physicians to optimize our IVL System procedure and obtain better outcomes. Through analysis of the study data, we learned that correct balloon sizing and appropriate therapeutic overlap resulted in improved 12-month primary patency and TLR outcomes. Patients treated with optimal technique had less than 9% TLR at 12 months. Balloon sizing and appropriate therapeutic overlap are simple, intuitive techniques that have been incorporated into physician training to achieve optimal results.

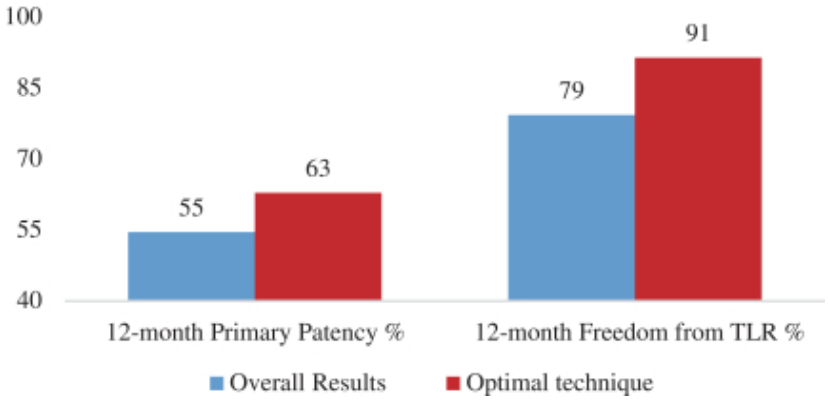
Optimal Technique Can Enhance IVL Energy Delivery and Improve Clinical Patency





Primary Patency: 55% for intent-to-treat versus 63% for those with optimal technique

Freedom from TLR: 79% for intent-to-treat versus 91% for those with optimal technique



Optimal IVL System Technique *was defined as the correct balloon sizing and the avoidance of therapeutic miss. In patients who received optimal technique, 12-month primary patency increased from 55% to 63% and 12-month clinically driven TLR decreased from 21% to 9%.*

The Disrupt BTK study was a prospective, non-randomized, multicenter study to demonstrate the safety and feasibility of our IVL System using the MV60 catheter in heavily calcified infrapopliteal lesions. We believe this study demonstrated the safety and feasibility of our IVL System in calcified, infrapopliteal lesions up to 30 days. Despite using a first generation MV60 catheter, it was successfully delivered in over 95% of this challenging patient population. We also believe that the safety of IVL System therapy for treatment of BTK was demonstrated in this study.

Between June 2016 and April 2017, 20 patients were enrolled at three centers in Europe and New Zealand. All patients had heavily calcified, infrapopliteal lesions, and were treated with standalone IVL System therapy. Key study endpoints included MAEs at 30 days, reduction in stenosis and procedural success. All results were adjudicated by an independent core lab.

The delivery of IVL catheters was successful in 95% of patients. The original stenosis was 72.6% and the final residual stenosis after IVL System therapy was 26.2%. There were no MAEs and no vascular complications, including flow-limiting dissections, perforation, distal embolization, abrupt closure and slow flow or no-reflow events. Two stents were placed per the physician discretion. The results showed a low residual stenosis and large acute gain, with minimal vascular complications that are consistent with IVL System results in femoropopliteal lesions. The Disrupt BTK experience informed the design of the S4 catheter in heavily calcified infrapopliteal lesions. These patients present with CLI, which has a risk of target limb major amputation and responds poorly to traditional balloon angioplasty.

Clinical Studies to Support IVL System Use in the Treatment of CAD to Date

The Disrupt CAD I study was a prospective, non-randomized, multicenter study to demonstrate the safety and performance of our first generation coronary IVL catheter in heavily calcified coronary lesions prior to stenting. This study was our first in CAD and we believe it demonstrated the safety and performance of our IVL System in heavily calcified coronary lesions prior to stenting. The results of this study supported CE Mark approval of the use of our C2 catheters in our IVL System.

Between December 2015 and September 2016, 60 patients were enrolled at seven centers in Europe and Australia. All patients had heavily calcified, coronary lesions and were treated with IVL System therapy followed by DES implantation. Key study endpoints included major adverse cardiac events (â€œMACEâ€) at 30 days, and procedural success was defined as residual stenosis < 50% after stenting and no in-hospital MACE. Additional

endpoints include MACE at six months and angiographic success. All results were adjudicated by an independent core lab and CEC.

Angiographic Complications

Complications	Procedural	Post Stent
Dissections D E F	3.3% 0% 0%	0% 0% 0%
Perforation	0.0%	0.0%
Abrupt Closure	0.0%	0.0%
Slow flow	0.0%	0.0%
No reflow	0.0%	0.0%

[1]Core Lab adjudicated
[2]CEC adjudicated
[3]NQWMI defined as 3x upper limit CK-MB

Achieved <50% stenosis in all patients, despite >90% of patients having moderate-to-severe CAD

Safety	Results	Events
30 day MACE[1] Cardiac death, MI or TVR	5%	Death N = 0 QWMI N = 0 *NQWMI N = 3 TVR N = 0
6 month MACE[1] Cardiac death, MI or TVR	8.5%	Death N = 2 QWMI N = 0 *NQWMI N = 3 TVR N = 0

Efficacy	Results
Clinical Success[2] Residual stenosis <50% post-PCI with no evidence of in-hospital MACE	95%
Device Success Successful device delivery and IVL treatment at target lesion	98.3%
Stent Delivery	100%

Disrupt CAD I results showed safety and effectiveness at 30 days and six months

The results of Disrupt CAD I Study were positive and we believe demonstrated the safety and effectiveness of our IVL System in heavily calcified coronary lesions prior to stenting. There were no instances of perforation, abrupt closure or slow flow or reflow events. There were two procedural dissections that were treated as per the standard of care with a DES and did not require additional procedures or result in an event. The 30-day MAE rate was five percent. There were only three non-Q-wave myocardial infarctions, as determined by cardiac biomarkers and all three patients were discharged without additional events. The IVL catheter was delivered in 98% of patients, and all patients were treated with a DES and successfully facilitated stent delivery and expansion. We believe this trial showed excellent procedural results and safety at 30 days and six months.

The Disrupt CAD I OCT Sub-study was a pre-specified sub-study to demonstrate the mechanism of action and effectiveness of coronary IVL in heavily calcified coronary lesions prior to stenting. The study utilized intravascular OCT imaging to demonstrate the mechanistic effects of our IVL System on calcium. OCT imaging clearly showed cracks in the calcified lesions after being treated with IVL System therapy. These cracks are consistent with the intended effect that IVL has on calcium.

Thirty-one of the 60 enrolled CAD I patients underwent OCT imaging at three time points: prior to IVL; after IVL but prior to stenting; and at the end of procedure. The goal was to assess the impact of IVL System therapy on calcified coronary lesions using high resolution, OCT intravascular imaging. Key study endpoints included acute area gain, minimal stent area, stent expansion and vascular complications. An independent core lab analyzed all images, showing that IVL resulted in calcium fractures at multiple locations along the treated lesion, resulting in a significant gain in the vessel area and favorable stent expansion.

Other Clinical Studies to Date

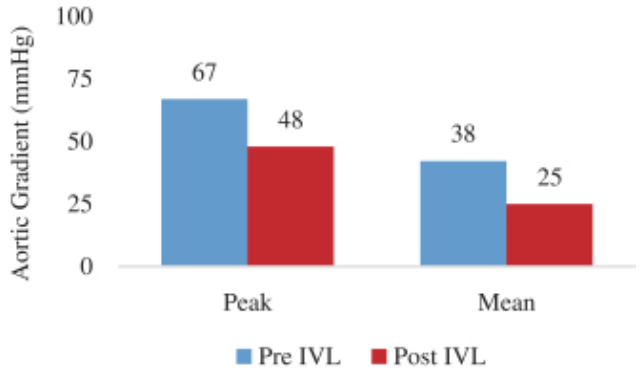
The Transcatheter Aortic Valve Lithotripsy Feasibility Study was a preliminary, first-in-man feasibility study to assess the early safety and feasibility of our TAVL System in calcified, stenotic aortic valves prior to a surgical valve replacement. In a small series, we believe we were able to demonstrate that our IVL Technology can be safely applied to calcified aortic valves and result in acutely increased valve areas and reduced gradients.

Aortic Regurgitation

Patient	Pre	Post
Patient 1	Trace	Trace
Patient 2	Trace	Trace
Patient 3	Trace	Trace
Patient 4	Mild Central	Mild Central

Aortic Regurgitation: *Data from the TAVL FIM study show that application of TAVL did not change the degree of aortic valve regurgitation.*

In December 2016, four patients at a single center with severe AS were treated with TAVL therapy immediately prior to surgical valve replacement. Distal embolic filters were placed in bilateral carotid arteries to confirm athero-embolic debris following TAVL treatment. Key study endpoints included MAEs at 30 days, successful delivery of IVL to the aortic valve and various success criteria, including reduction in the mean pressure gradient, improvement in leaflet mobility and successful AVR surgery. All results were adjudicated by an independent echocardiographic core lab.



Gradient Reduction: *Data from the TAVL FIM study show that both the peak and mean transvalvular gradients were reduced by TAVL.*

We believe this first-in-man study demonstrated that our IVL Technology could be safely delivered to calcified, stenotic aortic valves prior to AVR. All patients had improvement in aortic valve area and a reduction in peak and mean transvalvular gradients of 19 and 13 mmHg, respectively. IVL did not cause a change in aortic regurgitation, indicating that the native valve was not damaged. No embolic debris was identified in the filters following TAVL treatment.

Ongoing and Planned Clinical Studies

Further Clinical Studies to Support IVL System use in Peripheral Arterial Disease

The Disrupt PAD III Study is a prospective, randomized, multicenter, post-market study to demonstrate the safety and effectiveness of our IVL System using the MV60 and M5 catheters in combination with DCB

compared to standalone DCB in heavily calcified femoropopliteal lesions. The study is designed to demonstrate the optimal therapy to dilate heavily calcified, femoropopliteal lesions and to demonstrate the benefit of our IVL System when combined with DCB vs. standalone DCB, in severely calcified femoropopliteal lesions up to 24 months. Disrupt PAD III is the largest randomized clinical trial to assess the ideal treatment strategy for this difficult to treat patient population.

The study is currently enrolling, with enrollment expected to be completed in the second half of 2019 and clinical data expected in 2020. It is expected to enroll up to 400 patients at 60 global centers in the United States, Europe and New Zealand. All patients will present with severely calcified, femoropopliteal lesions. Patients will be randomized in a one-to-one fashion with IVL System therapy combined with DCB in the treatment arm and standalone DCB in the control arm. Patients with sub-optimal acute results may be treated with a bailout stent in both arms. Key study endpoints include MAEs at 30 days, six, 12 and 24 months, procedural success, in addition to primary patency and freedom from TLR at 12 and 24 months and functional outcomes at 30 days, six, 12 and 24 months. All results will be adjudicated by an independent core lab and CEC.

The Disrupt PAD III Observational Study is a prospective, multicenter, observational study to assess the real-world, acute performance of our IVL System using the MV60 and M5 catheters in calcified, peripheral arteries. The study will assess the real-world, acute performance of our IVL System in heavily calcified peripheral lesions. Lesions may include multi-level treatment of calcified iliac, common femoral, superficial femoral, popliteal and infrapopliteal lesions, in patients with claudication or CLI.

The study is currently enrolling patients, with enrollment expected to be completed in the second half of 2019. It is expected to enroll up to 1,000 patients presenting with heavily calcified, peripheral lesions. Patients may be treated with standalone IVL System therapy or adjunctive interventional therapies including DCB, atherectomy and bare metal or DES. Key study endpoints include procedural success and in-hospital adverse events.

Further Clinical Studies to Support IVL System use in Coronary Artery Disease

The Disrupt CAD II Study is a prospective, non-randomized, multicenter, post-market study to demonstrate the ongoing safety and performance of the coronary IVL catheter in heavily calcified coronary lesions up to 30 days prior to stenting. The study is a condition to support the CE Mark.

The study is currently enrolling patients, with enrollment expected to be completed in the first half of 2019. It will enroll up to 120 patients at 15 centers in Europe. All patients are expected to present with heavily calcified, stenotic coronary lesions, and will be treated with coronary IVL System therapy followed by DES implantation. Key study endpoints include in-hospital MACE, 30-day cardiac death and procedural success defined as residual stenosis <50% after stenting with no in-hospital MACE. All results will be adjudicated by an independent core lab and CEC. An OCT sub-study of approximately 60 patients will be included.

The Disrupt CAD III Study is a prospective, non-randomized, multicenter study to demonstrate the safety and effectiveness of our IVL System using the C2 catheter in heavily calcified coronary lesions prior to stenting. The study is an IDE study that has been approved by the FDA. The goal of this study is to provide the clinical evidence needed to support a PMA for the use of our C2 catheters in our IVL System in the United States.

This study is expected to enroll approximately 392 patients at 50 global centers in the United States and Europe. The first patient was enrolled in early 2019 and clinical data is expected in the second half of 2020. All patients will present with heavily calcified, coronary lesions, and will be treated with our IVL System followed by DES implantation. Key study endpoints will include 30-day MACE and procedural success compared to objective performance goals. Additional endpoints include MACE at six, 12 and 24 months, and device delivery success. All results will be adjudicated by an independent core lab and CEC. An OCT sub-study of approximately 100 patients will be included to show mechanistic effects and demonstrate acute area gain, minimal stent area, stent expansion and vascular complications.

The Disrupt CAD IV Study is a pre-market clinical trial notification (â€œCTNâ€) that is currently in the early planning phase with the Japanese PMDA. This study is expected to enroll approximately 60 patients at five centers in Japan. All patients will present with heavily calcified, coronary lesions and will be treated with our IVL System followed by DES implantation. The goal of this confirmatory study is to show that the safety and effectiveness results of IVL System therapy prior to stenting are consistent in a Japanese patient population. A Shonin submission would then be completed for Japanese approval.

Further Clinical Studies to Support TAVL System use in Aortic Stenosis

The TAVL Chronic Feasibility Study is a prospective, single-arm, multi-center study to demonstrate the safety and feasibility of our TAVL System in patients with symptomatic, severe aortic stenosis.

The study is currently enrolling, with enrollment expected to be completed in the first half of 2019. It is expected to enroll up to 20 patients at three centers in Australia. All patients will present with symptomatic, severe aortic stenosis. Patients will be treated with our TAVL System. The primary study endpoint is major adverse cardiac and cerebrovascular events (â€œMACCEâ€) defined as a composite of all-cause mortality, myocardial infarction, stroke, life-threatening and major bleeding events, stage two or three acute kidney injury or major vascular complications at 30 days post-procedure. The primary effectiveness endpoint is mean aortic valve pressure gradient at 30 days post-procedure measured by transthoracic echocardiography (â€œTTEâ€). Patients will have additional follow-up at three, six and 12 months to assess safety, mean gradients and quality of life measures. All results will be adjudicated by an independent core lab and CEC.

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 $18.0 million and $22.7 million for the years ended December 31, 2017, and December 31, 2018, 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

We produce substantially all of our IVL catheters in-house at our facilities in Fremont, California which, together with our research and development, controlled environment room and office space, currently totals 12,000 square feet. We stock inventory of raw materials, components and finished goods at our facilities in Fremont and with our direct sales representatives, who travel to our hospital customersâ€™ locations as part of their sales efforts. Our electronics (*i.e.*, our generators and connector cables) are produced by original equipment manufacturing (â€œOEMâ€) partners using our design specifications. We plan to move our production of IVL catheters to our new 35,000 square foot facility in Santa Clara, California in 2019. 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 Fremont to our hospital customers in the United States on a consignment basis, 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. Internationally, we ship our IVL products from Fremont to either our third-party logistic provider located in the Netherlands who then ship directly to hospital customers and distributors pursuant to purchase orders or from Fremont 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, 2018, we had approximately 43 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 MDD standards, allowing our products to be CE marked. 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; training is documented and considered part of the employee evaluation process.

Sales & Marketing

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 in Australia, the Baltics, Canada, Czech Republic, France, Italy, the Netherlands, New Zealand, the Nordic region, Poland, Spain and the United Kingdom. We are actively expanding our international field presence through new distributors, additional sales and clinical personnel, and are adding new U.S. sales territories. We have the CE Mark in Europe and the 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 catheter.

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 totals 53 professionals as of December 31, 2018.

In the United States, our IVL generators and connector cables are typically provided, on loan, to our hospital customers at no charge, while our disposable IVL catheters are provided on a consignment basis whereby title to such catheters passes to the hospital once they are used in a clinical procedure. Following such use, we charge the hospital a predetermined set fee for each IVL catheter, which fee may be determined based on the hospitalâ€™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 sales people. Moreover, our vascular IVL catheters have similar call points, meaning we can further leverage our field sales team.

Reimbursement

United States

In the United States, hospitals are the primary purchasers of our products. Hospitals bill various third-party payors, primarily Medicare in the case of PAD and CAD, for the total healthcare services required to treat the patient. Endovascular interventions to treat PAD and CAD are performed in two primary settings of care:

hospital inpatient and hospital outpatient, each with different coding and payment schemes. For PAD, a minority of interventions are performed in a third setting of care known as physician office-based labs (â€œOBLsâ€).

Setting	Payment System	Common Setting for IVL Application
Inpatient	Medicare Severity Diagnosis Related Groups (â€œMS-DRGsâ€)	â€¢â€‚CLI (more severe PAD) â€¢â€‚Infrapopliteal (BTK) â€¢â€‚EVAR & TEVAR Access â€¢â€‚TAVR Access â€¢â€‚PCI
Outpatient	Ambulatory Payment Classifications (â€œAPCsâ€)	â€¢â€‚Claudicants (less severe PAD) â€¢â€‚Femoropopliteal â€¢â€‚Iliac occlusive â€¢â€‚PCI

Our IVL System incorporates an integrated balloon that is used by the physicians to perform angioplasty during the relevant procedure. Angioplasty procedures have coding, coverage and payment in all settings of care. The IVL System therapy delivered by our vascular IVL catheters is novel and, as is typical of novel technologies, does not yet have its own specific reimbursement coding. We believe there is an opportunity in the future for increased reimbursement over current levels for procedures using our IVL System by generating additional clinical evidence, gaining advocacy in the respective physician societies and by working with the Centers for Medicare and Medicaid Services (â€œCMSâ€) and payors.

Absent any incremental payment to hospitals for IVL System procedures to treat PAD, our initial commercial success suggests that our IVL System provides compelling economic value. We address the procedural complications that drive up supply costs for complex calcified lesions. As has been published in the *Journal of Vascular Surgery*, while the treatment of standard lesions can be profitable, a minority of severe lesions can cause a hospital to lose money because the significantly higher number of devices needed to complete treatment exceeds reimbursement levels.

Hospital Inpatient

Medicare reimbursement in the hospital inpatient department is determined according to the hospital inpatient prospective payment system (â€œIPPSâ€). Payment is determined by the applicable MS-DRGs, which groups patients by similar diagnoses and/or performed procedures and are used to determine the payment rate that is used to reimburse hospitals for an inpatient stay. The IPPS payment covers the entire admission, including any secondary procedures. For endovascular interventions, the difference between whether a patient is classified as an inpatient or outpatient is a medical decision, but in general, sicker patients and/or those expected to need a longer length of stay are admitted as inpatients.

In the inpatient setting, endovascular treatment of PAD and CAD is assigned to one of two groups of surgical MS-DRGs, depending if atherectomy is also performed during the procedure or not. These MS-DRGs are independent of anatomical location. When IVL System therapy is performed as an adjunctive therapy during an EVAR, TEVAR or TAVR procedure, the applicable MS-DRG is based on those procedures, not the IVL System procedure.

U.S. Hospital Inpatient Payments for PAD & CAD Interventions
(FY19 Unadjusted Medicare Payment)

IVL Performed in Conjunction with	DRG Codes*	FY19 National Average Hospital Payment**
PAD Intervention: PTA, Stent	DRG 254, 253, 252	$11,050.94 - $19,902.68
PAD Intervention: Atherectomy	DRG 272, 271, 270	$15,984.78 - $30,904.16
CAD Intervention: DES with or without Atherectomy	DRG 247, 246	$12,681.71 - $19,774.46

EVAR (AAA)	DRG 269,268	$25,343.28 - $40,929.37
TAVR	DRG 267, 266	$35,705.52 - $43,907.63

** DRG coding groups listed are assigned depending if complications and comorbidities present.*

***Medicare rates for the same or similar procedures vary due to geographic location, nature of facility in which the procedure is performed (i.e., teaching or community hospital) and other factors.*

Hospital Outpatient

Reimbursement is determined by Medicareâ€™s comprehensive APC, which is a smaller bundle than a DRG more specifically related to a single procedure. Hospitals receive a Medicare outpatient payment based on the APC group assigned to the physician service or procedure performed, which are described by Current Procedure Terminology (â€œCPTâ€) codes. CPT codes are specific to the approach, the technique used and the specific anatomy in which the procedure is performed. For PAD and CAD interventions, the main drivers of APC assignment are anatomical location and which devices are used during the procedure.

U.S. Hospital Outpatient Payments for PAD & CAD Interventions
(FY19 National Payment Rates)

	Treatment Strategy			
Vessel Anatomy	**IVL + PTA**	**IVL + Stent**	**IVL + Atherectomy + PTA**	**IVL+ Atherectomy + Stent**
Iliac	$4,755.58 (APC 5192)	$9,765.28 (APC 5193)	*Atherectomy not indicated for use in iliac arteries*	*Atherectomy not indicated for use in iliac arteries*
Femoropopliteal	$4,755.58 (APC 5192)	$9,765.28 (APC 5193)	$9,765.28 (APC 5193)	$15,503.79 (APC 5194)
Tibial-Peroneal	$9,765.28 (APC 5193)	$15,503.79 (APC 5194)	$15,503.79 (APC 5194)	$15,503.79 (APC 5194)
Coronary	*IVL will be indicated for use prior to stenting*	$9,765.28 (APC 5193)	*IVL will be indicated for use prior to stenting*	$15,503.79 (APC 5194)

Office-Based Procedures

A minority of U.S. PAD interventions are performed in non-hospital, freestanding facilities that may be treated by payors like physician offices. Medicare pays for procedures in the physician office setting based on submission of a claim using one or more eligible CPT or Healthcare Common Procedure Coding System codes. Procedures are reimbursed based on Medicare under the Medicare physician fee schedule, which reimburses for supplies, equipment, professional fees and overhead to perform the procedure. These non-hospital, freestanding facilities are a highly financially sensitive segment of the U.S. PAD market and as such are not an initial target of our sales and marketing efforts.

Commercial Third-Party Payors

No uniform policy for coverage and reimbursement for medical procedures exists in the United States. 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. Therefore, coverage and reimbursement can differ significantly from payor to payor.

International

Outside the United States, market acceptance of medical devices depends partly upon the availability of reimbursement within the prevailing healthcare payment system. Reimbursement levels vary significantly by country and, within some countries, by region. Reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans, and combinations of both. PCI is a standard of care in developed international markets and procedure reimbursement exists. However, specific reimbursement for plaque modification devices is not common in most developed international markets. For PAD, the standard of care varies widely by country and so does reimbursement. Our plan is to broadly access international markets for coronary IVL System therapies and we plan to selectively approach markets and opportunities for peripheral IVL System therapies where it makes economic sense and where we believe the clinical benefit is large enough that the overall value to the system outweighs the cost of the device.

In Germany, in contrast to the other major European markets, there is an established path to secure reimbursement, making incremental payments viable in that market. We have obtained codes for peripheral and coronary IVL System therapies to track procedure costs, and we expect that the data will support incremental payment in the near- to mid-term.

Japan also provides incremental payment for atherectomy devices used during PCI procedures. We intend to work with Japanese regulators to secure payment for IVL System therapy that is similar to atherectomy.

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. Our most notable competitors in the highly competitive cardiovascular field include 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:

- â€¢ significantly greater name recognition;
- â€¢ broader or deeper relations with healthcare professionals, customers and third-party payors;
- â€¢ more established distribution networks;
- â€¢ 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;
- â€¢ greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- â€¢ 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:

- â€¢ 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;
- â€¢ continue to innovate and develop scientifically advanced technology;
- â€¢ obtain and maintain regulatory clearances or approvals;
- â€¢ demonstrate efficacy in our sponsored and third-party clinical trials and studies;
- â€¢ obtaining and maintaining adequate reimbursement for procedures using our products;
- â€¢ apply technology across product lines and markets;
- â€¢ attract and retain skilled research and development and sales personnel; and
- â€¢ 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, 2018, we owned 31 issued U.S. patents and 38 issued foreign patents, 19 pending U.S. patent applications and 21 pending foreign patent applications (including six Patent Cooperation Treaty (â€œPCTâ€) applications). This portfolio includes 16 issued U.S. patents, 23 issued foreign patents, five pending U.S. patent applications and 11 pending foreign patent applications (including one PCT application) relating to our current IVL Technology. These issued patents, and any patents granted from such applications, are expected to expire between 2029 and 2037, without taking potential patent term extensions or adjustments into account. 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 proceedings filed by Cardiovascular Systems, Inc., one of our competitors. For more information regarding these proceedings, please see the section titled â€œBusinessâ€”Legal Proceedings.â€

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 patentâ€™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 our pending patent applications that we

have filed or may file in the future will result in issued patents, and we can give no assurance that any patents that have issued or might issue 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 *inter partes* reviews, please see the section titled â€œRisk Factorsâ€” Risks Related to Our Intellectual Property.â€

Government Regulation

United States

Our products are medical devices subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act (â€œFD&C Actâ€) and its implementing regulations, as well as other federal and state regulatory bodies in the United States and comparable authorities in other countries under other statutes and regulations. The laws and regulations govern, among other things, product design and development, preclinical and clinical testing, manufacturing, packaging, labeling, storage, recordkeeping and reporting, clearance or approval, marketing, distribution, promotion, import and export and post-marketing surveillance. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as issuance of warning letters, import detentions, civil monetary penalties and/or judicial sanctions, such as product seizures, injunctions and criminal prosecution.

FDAâ€™s Pre-market 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 pre-market approval from the FDA. Generally, if a new device has a predicate that is already on the market under a 510(k) clearance, the FDA will allow that new device to be marketed under a 510(k) clearance; otherwise, a PMA is required. Medical devices are classified into one of three classesâ€”Class I, Class II or Class IIIâ€”depending on the degree of risk associated with each medical device and the extent of 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 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 pre-market 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 include performance standards, post market surveillance, patient registries and guidance documents. A manufacturer may be required to submit to the FDA a pre-market notification requesting permission to commercially distribute some Class II devices. Devices 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, are placed in Class III. A Class III device cannot be marketed in the United States unless the FDA approves the device after submission of a PMA. However, there are some Class III devices for which FDA has not yet called for a PMA. For these devices, the manufacturer must submit a pre-market notification and obtain 510(k) clearance in orders to commercially distribute these devices. The FDA can also impose sales, marketing or other restrictions on devices in order 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 pre-market 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 pre-market notification must be submitted to the FDA at least 90 days before we intend to distribute

a device. As a practical matter, clearance often takes significantly longer. 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 pre-market 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 for devices that are modified and the modification needs a new 510(k) but does not affect the intended use or alter the fundamental scientific technology of the device. Abbreviated 510(k)s are for devices that conform 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*

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the â€œRequest for Evaluation of Automatic Class III Designation,â€ or the *de novo* classification procedure.

This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012 (â€œFDASIAâ€), a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) pre-market notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the *de novo* application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

Pre-market Approval Pathway

A pre-market approval application must be submitted to the FDA for Class III devices for which the FDA has required a PMA. The pre-market approval application process is much more demanding than the 510(k) pre-market notification process. A pre-market approval application must be supported by extensive data, including but not limited to technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDAâ€™s satisfaction reasonable evidence of safety and effectiveness of the device.

After a pre-market approval 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 pre-market approval application, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. 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 panelâ€™s recommendations are important to the FDAâ€™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 (â€œQSRâ€). The agency also may inspect one or more clinical sites to assure compliance with FDAâ€™s regulations.

Upon completion of the PMA 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 FDAâ€™s belief that the PMA 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 FDAâ€™s review clock is reset.

Clinical Trials

Clinical trials are almost always required to support pre-market approval 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 FDAâ€™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 (â€œIRBsâ€) 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 FDAâ€™s IDE regulations and be approved by an IRB at the clinical trials sites. 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:

â€¢ establishment registration and device listing;

- â€¢ 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;
- â€¢ labeling regulations and the FDA prohibitions against the promotion of products for uncleared, unapproved or â€œoff-labelâ€ uses and other requirements related to promotional activities;
- â€¢ 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;
- â€¢ 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
- â€¢ post market surveillance regulations, which apply to certain Class II or 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 clearance or possibly a pre-market approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturerâ€™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 pre-market approval. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or pre-market approval 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 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, 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 PMAs.

FDA regulations require us to register as a medical device manufacturer with the FDA. Additionally, the California Department of Health Services (â€œCDHSâ€), 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:

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

The Medical Device Reporting laws and regulations require us to provide information to the FDA when we receive or otherwise become aware of information that reasonably suggests our device may have caused or contributed to a death or serious injury as well as a device malfunction that likely would cause or contribute to death or serious injury if the malfunction were to recur. In addition, the FDA prohibits an approved device from being marketed for off-label use. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

Newly discovered or developed safety or effectiveness data may require changes to a productâ€™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 FDAâ€™s policies may change, which could delay or prevent regulatory clearance or approval of our products under development.

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

European Union

Our products are regulated in the European Union as medical devices per the European Union Directive (93/42/EEC), also known as the Medical Device Directive. An authorized third party, Notified Body, must approve products for CE marking. The CE Mark is contingent upon continued compliance to the applicable regulations and the quality system requirements of the ISO 13485 standard.

Other Regions

Most major markets have different levels of regulatory requirements for medical devices. Modifications to the cleared or approved products may require a new regulatory submission in all major markets. The regulatory requirements, and the review time, vary significantly from country to country. Products can also be marketed in other countries that have minimal requirements for medical devices.

Fraud and Abuse and Other Healthcare Regulations

Federal and state governmental agencies and equivalent foreign authorities subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. These laws constrain the sales, marketing and other promotional activities of medical device manufacturers by limiting the kinds of financial arrangements we may have with hospitals, physicians and other potential purchasers of our products. Federal healthcare fraud and abuse laws apply to our business when a customer submits a claim for an item or service that is reimbursed under Medicare, Medicaid or other federally-funded healthcare programs. Patient privacy statutes and regulations by foreign, federal and state governments may also apply in the locations in which we do business. Descriptions of some of the U.S. laws and regulations that may affect our ability to operate follows.

Federal Healthcare Anti-Kickback Statute

The federal healthcare Anti-Kickback Statute (â€œAnti-Kickback Statuteâ€) prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good or service for which payment may be made, in whole or in part, by federal healthcare programs, such as the Medicare and Medicaid programs. The term â€œremunerationâ€ 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 it. 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 is no exception or safe harbor for many common business activities, such as reimbursement support programs, educational and research grants or charitable donations. The failure of a transaction or arrangement to fit precisely within one or more applicable statutory exceptions or regulatory safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy all requirements of an applicable safe harbor may result in increased scrutiny by government enforcement authorities and will be evaluated on a case-by-case basis based on a cumulative review of all facts and circumstances.

Federal Civil False Claims Act

The 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 for payment of government funds, or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim 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 â€œrelatorsâ€ or, more commonly, as â€œwhistleblowers,â€ 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. Qui tam actions are filed under seal and impose a mandatory duty on the U.S. Department of Justice to investigate such allegations. Most private citizen actions are declined by the Department of Justice or dismissed by federal courts. However, the investigation costs for a company can be significant and material even if the allegations are without merit. 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. Medical device manufacturers and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.

Healthcare Fraud Statute

The federal Health Insurance Portability and Accountability Act (â€œHIPAAâ€) and its implementing regulations created federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors knowingly and willfully falsifying, concealing or covering up a material fact or making any 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.

Sunshine Act

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Childrenâ€™s Health Insurance Program to report annually with certain exceptions to CMS information related to payments or other transfers of value made to a physician or teaching hospital, or to a third party at the request of a physician or

teaching hospital, 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.

Patient Data Privacy

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (â€œHITECH Actâ€), and their implementing regulations impose obligations on covered entities, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as business associates that provide services involving the use or disclosure of personal health information to or on behalf of covered entities. These obligations, such as mandatory contractual terms, relate to safeguarding the privacy and security of protected health information. Many states also have laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Other State Laws

Certain states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and/or require tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities.

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. Most recently, the Bipartisan Budget Act of 2018 (â€œBBAâ€) increased the criminal and civil penalties that can be imposed for violating certain federal healthcare laws, including the Anti-Kickback Statute. 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 other patient support programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, federal civil False Claims Act and violations of healthcare fraud and HIPAA privacy provisions.

Enforcement and Penalties for Noncompliance with Fraud and Abuse Laws and Regulations

Compliance with these federal and state laws and regulations requires substantial resources. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from participation in government healthcare programs such as the Medicare and Medicaid programs, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations. Companies settling federal civil False Claims Act, Anti-Kickback Statute and other fraud and abuse cases also may be required to enter into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General 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.

For additional information regarding obligations under federal healthcare statues and regulations, please see the section titled â€œRisk Factorsâ€”If we fail to comply with U.S. federal and state fraud and abuse 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.â€

United States Healthcare Reform

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.

For example, in the United States, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education and Reconciliation Act (collectively, the â€œACAâ€), was enacted. The ACA contains a number of significant provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The ACA, among other things, imposes an excise tax of 2.3% on the sale of most medical devices.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, since January 2017, President Trump has signed two 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. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 (â€œTCJAâ€) 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 â€œindividual mandate.â€ On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices through December 31, 2019. The 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 â€œdonut hole.â€ In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the â€œindividual mandateâ€ was repealed by Congress as part of the TCJA. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

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 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 2027 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.

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 and state legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control product costs. Additionally, 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.

Employees

As of December 31, 2018, we had 162 employees worldwide. None of our employees are represented by a collective bargaining agreement and we have never experienced a work stoppage. We believe our employee relations are good.

Facilities

We produce substantially all of our IVL catheters in-house at our facilities in Fremont, California which, together with our research and development, controlled environment room and office space, currently totals 12,000 square feet. We plan to move our production of IVL catheters to our new 35,000 square foot facility in Santa Clara, California in 2019.

We believe that our Santa Clara facility meets our current and future anticipated needs.

Legal Proceedings

Petitions for *inter partes* review of U.S. Pat. Nos. 9,642,673, 8,956,371 and 8,728,091 (the â€œIPR Patentsâ€), which are three of our issued U.S. patents that relate to our current IVL Technology, were filed in December 2018 at the USPTOâ€™s Patent Trial and Appeal Board (the â€œPTABâ€) by Cardiovascular Systems, Inc., one of our competitors. Our preliminary responses to these petitions are due by April 2019, and the PTAB is expected to decide whether or not to institute the *inter partes* reviews by July 2019. If the PTAB decides to institute an *inter partes* review with respect to one or more of the IPR Patents, it could result in the loss or narrowing in scope of such 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 titled â€œRisk Factorsâ€”Risks Related to Our Intellectual Property.â€

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.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors as of January 31, 2019:

Name	Age	Position
Douglas Godshall	54	President, Chief Executive Officer & Director
Dan Puckett	55	Chief Financial Officer & Secretary
Isaac Zacharias	44	Chief Commercial Officer
C. Raymond Larkin, Jr.(2)(3)	70	Chairman & Director
F.T. â€œJayâ€ Watkins(1)	66	Director
Antoine Papiernik(2)	52	Director
Colin Cahill(1)(3)	43	Director
Frederic Moll, M.D.(3)	67	Director
Marc-Andre Marcotte(4)	44	Director
Laura Francis(1)(2)	52	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.
(4) Mr. Marcotte will resign from our board of directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. As Mr. Marcotte is a partner at Sectoral Asset Management Inc., the firmâ€™s policy prohibits Mr. Marcotte from serving on the board of directors of a public company of the firmâ€™s portfolio companies.

Executive Officers

Douglas Godshall. Mr. Godshall has served as our President and Chief Executive Officer and as a member of our board of directors since May 2017. Previously, Mr. Godshall served as the Chief Executive Officer of HeartWare International, Inc. (â€œHeartWareâ€), a Nasdaq-listed company, from September 2006 until August 2016 and as director from October 2006 until its acquisition by Medtronic plc in August 2016. Prior to joining HeartWare, Mr. Godshall served in various executive, managerial and leadership positions at Boston Scientific Corporation (â€œBoston Scientificâ€), where he had been employed since 1990. Mr. Godshall also serves on the board of directors of Eyepoint Pharmaceuticals, Inc. Mr. Godshall has a B.A. in Business from Lafayette College and M.B.A from Northeastern University. Mr. Godshallâ€™s experience in the clinical development, business execution, and regulatory strategy for medical devices and pharmaceuticals provides him with the qualifications and skills to serve on our board of directors.

Dan Puckett. Mr. Puckett has served as our Chief Financial Officer since April 2016 and has served as our Secretary since November 2018. Prior to joining ShockWave Medical, from June 2015 to April 2016, Mr. Puckett served as Chief Financial Officer for Counsyl, a venture backed DNA testing and genetic counseling company. From 2011 to June 2015, Mr. Puckett served as Chief Financial Officer for Ariosa Diagnostics, Inc. (â€œAriosaâ€), a molecular diagnostics company, until June 2015. Ariosa was acquired by Roche in January 2015. Mr. Puckett came to Ariosa from Forest Laboratories, Inc. in September 2011, where he served as Executive Director, Operations of Cerexa, Inc., a Forest Laboratories, Inc. subsidiary. Prior to Cerexa, Inc., Mr. Puckett held senior finance and operations positions at Affymetrix, Inc. and AOL. Mr. Puckett holds an M.B.A. from the University of San Francisco and a B.A. in Accounting from Washington State University.

Isaac Zacharias. Mr. Zacharias has served as our Chief Commercial Officer since November 2018. Previously, Mr. Zacharias served as our General Manager of Structural Heart and Vice President of International Sales from March 2018 to November 2018. Prior to joining Shockwave Medical, Mr. Zacharias served as the Vice President, General Manager for the PCI Guidance business at Boston Scientific from July 2011 to March

2018. Prior to that, Mr. Zacharias also served as the Vice President, New Business Development for Boston Scientific where he negotiated investments and acquisitions for the Cardiology, Rhythm Management and Vascular business units. Mr. Zacharias began his career as an R&D engineer and has held a variety of clinical and marketing roles. Mr. Zacharias holds B.S. and M.S. degrees in Mechanical Engineering from the University of California, Davis.

Nonemployee Directors

C. Raymond Larkin, Jr. Mr. Larkin has served as a member and as Chairman of our board of directors since January 2019. Mr. Larkin has served as a principal of Group Outcome LLC., a merchant banking firm concentrating on medical technologies, since 2000. Mr. Larkin is presently also Chairman of the Board of Align Technology Inc., where he has served as a director since March 2004 and as Chairman of the Board since February 2006. In addition, Mr. Larkin has also served as Chairman of the Board of Reva Medical Inc. since July 2017. Previously, Mr. Larkin served as a director of HeartWare International, Inc. from October 2008 and as Chairman of its Board from June 2010 until its acquisition by Medtronic, plc in August 2016. Previously, he was President and Chief Executive Officer of Nellcor Puritan Bennett, Inc., one of the worldâ€™s preeminent respiratory products companies. Mr. Larkin also served as Chief Executive Officer of Eunoe, a company focused a developing a technology to slow the progression of Alzheimerâ€™s disease. Mr. Larkin received his B.S. in Industrial Management from LaSalle University. Mr. Larkinâ€™s experience in the healthcare industry provides him with the qualifications and skills to serve on our board of directors.

F.T. â€œJayâ€ Watkins. Mr. Watkins has served as a member of our board of directors since 2013. He previously served as the Chairman of our board from May 2017 to January 2019. Mr. Watkins has been a Managing Director at De Novo Ventures (â€œDe Novoâ€) since 2002. Prior to joining De Novo in 2002, Mr. Watkins was a co-founder and founding Chief Executive Officer of Origin Medsystems, Inc. (â€œOriginâ€), a venture funded medical technology start-up, until its acquisition by Eli Lilly & Company (â€œEli Lillyâ€) in 1995. When Eli Lilly spun out its medical device businesses as Guidant Corporation (â€œGuidantâ€), Mr. Watkins became a member of Guidantâ€™s Management Committee and served as president of several divisions including the Minimally Invasive Surgery Group, the Cardiac and Vascular Surgery Group and Heart Rhythm Technologies. Mr. Watkins also co-founded Gynecare, Inc., a womanâ€™s health care company, which was spun out, taken public and subsequently acquired by Johnson & Johnson. Mr. Watkins was also the founding president of Compass, Guidantâ€™s corporate business development and new ventures group. where he was involved in the acquisition of two public companies and led venture investments in 14 companies. Prior to joining Origin, Mr. Watkins also held management positions in several start-ups, including Microgenics (acquired by Boehringer Manngheim) and was a consultant with McKinsey & Company. Mr. Watkins received his M.B.A. from Harvard Business School and his B.A. from Stanford University. Mr. Watkinâ€™s experience in the healthcare industry provides him with the qualifications and skills to serve on our board of directors.

Antoine Papiernik. Mr. Papiernik has served as a member of our board of directors since July 2013. Mr. Papiernik has been Managing Partner of Sofinnova Partners since 1997. Mr. Papiernik has been an initial investor and a board member in public companies, including ProQr Therapeutics N.V. and Mainstay Medical International plc. Mr. Papiernik is also a board member of private companies MedDay Pharmaceuticals, MD Start, Reflexion Medical, Gecko Biomedical, SafeHeal, Highlife and Rgenix. Mr. Papiernik served on the boards of EOS (Ethical Oncology Science S.p.A., CoAxia, Lectus Therapeutics Ltd, Entourage Medical Technologies, Inc., Corwave SA, Auris Medical Holding and Impatients. Mr. Papiernik previously was an initial investor and a board member of the following companies, Actelion Pharmaceuticals Ltd. (â€œActelionâ€), NovusPharma S.p.A. (sold to Cell Therapeutics, Inc.), Movetis NV (sold to Shire Plc), Pixium Vision SA and Stentys S, which went public respectively on the ZÃ¼rich stock exchange, Nasdaq, the Stockholm stock exchange, the Milan Nuovo Mercato, the Belgium Stock Exchange and the EuroNext Paris. He was also a board member for Cotherix Inc. (initially Nasdaq listed, then sold to Actelion), CoreValve (sold to Medtronic plc), Fovea Pharmaceuticals (sold to Sanofi-Aventis S.A.) and ReCor Medical, Inc. (sold to Otsuka Pharmaceutical Co., Ltd.). Mr. Papiernik received his M.B.A. from the Wharton School of Business, University of Pennsylvania and his B.S. from Institut

Etudes Economiques Commerciales. Mr. Papiernikâ€™s experience in the healthcare industry provides him with the qualifications and skills to serve on our board of directors.

Colin Cahill. Mr. Cahill has served as a member of our board of directors since May 2015. Mr. Cahill has been Vice-President of Venrock since 2012 and focuses on Venrockâ€™s public and cross-over biotech fund. Prior to joining Venrock, Mr. Cahill was a co-founder and Chief Development Officer at Simpirica Spine, Inc. (â€œSimpiricaâ€), a Bay Area medical device company focused on the development and commercialization of devices for spinal stabilization. Mr. Cahill also served as Simpiricaâ€™s Chief Executive Officer from 2006 until 2009. Prior to graduate school, Mr. Cahill worked at the Boston Consulting Group as a strategy consultant. Mr. Cahill received a M.B.A. from the Stanford Graduate School of Business and his M.S. in biological sciences from Stanford University. Mr. Cahill received his B.A. and B.S. in biological sciences and economics, respectively, from Stanford University. Mr. Cahillâ€™s experience in life science operations and investment provides him with the qualifications and skills to serve on our board of directors.

Frederic Moll, M.D. Dr. Moll has served as a member of our board of directors since 2011. Dr. Moll has been a member and served as Chairman of the board of Restoration Robotics, Inc. since November 2002. Dr. Moll is also a co-founder, and, since September 2012, has been the Chairman and Chief Executive Officer of Auris Health, Inc. Dr. Moll has served in a leadership capacity of Circuit Therapeutics since 2011. From 2002 to 2010, Dr. Moll served as the Chief Executive Officer of Hansen Medical, which he also co-founded. Previously, Dr. Moll co-founded Intuitive Surgical, Inc. and from 1995 to 2002 served as its first Chief Executive Officer. Dr. Moll also co-founded Endo-Therapeutics, Inc. and Origin, which later became an operating company within Guidant Corporation following its acquisition by Eli Lilly & Company. Dr. Moll serves on the boards of directors of IntersectENT, Inc. Dr. Moll received a B.A. in economics from the University of California at Berkeley, an M.S. in management from Stanford University and an M.D. from the University of Washington. Dr. Mollâ€™s experience in the healthcare sector and his medical background and experience provide him with the qualifications and skills to serve on our board of directors.

Marc-Andre Marcotte, CFA. Mr. Marcotte has served as a member of our board of directors since August 2018. He serves as Partner at Sectoral Asset Management Inc., which he joined in 2006. There, Mr. Marcotte has been Chief Operating Officer since April 2018. Prior to his current position, Mr. Marcotte was a Managing Director of Sectoral Asset Management from December 2013 to April 2018. Prior to Sectoral Asset Management Inc., Mr. Marcotte served at CryoCath Technologies, Inc. as the Director of Quality. Prior to that, Mr. Marcotte worked at Arterial Vascular Engineering in Vancouver as an engineer on angioplasty catheters and stents. Mr. Marcotte has been a C.F.A. charterholder since 2010. Mr. Marcotte graduated from Sherbrooke University in 1997 with a B.E. and completed a M.B.A. at HEC Montreal in 2004. Mr. Marcotteâ€™s perspective as a partner of a healthcare investment firm, along with his experience in the healthcare industry, provides him with the qualifications and skills to serve on our board of directors. Mr. Marcotte will resign from our board of directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. As Mr. Marcotte is a partner at Sectoral Asset Management Inc., the firmâ€™s policy prohibits Mr. Marcotte from serving on the board of directors of a public company of the firmâ€™s portfolio companies.

Laura Francis. Ms. Francis has served as a member of our board of directors since January 2019. Ms. Francis has been Chief Financial Officer of SI-BONE, Inc., an orthopedic device company, since May 2015. Prior to that position, she was the Chief Financial Officer for Auxogyn, Inc., a womenâ€™s health company, from December 2012 to September 2014. From September 2004 to December 2012, Ms. Francis served as Vice President of Finance, Chief Financial Officer and Treasurer for Promega Corporation, a life science reagent company. From March 2002 to September 2004, she served as the Chief Financial Officer of Bruker BioSciences Corporation, a public life science instrumentation company. From May 2001 to March 2002, Ms. Francis served as Chief Operating Officer and Chief Financial Officer of Nutra-Park Inc., an agricultural biotechnology company. From April 1999 to May 2001, Ms. Francis was Chief Financial Officer of Hypercosm, Inc., a software company. From October 1995 to April 1999, she was an engagement manager with McKinsey & Company. Early in her career, Ms. Francis was an audit manager with Coopers & Lybrand, an accounting firm. Ms. Francis

received a B.B.A. from the University of Wisconsin and an M.B.A. from Stanford University. She is a Certified Public Accountant (inactive) in the State of California. Ms. Francisâ€™s experience in the healthcare industry provides her with the qualifications and skills to serve on our board of directors.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Board Structure and Compensation of Directors

Our board of directors currently consists of eight members, which will be reduced to seven members following the resignation of Mr. Marcotte immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. In accordance with our amended and restated certificate of incorporation and our amended and restated bylaws, immediately after the completion of this offering, our directors will be divided into three classes serving staggered three-year terms. At each annual meeting of stockholders, our directors will be elected to succeed the class of directors whose terms have expired. Our current directors will be divided among the three classes as follows:

- â€¢ the Class I directors will consist of C. Raymond Larkin, Jr. and Laura Francis, and their terms will expire at the annual meeting of stockholders to be held in 2020;
- â€¢ the Class II directors will consist of Antoine Papiernik and Colin Cahill, and their terms will expire at the annual meeting of stockholders to be held in 2021; and
- â€¢ the Class III directors will consist of Douglas Godshall, F.T. â€œJayâ€ Watkins and Frederic Moll, and their terms will expire at the annual meeting of stockholders to be held in 2022.

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.

Director Independence

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning his background, employment and affiliations, our board of directors has determined that each of F.T. â€œJayâ€ Watkins, Antoine Papiernik, Frederic Moll, Colin Cahill, C. Raymond Larkin, Jr. and Laura Francis do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and is independent under applicable Nasdaq rules. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled â€œCertain Relationships and Related Party Transactions.â€

Compensation of Directors

Upon the closing of this offering, directors who are also full-time officers or employees of our company will receive no additional compensation for serving as directors, and directors who are not full-time officers or employees of our company (â€œnon-employee directorsâ€) will receive the following compensation.

Each non-employee director will receive an annual cash retainer in recognition of his or her service to the board, along with an additional annual cash retainer for service as chairperson or a member of each committee of our board on which the director serves.

Position	Annual Cash Retainer
Board Member	$ 35,000
Committee Chair:	
Audit	$ 16,000
Compensation	$ 12,000
Nominating and Governance	$ 8,000
Committee Member:	
Audit	$ 8,000
Compensation	$ 6,000
Nominating and Governance	$ 4,000

Equity Awards in Connection with Offering.

In addition to the Annual Cash Retainer, in connection with the offering hereunder, certain non-employee directors will receive a one-time grant of stock options under our 2019 Plan, with an aggregate value of $150,000 based on the Black-Scholes option-pricing model and a per share exercise price equal to the initial public offering price in this offering.

Ongoing Equity Compensation.

We are considering whether to provide annual equity grants to our non-employee directors and, if so, in what forms.

For any director whose employer or fund does not permit the director to take securities as compensation for service on the board of directors, the director compensation plan will provide for one or more cash-based awards that such a director may elect to receive in lieu of the options or other securities to which he or she would otherwise be entitled, subject to such terms and conditions as may be determined by the board of directors or the compensation committee, as applicable.

Board Committees

Audit Committee

The members of our audit committee are Laura Francis, Colin Cahill and F.T. â€œJayâ€ Watkins. Ms. Francis is the chairwoman of our audit committee. The composition of our audit committee meets the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations. Each member of our audit committee is financially literate. In addition, our board of directors has determined that Laura Francis is an â€œaudit committee financial expertâ€ as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act. This designation does not impose on either any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is directly responsible for, among other things:

- â€¢ selecting a firm to serve as the independent registered public accounting firm to audit our financial statements;
- â€¢ ensuring the independence of the independent registered public accounting firm;
- â€¢ discussing the scope and results of the audit with the independent registered public accounting firm and reviewing, with management and that firm, our interim and year-end operating results;
- â€¢ establishing procedures for employees to anonymously submit concerns about questionable accounting or audit matters;
- â€¢ considering the adequacy of our internal controls and internal audit function;

- â€¢ reviewing material related party transactions or those that require disclosure; and
- â€¢ approving or, as permitted, pre-approving all audit and non-audit services to be performed by the independent registered public accounting firm.

Our audit committee will operate under a written charter, to be effective prior to the completion of this offering, that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq.

Compensation Committee

The members of our compensation committee are Antoine Papiernik, Laura Francis and C. Raymond Larkin, Jr. Mr. Papiernik is the chairman of our compensation committee. Each member of this committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1989, as amended, (the â€œCodeâ€), and meets the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations. Our compensation committee is responsible for, among other things:

- â€¢ reviewing and approving, or recommending that our board of directors approve, the compensation of our executive officers;
- â€¢ reviewing and recommending to our board of directors the compensation of our directors;
- â€¢ administering our stock and equity incentive plans;
- â€¢ reviewing and approving, or making recommendations to our board of directors with respect to, incentive compensation and equity plans; and
- â€¢ reviewing our overall compensation philosophy.

Our compensation committee will operate under a written charter, to be effective prior to the completion of this offering, that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq.

Nominating and Governance Committee

The members of our nominating and governance committee are C. Raymond Larkin, Jr., Frederic Moll, M.D. and Colin Cahill. Mr. Larkin is the chairman of our nominating and governance committee. Mr. Larkin, Mr. Moll and Mr. Cahill all meet the requirements for independence under the current Nasdaq listing standards. Our nominating and governance committee is responsible for, among other things:

- â€¢ identifying and recommending candidates for membership on our board of directors;
- â€¢ reviewing and recommending our corporate governance guidelines and policies;
- â€¢ reviewing proposed waivers of the code of conduct for directors and executive officers;
- â€¢ overseeing the process of evaluating the performance of our board of directors; and
- â€¢ assisting our board of directors on corporate governance matters.

Our nominating and governance committee will operate under a written charter, to be effective prior to the completion of this offering, that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq.

Code of Ethics

In connection with this offering, our board of directors will adopt a code of ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive and senior financial officers. Upon completion of this offering, the full text of our code of business conduct and ethics will be posted on the investor relations section of our website. We intend to disclose future

amendments to our code of business conduct and ethics, or any waivers of such code, on our website or in public filings.

Limitation of Liability and Indemnification

Our amended and restated certificate of incorporation, which will be in effect upon the completion of this offering, contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- â€¢ any breach of the directorâ€™s duty of loyalty to us or our stockholders;
- â€¢ any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- â€¢ unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- â€¢ any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation to be in effect upon the completion of this offering will provide that we may indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws to be in effect upon the completion of this offering will also provide that we are obligated to indemnify our directors and officers to the fullest extent permitted by Delaware law and advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With specified exceptions, these agreements will provide for indemnification for related expenses including, among other things, attorneysâ€™ fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe these limitations of liability provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directorsâ€™ and officersâ€™ liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation, amended and restated bylaws and indemnification agreements may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. Our amended and restated certificate of incorporation will provide that any such lawsuit must be brought in the Court of Chancery of the State of Delaware. The foregoing provisions may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholderâ€™s investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

Compensation Committee Interlocks and Insider Participation

Prior to this offering, our compensation committee consisted of F.T. â€œJayâ€ Watkins, our Chairman, Antoine Papiernik and Frederic Moll. As a result, Mr. Watkins, Mr. Papiernik and Dr. Moll determined the compensation of our executive officers. None of our executive officers has served as a member of a compensation committee (or if no committee performs that function, the board of directors) of any other entity that has an executive officer serving as a member of our board of directors.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth information concerning the compensation paid to our principal executive officer, and our two other most highly compensated executive officers during our fiscal year ended December 31, 2018.

2018 SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Stock Awards ($)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)(3)	Total ($)
Douglas Godshall, Chief Executive Officer	2018	375,595	135,000	â€”	â€”	â€”	â€”	330	510,925
Dan Puckett, Chief Financial Officer & Secretary	2018	314,863	88,594	â€”	25,965	â€”	â€”	330	429,752
Isaac Zacharias, Chief Commercial Officer(4)	2018	236,064	113,103	â€”	558,480	â€”	â€”	248	907,895

(1) These figures reflect the annual bonus earned by each executive based on his service in 2018, which was paid in February 2019.
(2) Amounts shown in this column do not reflect dollar amounts actually received by our named executive officers. Instead, these amounts reflect the aggregate grant date fair value of each stock option granted in 2018 computed in accordance with the provisions of FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 10 to our financial statements included in this prospectus. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.
(3) These figures reflect life insurance premiums paid with respect to each executive.
(4) Mr. Zacharias served as our General Manager of Structural Heart and Vice President of International Sales from March 2018 to November 2018, when he was promoted to the position of Chief Commercial Officer. As required by SEC rules, the amounts shown reflect all compensation paid or provided to Mr. Zacharias for his service to the Company in 2018, including the period prior to his promotion. The figure in the Bonus column for Mr. Zacharias includes a $40,000 sign-on bonus granted upon Mr. Zachariasâ€™ joining the Company. The figure in the Option Awards column for Mr. Zacharias reflects the value of options granted upon Mr. Zachariasâ€™ joining the Company and upon his promotion.

Executive Officer Employment Arrangements

We have entered into employment agreements with each of our named executive officers, the key terms of which are described below. In addition, as a condition of employment each of our named executive officers has also entered into our standard, at-will employment, confidential information, invention assignment and arbitration agreement. Under these agreements, each officer has made a covenant not to solicit our employees, both during the officerâ€™s employment and for the 12-month period following termination of employment for any reason.

Douglas Godshall

We are party to an offer letter with Mr. Godshall dated April 28, 2017, under which Mr. Godshall has agreed to serve as our President and Chief Executive Officer, and as a member of our board of directors.

This offer letter provides that Mr. Godshall will receive an initial compensation package including (i) an annual base salary of $375,000, (ii) an annual bonus with a target opportunity of 40% of annual base salary, subject to Mr. Godshall and our achievement of milestones to be established by our board of directors, and (iii) an option award to purchase 6% of the fully diluted shares of our common stock as of the date of grant, with an exercise price equal to the fair market value of the common stock on the date of grant, to vest as to 25% of the

award on the first anniversary of the date of grant, with the remainder of the award to vest in equal amounts over the next 36 months (with any then unvested shares vesting upon the closing of a change of control, if Mr. Godshall is employed through the date we sign a definitive agreement with respect to that change of control and subject to Mr. Godshallâ€™s release of claims).

Under his offer letter, Mr. Godshallâ€™s employment is for no specified period and constitutes at-will employment. In the event that Mr. Godshallâ€™s employment is terminated by us without cause (as defined in the offer letter and described below) or by Mr. Godshall for good reason (as defined in the offer letter and described below) then, subject to Mr. Godshallâ€™s release of claims in a form acceptable to us, Mr. Godshall will receive a continuation of benefits and base salary for twelve months following termination. Unless we have conducted an initial public offering and experienced a subsequent change of control prior to Mr. Godshallâ€™s termination or resignation, this severance arrangement will terminate early if Mr. Godshall commences new employment fewer than twelve months after such termination or resignation.

For purposes of Mr. Godshallâ€™s offer letter, â€œcauseâ€ is defined as Mr. Godshallâ€™s (i) failure to substantially perform material duties and obligations, which failure is not cured to the reasonable satisfaction of our board of directors within ten business days after written notice; (ii) act of personal dishonesty, moral turpitude, fraud, embezzlement, misrepresentation or other unlawful act that results in harm to us or our affiliates; (iii) violation of law or regulation applicable to our business; (iv) conviction of, or plea of nolo contendere or guilty to, a felony; or (v) material breach of the terms of any agreement with us or one of our affiliates.

For purposes of Mr. Godshallâ€™s offer letter, â€œgood reasonâ€ is defined as the occurrence, without Mr. Godshallâ€™s prior written consent, of: (i) a material diminution of Mr. Godshallâ€™s base salary (unless part of a generalized reduction affecting senior level employees); (ii) a material diminution of authority, duties or responsibilities (unless in connection with a change of control if Mr. Godshall has reasonably comparable authority, duties and responsibilities after the change of control, regardless of any change in title or whether he subsequently provides services to a subsidiary, affiliate, business unit, division or otherwise); (iii) our requirement that Mr. Godshall relocate his principal residence to the state in which we conduct our principal business; or (iv) our material breach of the agreement under which Mr. Godshall provides services to us, which is not cured to Mr. Godshallâ€™s reasonable satisfaction within ten business days after notice.

For purposes of Mr. Godshallâ€™s offer letter, â€œchange of controlâ€ is defined as: (1) our acquisition by another entity by means of any transaction (including a series of related transactions, but excluding our sale of securities for the purpose of raising additional funds) unless our stockholders of record immediately prior to such transaction hold, immediately after such transactions, at least 50% of the voting power of the surviving or acquiring entity; or (2) a sale of all or substantially all of our assets.

Dan Puckett

We are party to an offer letter with Mr. Puckett dated March 21, 2016, under which Mr. Puckett has agreed to serve as our Chief Financial Officer.

This offer letter provides that Mr. Puckett will receive an initial compensation package, including (i) an annual base salary of $290,000 and (ii) an option award to purchase 1.01% of the fully diluted shares of our common stock as of the date of grant, with an exercise price equal to the fair market value of the common stock on the date of grant, to vest as to 25% of the award on the first anniversary of the date of grant, with the remainder of the award to vest in equal amounts over the next 36 months subject to his continued employment with the company (with any then unvested shares vesting on a â€œdouble triggerâ€ basis in the event of a change of control). Mr. Puckettâ€™s employment with the company is on an at-will basis. We are free to conclude his employment at any time, with or without cause and with or without notice.

Isaac Zacharias

We are party to a letter agreement with Mr. Zacharias dated November 26, 2018, under which Mr. Zacharias has agreed to serve as our Chief Commercial Officer. This letter agreement, which is cast as an offer letter, sets forth the terms and conditions of Mr. Zachariasâ€™ continued employment with us in his new role.

This letter agreement provides that Mr. Zacharias will receive a compensation package including (i) an annual base salary of $310,000, (ii) an annual bonus of up to 25% of annual base salary and (iii) an option award to purchase 81,967 shares of our common stock with an exercise price equal to the fair market value of the common stock on the date of grant, to vest in equal amounts over the next 48 months subject to his continued employment with the company. Mr. Zachariasâ€™ employment with the company is on an at-will basis. We are free to conclude his employment at any time, with or without cause and with or without notice.

Changes to Executive Officer Compensation in Connection with this Offering

In connection with our initial public offering hereunder, our Compensation Committee has approved the following changes to the compensation arrangements for our named executive officers, effective upon the closing of this offering:

- Mr. Godshallâ€™s annual base salary will increase to $500,000 and his annual bonus target opportunity will be 75% of his annual base salary;
- Mr. Puckettâ€™s annual base salary will increase to $350,000 and his annual bonus target opportunity will be 50% of his annual base salary; and
- Mr. Zachariasâ€™ annual base salary will remain $310,000 and his annual bonus target opportunity will be 45% of his annual base salary.

Also in connection with our initial public offering, Mr. Godshall and Mr. Puckett will receive stock option awards to acquire up to 81,967 shares and 53,278 shares, respectively, of common stock of the Company under its 2019 Equity Incentive Plan at an exercise price equal to the initial public offering price of this offering, with such awards scheduled to vest monthly in substantially equal installments for four years from the date of grant, subject in each case to continued service through each applicable vesting date.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth information concerning unexercised options, stock that has not vested and equity incentive plan awards for the executive officers named in the Summary Compensation Table as of the end of our fiscal year ended December 31, 2018.

OUTSTANDING EQUITY AWARDS AT 2018 FISCAL YEAR END

		Option Awards				
Name	Grant Date	Numbers of Securities Underlying Unexercised Options (#) Exercisable	Numbers of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Douglas Godshall	05/09/2017	468,982	715,817(1)	â€”	3.42	05/09/2027
Dan Puckett	05/18/2016	98,360	49,180(1)	â€”	2.20	05/18/2026
	08/03/2017	5,805	10,588(2)	â€”	3.42	08/03/2027
	07/19/2018	1,280	11,015(2)	â€”	4.03	07/19/2028
Isaac Zacharias	04/10/2018	â€”	147,540(1)	â€”	4.03	04/10/2028
	11/14/2018	â€”	81,967(1)	â€”	6.71	11/14/2028

(1) Subject to vesting as to 1/4 of the award upon continued service through the first anniversary of the date of grant and as to 1/48 of the award upon continued service through each month thereafter, through the fourth anniversary of the date of grant.
(2) Subject to vesting as to 1/48 of the award upon continued service through each month following the date of grant, through the fourth anniversary of the date of grant.

Employee Benefit Plans

Our officers are entitled to participate in our equity incentive plans. All officers are eligible to participate in the companyâ€™s 401(k) plan on the same terms as all other employees.

Annual Bonus Program

We maintain an annual bonus program that rewards each of our named executive officers for our performance against business goals, and for the officerâ€™s performance against his or her individual goals. Our board of directors establishes performance goals for this program each year and then evaluates performance to these established goals to determine the amount of each award. This program is based on performance over a calendar year and pays out on or before March 15 of the following year, subject to the executiveâ€™s continued service through the payment date. All awards under this program are subject to management discretion.

2019 Equity Incentive Plan

In February 2019, our board of directors adopted and our stockholders approved our 2019 Equity Incentive Plan (the â€œ2019 Planâ€), which became effective upon the effectiveness of the registration statement, of which this prospectus forms a part. Our 2019 Plan replaces our 2009 Equity Incentive Plan (the â€œ2009 Planâ€). Following the effectiveness of the 2019 Plan, no further equity awards may be granted under our 2009 Plan.

Stock awards. The 2019 Plan provides for the grant of incentive stock options (â€œISOsâ€), nonstatutory stock options (â€œNSOsâ€), stock appreciation rights, restricted stock awards and restricted stock unit awards (collectively, â€œstock awardsâ€). ISOs may be granted only to employees. All other awards may be granted to employees, directors and consultants.

Share reserve. The aggregate number of shares of our common stock initially reserved for issuance pursuant to stock awards under the 2019 Plan is 2,000,430, plus (i) any shares subject to stock options or other stock awards granted under our 2009 Plan that expire or terminate for any reason, are forfeited or repurchased by us or are reacquired, withheld or not issued to satisfy a tax withholding obligation, up to a maximum of 3,636,224 shares. The maximum number of shares that may be issued upon the exercise of incentive stock options will equal this aggregate maximum number of shares plus other shares that become available upon lapsed awards or

certain other conditions, to the extent allowed by Section 422 of the Code and the regulations promulgated thereunder. The 2019 Plan provides that the number of shares reserved and available for purchase under the plan will automatically increase on the first day of each fiscal year beginning with the 2020 fiscal year and ending with the 2028 fiscal year, in an amount equal to the least of (i) 3% of the outstanding shares of our common stock on the last business day of immediately preceding fiscal year and (ii) such number of shares of our common stock determined by our board of directors.

If a stock award granted under the 2019 Plan is forfeited back to us because of the failure to meet a contingency or condition required to vest, such shares will become available for subsequent issuance under the 2019 Plan. In addition, shares withheld to satisfy income or employment withholding taxes and shares used to pay the exercise price of a stock option will become available for the grant of new stock awards under the 2019 Plan.

Administration. Our board of directors, or one or more duly authorized committees thereof, have the authority to administer the 2019 Plan. Subject to the terms of the 2019 Plan, our board of directors or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award. The plan administrator has the authority to modify outstanding awards made under the 2019 Plan, but is not authorized to reduce the exercise price of stock options or stock appreciation rights without stockholder consent.

Stock Options. Incentive and nonstatutory stock options are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2019 Plan, provided that the exercise price of a stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. In the case of an ISO granted to an employee who owns stock representing more than 10% of the voting power of all classes of our stock or any parent or subsidiary of us, the exercise price will be no less 110% of the fair market value on the date of the grant. Options vest at the rate specified by the plan administrator. At the time an option is granted, the plan administrator will fix the period within which the option may be exercised and will determine any conditions that must be satisfied before the option may be exercised.

The plan administrator determines the term of stock options granted under the 2019 Plan, up to a maximum of 10 years. In the case of an incentive stock option granted to an employee who owns stock representing more than 10% of the voting power of all classes of our stock or the stock of any of our parents or subsidiaries, the maximum term will be five years. Unless the terms of an optionholderâ€™s stock option agreement provide otherwise, if an optionholderâ€™s service relationship with us ceases for any reason other than disability or death, the optionholder may generally exercise any vested options for a period of 30 days following the cessation of service. If an optionholderâ€™s service relationship with us ceases due to disability or death, the optionholder or a beneficiary may generally exercise any vested options for a period of six months, or within such longer period of time as is specified in the award agreement. In no event may an option be exercised beyond the expiration of its term. Subject to the terms of our 2019 Plan, the plan administrator has the authority to extend the post-termination exercisability period of awards and to extend the maximum term of an option.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, (2) check, (3) promissory note, (4) other shares, (5) a broker-assisted cashless exercise, (6) by net exercise or (7) combination of the foregoing methods of payment.

Unless the plan administrator provides otherwise, options generally are not transferable except by will or by the laws of descent and distribution. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholderâ€™s death.

Stock Appreciation Rights. The 2019 Plan permits the grant of stock appreciation rights. Stock appreciation rights give recipients the right to acquire a specified number of shares of stock at a predetermined price. The terms of the stock appreciation rights granted under the 2019 Plan are determined by the plan administrator in the award agreement evidencing the award, including the number of shares, exercise price, expiration date and other terms.

Restricted Stock and Restricted Stock Units. The 2019 Plan permits the grant of restricted stock and/or restricted stock units. Restricted stock awards are grants of shares of our common stock. Restricted stock units represent the right to receive shares of our common stock (or a cash amount equal to the value of our common stock) on future specified dates. The terms of the restricted stock and/or restricted stock units granted under the 2019 Plan are determined by the plan administrator in the award agreement evidencing the award, including the number of shares, period of restriction or vesting schedule and other terms.

Tax Limitations on Incentive Stock Options. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (2) the option is not exercisable after the expiration of five years from the date of grant.

Adjustments; Corporate Transactions. In the event of certain changes in our corporate structure, including any dividend or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase or exchange of shares of the company, the plan administrator will make appropriate adjustments to outstanding awards to prevent diminution or enlargement of the benefits or potential benefits available under the 2019 Plan.

Merger or Change of Control. In the event of certain corporate transactions specified in the 2019 Plan, including a merger or change of control, as defined in the 2019 Plan, each outstanding award will be treated as the plan administrator determines, without a participantâ€™s consent, including that (i) awards will be assumed or substituted by the succeeding corporation; (ii) the awards will terminate; (iii) outstanding awards will vest and become exercisable; (iv) the awards will terminate in exchange for an amount of cash and/or property, if any, equal to the amount that would have been attained upon the exercise of the award or realization of the rights under the award as of the date of the transaction; (v) the replacement of any award with rights or property selected by the plan administrator; or (vi) any combination of the above. In the event that the successor corporation does not assume or substitute the award, the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, and all restrictions on restricted stock and restricted stock units will lapse and performance goals will be deemed achieved at 100% of the target levels. Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner. Under the 2019 Plan, a change of control is generally: (i) the acquisition by a person or entity of more than 50% of our combined voting power other than by private financing that is approved by our board of directors; (ii) if we are public, the date on which a majority of our board of directors has been replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of our board of directors prior to the date of appointment or election; or (iii) change in ownership of a substantial portion of our assets.

Amendment and Termination. The 2019 Plan will terminate in 2029. However, our board of directors has the authority to amend, alter, or terminate our 2019 Plan, provided that such action does not materially impair the existing rights of any participant without such participantâ€™s written consent.

Employee Stock Purchase Plan

In February 2019, our board of directors adopted and our stockholders approved our Employee Stock Purchase Plan (â€œESPPâ€). The ESPP became effective upon the effectiveness of the registration statement of which this prospectus forms a part. Unless otherwise determined by the board of directors, the ESPP will be administered by our compensation committee.

Share Reserve. The ESPP authorizes the initial issuance of up to a total of 300,650 shares of our common stock to participating employees. The ESPP provides that the number of shares reserved and available for purchase under the plan will automatically increase on the first day of each fiscal year beginning with the 2020 fiscal year and ending with the 2028 fiscal year, in an amount equal to the least of (i) 1% of the outstanding shares of our common stock on the last day of immediately preceding fiscal year and (ii) such number of shares of our common stock determined by our board of directors. The number of shares authorized under the ESPP at any time is subject to antidilution adjustment in the event of a stock split, stock dividend or other change in our capitalization.

Eligible Employees. All employees who have been employed by us or our designated subsidiaries are eligible to participate in the ESPP, provided that the plan administrator may determine from time to time in its discretion to not include in the ESPP or any particular offering period employees who work less than 20 hours per week or less than five months in any calendar year. Any employee who owns, or would own upon such purchase under the ESPP, 5% or more of the voting power or value of our stock is not eligible to purchase shares under our the ESPP.

Offering Periods. Unless otherwise determined by the administrator of the ESPP, each offering to our 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, each referred to as offering periods, provided that the first offering period will begin on September 1, 2019 and will end on February 29, 2020. The administrator may designate different offering periods prior to the beginning of an offering period in its discretion, but no offering shall exceed 27 months in duration.

Purchase Limits and Offering Price. Each employee who is a participant in the ESPP may purchase shares by authorizing payroll deductions at a minimum of 1% and up to 15% of his or her eligible compensation for each pay period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase our common stock on the last business day of the offering period at a price equal to 85% of the fair market value of the common stock on either the first or the last day of the offering period, whichever is lower, or such higher price for any given offering period as may be determined by the Committee, provided that no more than 1,250 shares of our common stock or such other lesser maximum number established by the plan administrator may be purchased by any one employee during each offering period. Under applicable tax rules, an employee may purchase no more than $25,000 worth of common stock, valued at the start of the purchase period, under the ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded or retained for use in the next offering period. An employeeâ€™s rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment for any reason. Eligible employees who have withdrawn from participation may reenroll effective the next offering period.

Corporate Transaction. Prior to the effective time of any Corporate Transaction, as defined in the ESPP, the ESPP will terminate and shares will be purchased prior to the effective time as determined by the plan administrator, unless the ESPP is continued by the company or assumed by the surviving corporation.

Non-Transferability. An employee may not transfer rights granted under the ESPP other than by beneficiary designation or the laws of descent and distribution.

Amendment and Termination. The ESPP may be terminated or amended by our board of directors at any time. Amendments that increase the number of shares of our common stock authorized under the ESPP and certain other amendments require the approval of our stockholders. The plan administrator may adopt and amend stock purchase subplans for employees of our non-U.S. subsidiaries.

2009 Equity Incentive Plan

Our board of directors approved our 2009 Plan in June 2009, and was approved by our stockholders in January 2010. The 2009 Plan provides for grants of stock options, stock appreciation rights, restricted stock awards and restricted stock unit awards (collectively, stock awards) to employees, directors or consultants.

Stock Options. Each of our named executive officers has received one or more grants of stock options under the 2009 Plan. Each of these awards has been designated as an ISO, and will be treated as such to the extent that the award complies with the Code requirements for ISOs, including the requirement that not more than $100,000 in ISOs shall become exercisable for any given employee in any given year. Any portion of the options granted to our named executive officers that do not comply as ISOs will be treated as NSOs.

Each stock option granted to any of our named executive officers under our 2009 Plan has an exercise price equal to the fair market value of the common stock on the date of grant, as determined by our board of directors. The first such stock option award granted to each of our named executive officers is scheduled to vest as to 25% of the award on the first anniversary of the date of grant, with the remainder of the award to vest in equal monthly amounts over the next 36 months. Each stock option award granted to a named executive officer after the officerâ€™s initial award, is scheduled to vest in equal monthly amounts over the next 48 months.

As described above, the offer letter for Mr. Godshall provides for single-trigger vesting on a change of control for his initial option grant, and Mr. Puckettâ€™s offer letter provides for double-trigger vesting on a termination in connection with a change of control for his initial option grant. Other option awards to our named executive officers under the 2009 Plan will vest upon a change of control to the extent provided in the 2009 Plan.

In the event of certain corporate transactions specified in the 2009 Plan, including a merger or change of control, as defined in the 2009 Plan, each outstanding award will be treated as the plan administrator determines, without a participantâ€™s consent, including that: (i) awards will be assumed or substituted by the succeeding corporation; (ii) the awards will terminate; (iii) outstanding awards will vest and become exercisable; (iv) the awards will terminate in exchange for an amount of cash and/or property, if any, equal to the amount that would have been attained upon the exercise of the award or realization of the rights under the award as of the date of the transaction; (v) the replacement of any award with rights or property selected by the plan administrator; or (vi) any combination of the above. In the event that the successor corporation does not assume or substitute the award, the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, and all restrictions on restricted stock and restricted stock units will lapse and performance goals will be deemed achieved at 100% of the target levels. Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner. Under the 2009 Plan, a change of control is generally: (i) the acquisition by a person or entity of more than 50% of our combined voting power other than by private financing that is approved by our board of directors; (ii) if we are public, the date on which a majority of the board has been replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of our board of directors prior to the date of appointment or election; or (iii) change in ownership of a substantial portion of our assets.

Each of these stock options will become exercisable upon vesting, and will remain exercisable until its termination date on the tenth anniversary of the award, or, if earlier, until the day that is twelve months after the

recipient ceases to be a service provider due to death or disability, or the day that is three months after the recipient ceases to be a service provider for any other reason.

Each of these options includes an agreement by the applicable named executive officer to comply with the trading restrictions under any lock-up period following a public offering of our securities.

Defined Contribution Plan

We currently maintain a 401(k) retirement savings plan (the â€œ401(k) planâ€) for our employees, including our named executive officers, who satisfy certain eligibility requirements. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Code. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The Code allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) plan. We reserve the right to make discretionary matching contributions or non-elective contributions under the 401(k) plan. In 2018, we did not provide a matching contribution or a non-elective contribution under the 401(k) plan.

We do not maintain any defined benefit pension plans.

Nonqualified Deferred Compensation

We do not maintain any nonqualified deferred compensation plans.

DIRECTOR COMPENSATION

We have not historically provided any compensation to any member of our board of directors who has been designated to serve on our board by one of our significant investors. Our other non-employee directors each received $15,000 for their service on our board during the year ended December 31, 2018. None of our directors have been granted stock or option awards for service on our board of directors. We do, however, reimburse our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of directors and committee meetings.

Mr. Godshall, our Chief Executive Officer and President, did not receive additional compensation for his services as a director. For more information on Mr. Godshallâ€™s compensation as an officer, see the section titled â€œExecutive Compensation.â€

In connection with this offering, we implemented a new compensation policy for certain of our independent directors pursuant to which they will each be given an annual cash payment and may be granted equity in the form of options. In connection with the appointment of Mr. Larkin and Ms. Francis to our board of directors on January 3, 2019, the board of directors approved stock option awards to each of them in the amount of 28,688 and 24,590 shares of common stock, respectively, at a price of $6.59 per share, to vest in equal monthly installments subject to each directorâ€™s continuous service through the three-year period following the date of grant. In addition the board of directors has determined to provide a one-time grant of stock options under our 2019 Plan to each of our other non-employee directors with an aggregate value of $150,000, each based on the Black-Scholes pricing method, and a per-share exercise price equal to the initial public offering price in this offering.

The following table presents the total compensation for each person who served as a non-employee director of the Company during the fiscal year ended December 31, 2018.

DIRECTOR COMPENSATION TABLE

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Todd Brinton, M.D.(2)	15,000	â€”	â€”	144,000	159,000
Colin Cahill	â€”	â€”	â€”	â€”	â€”
Marc-Andre Marcotte(3)	â€”	â€”	â€”	â€”	â€”
Frederic Moll, M.D.	15,000	â€”	â€”	â€”	15,000
Antoine Papiernik	â€”	â€”	â€”	â€”	â€”
F.T. â€œJayâ€ Watkins	15,000	â€”	â€”	â€”	15,000

(1) As of December 31, 2018, the following stock option awards held by our directors were outstanding: an option held by Dr. Brinton to acquire 28,688 shares of common stock, options held by Dr. Moll to acquire 110,655 shares of common stock and options held by Mr. Watkins to acquire 133,314 shares of common stock. Each of these awards was granted in connection with the recipientâ€™s services to the Company as a consultant, and not in connection with service as a member of our board of directors. In addition, as of December 31, 2018, Dr. Brinton held a warrant to acquire 41,115 shares of common stock; we issued this non-compensatory warrant to Dr. Brinton in May 2015 in consideration for the transfer to the Company of the intellectual property rights of DJT, LLC (â€œDJTâ€), a dissolved entity formerly affiliated with Dr. Brinton. The warrant has an exercise price of $2.196 per share.

(2) The figure in the All Other Compensation column reflects $144,000 of fees paid to Dr. Brinton in consideration for services provided to the Company as a consultant. See â€œCertain Relationships and Related Party Transactionsâ€ for additional information. Effective January 1, 2019, Dr. Brinton has resigned from his position as a member of our board of directors.

(3) Mr. Marcotte will resign from our board of directors effective immediately upon the effectiveness of the registration statement of which this prospectus forms a part. As Mr. Marcotte is a partner at Sectoral Asset Management Inc., the firmâ€™s policy prohibits Mr. Marcotte from serving on the board of directors of a public company of the firmâ€™s portfolio companies.

Benefit Plans for Directors

Our directors are entitled to participate in our equity incentive plans, described above, and, following this offering, we may include equity awards in our compensation policy for independent directors.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

We describe below transactions and series of similar transactions, during our last three fiscal years or currently proposed, to which we were a party or will be a party, in which:

- â€¢ the amounts involved exceeds $120,000; and
- â€¢ any of our directors, executive officers or beneficial holders of more than 5% of any class of our capital stock had or will have a direct or indirect material interest.

Other than as described below, there have not been, nor are there any currently proposed, transactions or series of similar transactions meeting this criteria to which we have been or will be a party other than compensation arrangements, which are described where required under the sections titled â€œManagementâ€”Board Structure and Compensation of Directorsâ€ and â€œExecutive Compensation.â€

Convertible Preferred Stock Financings

Series C Convertible Preferred Stock Financing. In November 2016 and September 2017, we issued an aggregate of 6,492,564 shares of our Series C convertible preferred stock at $12.32176 per share, for an aggregate consideration of approximately $80.0 million. All shares of our Series C convertible preferred stock will convert into shares of our common stock immediately prior to the closing of this offering in accordance with our current certificate of incorporation.

Series D Convertible Preferred Stock Financing. In December 2018, we issued an aggregate of 1,090,608 shares of our Series D convertible preferred stock at $13.75379 per share, for an aggregate consideration of approximately $15.0 million. The Series D convertible preferred stockholder, Abiomed Inc., has the option to purchase up to $10.0 million in common stock in a concurrent private placement at a price per share equal to the price per share of the common stock to the public in an initial public offering. All shares of our Series D convertible preferred stock will convert into shares of our common stock immediately prior to the closing of this offering in accordance with our current certificate of incorporation.

The following table sets forth the aggregate number of shares of our capital stock acquired by our directors, officers and beneficial owners of more than 5% of our capital stock in the financing transactions described above.

Participant(1)	Series C Preferred Stock	Series D Preferred Stock	Cash Purchase Price
Greater than 5% Stockholders:			
Sofinnova Capital VII FCPR	592,447	â€”	$7,299,999.09
Entities affiliated with Venrock Funds	1,016,492	â€”	$ 12,524,999.33
Entities managed by Fidelity Management & Research Company or its affiliates	2,028,929	â€”	$ 24,999,999.62
Certain funds and accounts advised by T. Rowe Price Associates, Inc.	1,095,622	â€”	$ 13,499,999.72
Entities affiliated with Sectoral Asset Management	783,533	â€”	$ 14,199,974.40
Abiomed, Inc.(2)	â€”	1,090,608	$ 15,000,000.55
Directors:			
Frederic Moll, M.D.	24,347	â€”	$299,999.41

(1) Additional details regarding these participants and their equity holdings are provided in â€œPrincipal Stockholders.â€

(2) Pursuant to the Series D convertible preferred stock financing, Abiomed, Inc. has the option to purchase up to $10.0 million in common stock in a concurrent private placement at a price per share equal to the price per share of the common stock to the public in an initial public offering.

Investor Rights Agreement

We are party to an Amended and Restated Investor Rights Agreement (the â€œIRAâ€) with the holders of our preferred stock, including certain of our directors and entities to which certain of our directors are related. The agreement provides these holders the right, subject to the terms of the lock-up agreements entered into in connection with this offering, to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. See the section titled â€œDescription of Capital Stockâ€”Registration Rightsâ€ for additional information. The agreement also provides these holders pro rata participation rights and information rights, which will terminate upon completion of this offering.

Todd Brinton, M.D. Consulting Agreement

On June 17, 2009, we entered into a consulting agreement with our former director, Todd Brinton, M.D., on an independent contractor basis, pursuant to which Dr. Brinton provides advisory services to us in areas including clinical study design input and other professional services related to the use of medical devices. On May 18, 2016, our board of directors increased Dr. Brintonâ€™s compensation under the agreement to $12,000 per month. Effective January 1, 2019, Dr. Brinton resigned as a member of our board of directors. On February 13, 2019, we entered into a revised consulting agreement with Dr. Brinton. Under the revised agreement, Dr. Brinton continues to provide clinical study design input and other professional services to us, but only in relation to the use of our device to treat calcifications with shock waves in the peripheral or coronary arteries. Dr. Brintonâ€™s time commitment under the revised agreement is capped at twelve hours per month until February 2020, when his time commitment will be reduced to five hours per month. For his services to us under the revised agreement, Dr. Brinton will be paid a retainer of $6,000 per month until February 2020, when his retainer will be reduced to $2,500 per month (unless the agreement is terminated at an earlier date).

Director and Officer Indemnification

We have entered into an indemnification agreement with each of our directors and executive officers. These indemnification agreements and our amended and restated certificate of incorporation and amended and restated bylaws indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. For information regarding these indemnification arrangements, please refer to the section titled â€œManagementâ€”Limitations on Liability and Indemnification of Directors and Officers.â€

Equity Grants to Executive Officers and Directors

We have granted options to our named executive officers and certain of our non-employee directors as more fully described in the sections titled â€œDirector Compensationâ€ and â€œExecutive Compensation.â€

Policies and Procedures for Related Party Transactions

Our board of directors will adopt a written related party transaction policy, to be effective upon the completion of this offering, setting forth the policies and procedures for the review and approval or ratification of related-party transactions. This policy will cover any transaction, arrangement or relationship or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant and a related party had or will have a direct or indirect material interest, as determined by the audit committee of our board of directors, including, without limitation, purchases of goods or services by or from the related party or entities in which the related party has a material interest, and indebtedness, guarantees of indebtedness or employment by us of a related party.

All related party transactions described in this section occurred prior to adoption of this policy and as such, these transactions were not subject to the approval and review procedures set forth in the policy. However, these transactions were reviewed and approved by our board of directors.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our common stock as of December 31, 2018, by:

- â€¢ each person whom we know to own beneficially more than 5% of our common stock;
- â€¢ each of our directors and named executive officers individually; and
- â€¢ all of our directors and executive officers as a group.

In accordance with the rules of the SEC, beneficial ownership includes voting or investment power with respect to securities and includes the shares issuable pursuant to stock options that are exercisable within 60 days of December 31, 2018. Shares issuable pursuant to stock options are deemed outstanding for computing the percentage of the person holding such options but are not outstanding for computing the percentage of any other person. The number of shares of common stock outstanding after this offering includes 5,700,000 shares of common stock being offered for sale by us in this offering. The percentage ownership of our common stock in the â€œShares Beneficially Owned Before the Offeringâ€ column in the table is based on 20,495,066 shares of our common stock issued and outstanding as of December 31, 2018, assuming the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately prior to the completion of this offering. The percentage ownership of our common stock in the â€œShares Beneficially Owned After the Offeringâ€ column in the table is based on 26,906,762 shares of our common stock issued and outstanding as of December 31, 2018, assuming (i) the automatic conversion described above, (ii) the net exercise of our outstanding warrants to purchase 141,777 shares of our common stock into 123,461 shares of our common stock immediately prior to the completion of this offering, (iii) the issuance of 588,235 shares of our common stock in the Concurrent Private Placement and (iv) the issuance of 5,700,000 shares of our common stock in this offering and no exercise of the underwritersâ€™ option to purchase additional shares.

Unless otherwise indicated, the address for each listed stockholder is: c/o ShockWave Medical, Inc., 5403 Betsy Ross Drive, Santa Clara, California 95054. To our knowledge, except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock.

	Shares Beneficially Owned Before the Offering		Shares Beneficially Owned After the Offering	
Name and Address of Beneficial Owner	Number	Percent	Number	Percent
Greater than 5% Stockholders:				
Sofinnova Capital VII FCPR(1)	4,044,207	19.7%	4,044,207	15.0%
Entities affiliated with Venrock Funds(2)	2,122,021	10.4%	2,122,021	7.9%
Entities managed by Fidelity Management & Research Company or its affiliates(3)	2,028,929	9.9%	2,028,929	7.5%
Certain funds and accounts advised by T. Rowe Price Associates, Inc.(4)	1,193,176	5.8%	1,193,176	4.4%
Entities affiliated with Baran Holdings Inc.(5)	1,102,480	5.4%	1,102,480	4.1%
Abiomed, Inc.(6)	1,090,608	5.3%	1,678,843	6.2%
Entities affiliated with Sectoral Asset Management(7)	1,049,013	5.1%	1,049,013	3.9%
Directors and Named Executive Officers:				
Douglas Godshall(8)	518,349	2.5%	518,349	1.9%
Dan Puckett(9)	112,788	*	112,788	*
Isaac Zacharias(10)	36,885	*	36,885	*
F.T. â€œJayâ€ Watkins(11)	187,872	*	187,872	*
Antoine Papiernik(1)	4,044,207	19.7%	4,044,207	15.0%
Colin Cahill	â€”	*	â€”	*
Frederic Moll, M.D.(12)	400,510	1.9%	400,510	1.5%
Todd Brinton, M.D.(13)	476,288	2.3%	470,268	1.7%
Marc-Andre Marcotte(7)(14)	1,049,013	5.1%	1,049,013	3.9%
C. Raymond Larkin, Jr.(15)	â€”	*	â€”	*
Laura Francis(15)	â€”	*	â€”	*
Directors and Officers as a Group (11 persons)(16)	6,825,912	31.9%	6,819,892	24.5%

* Represents beneficial ownership of less than one percent (1%) of the outstanding common stock.

(1) Sofinnova Partners SAS, a French corporation and the management company of Sofinnova Capital VII FCPR, may be deemed to have sole voting and dispositive power over the shares held by Sofinnova Capital VII FCPR. The managing partners of Sofinnova Partners SAS, Denis Lucquin, Antoine Papiernik (a member of our board of directors) and Monique Saulnier, may be deemed to have shared voting and dispositive power with respect to such shares. The address of Sofinnova Capital VII FCPR is Sofinnova Partners, Immeuble le Centorial, 16-18 Rue du Quatre-Septembre, 75002 Paris, France.

(2) Consists of (a) 1,127,377 shares held by Venrock Associates VII, L.P. (â€œVA VIIâ€), (b) 641,244 shares held by Venrock Healthcare Capital Partners II, L.P. (â€œVHCP IIâ€), (c) 260,012 shares held by VHCP Co-Investment Holdings II, LLC (â€œCo-Invest IIâ€) and (d) 93,388 shares held by Venrock Partners VII, L.P. (â€œVP VIIâ€). VHCP Management II, LLC (â€œVHCP Management IIâ€) is the general partner of VHCP II and the manager of Co-Invest II and may be deemed to beneficially own the shares held by VHCP II and Co-Invest II (the â€œVHCP II Sharesâ€). Drs. Bong Koh and Nimish Shah are the managing members of VHCP Management II and may be deemed to beneficially own the VHCP II Shares. Drs. Koh and Shah and VHCP Management II expressly disclaim beneficial ownership over the VHCP II Shares except to the extent of their indirect pecuniary interests therein. Venrock Management VII, LLC is the general partner of VA VII and VP VII and may be deemed to beneficially own the shares held by VA VII and VP VII (the â€œVII Sharesâ€). Venrock Management VII, LLC expressly disclaims beneficial ownership over the VII Shares except to the extent of its indirect pecuniary interests therein. The address for VHCP II, Co-Invest II, and Drs. Koh and Shah is 7 Bryant Park, 23rd Floor, New York, NY 10018. The address for VA VII and VP VII is 3340 Hillview Avenue, Palo Alto, CA 94304.

(3) Consists of (a) 608,679 shares held by Fidelity Select Portfolios: Health Care Portfolio (â€œFidelity Healthâ€), (b) 608,679 shares held by Fidelity Select Portfolios: Medical Equipment and Systems Portfolio (â€œFidelity Medical Equipmentâ€), (c) 443,695 shares held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund (â€œFidelity Growthâ€), (d) 284,655 shares held by Fidelity Growth Company Commingled Pool (â€œFidelity Growth Commingled Poolâ€) and (e) 83,221 shares held by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund (â€œFidelity Series Growthâ€). Fidelity Health, Fidelity Medical Equipment, Fidelity Growth, Fidelity Growth Commingled Pool and Fidelity Series Growth are managed by Fidelity Management & Research Company (FMR Co.) or another direct or indirect subsidiary of FMR LLC. Abigail P. Johnson is a Director, the Chairman, the Chief Executive Officer and the President of

FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholdersâ€™ voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholdersâ€™ voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act (â€œFidelity Fundsâ€) advised by FMR Co., a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Fundsâ€™ Boards of Trustees. FMR Co. carries out the voting of the shares under written guidelines established by the Fidelity Fundsâ€™ Boards of Trustees. The address for FMR LLC is 200 Seaport Blvd. V12G, Boston, Massachusetts 02210.

(4) Consists of (a) 1,015,505 shares held by T. Rowe Price Health Sciences Fund, Inc., (b) 65,997 shares held by VALIC Company Iâ€”Health Sciences Fund, (c) 57,762 shares held by T. Rowe Price Health Sciences Portfolio and (d) 53,912 shares held by TD Mutual Fundsâ€”TD Health Sciences Fund. T. Rowe Price Associates, Inc. is the investment adviser or subadviser, as applicable, for each of T. Rowe Price Health Sciences Fund, Inc., VALIC Company Iâ€”Health Sciences Fund, T. Rowe Price Health Sciences Portfolio and TD Mutual Fundsâ€”TD Health Sciences Fund. T. Rowe Price Associates, Inc. (â€œTRPAâ€) serves as investment adviser or subadviser, as applicable, with power to direct investments and/or sole power to vote the securities owned by these funds and accounts (with the exception of VALIC Company Iâ€”Health Sciences Fund that retains voting authority). The T. Rowe Price Proxy Committee (the â€œProxy Committeeâ€) develops the firmâ€™s positions on all major proxy voting issues, creates guidelines and oversees the voting process. Once the Proxy Committee establishes its recommendations, they are distributed to the firmâ€™s portfolio managers as voting guidelines. Ultimately, the portfolio managers for each account decide how to vote on the proxy proposals of companies in their portfolios. More information on the T. Rowe Price proxy voting guidelines is available on its website at troweprice.com. The T. Rowe Price portfolio manager of the funds and accounts that hold the securities is Ziad Bakri. For purposes of reporting requirements of the Securities Exchange Act of 1934, TRPA may be deemed to be the beneficial owner of all the shares listed above; however, TRPA expressly disclaims that it is, in fact, the beneficial owner of such securities. T. Rowe Price Associates, Inc. is the wholly owned subsidiary of T. Rowe Price Group, Inc., which is a publicly traded financial services holding company. The address for T. Rowe Price Associates, Inc. is 100 East Pratt Street, Baltimore, Maryland 21202. T. Rowe Price Investment Services, Inc. (â€œTRPISâ€), a registered broker-dealer, is a subsidiary of T. Rowe Price Associates, Inc. TRPIS was formed primarily for the limited purpose of acting as the principal underwriter and distributor of shares of the funds in the T. Rowe Price fund family and complements the other services provided to shareholders of the T. Rowe Price funds. TRPIS does not engage in underwriting or market-making activities involving individual securities.

(5) Consists of (a) 536,321 shares held by Trudell Medical Limited and (b) 566,159 shares held by Barvest Inc. Baran Holdings Inc. wholly owns Trudell Medical Limited and Barvest Inc. The address of Baran Holdings Inc. is 725 Third Street London, Ontario N5V 5G4 Canada.

(6) The address of Abiomed, Inc. is 22 Cherry Hill Drive Danvers, MA 01923. The shares beneficially owned after this offering include shares to be purchased in the Concurrent Private Placement.

(7) Consists of (a) 427,794 shares held by New Emerging Medical Opportunities Fund II Limited Partnership, (b) 422,017 shares held by New Emerging Medical Opportunities Fund III Limited Partnership and (c) 199,202 shares held by Sectoral Asset Management Holding Ltd. Marc-Andre Marcotte (a member of our board of directors), is Partner & COO for Sectoral Asset Management, Inc., which manages these funds, and may be deemed to have voting and dispositive power over the shares held by these funds. The address of each of these funds is 1010 Sherbrooke St. West, Suite 1610, Montreal, Quebec H3A 2R7, Canada.

(8) Consists of 518,349 shares issuable pursuant to options that are exercisable within 60 days of December 31, 2018 (of which all would be vested).

(9) Consists of 112,788 shares issuable pursuant to options that are exercisable within 60 days of December 31, 2018 (of which all would be vested).

(10) Consists of 36,885 shares issuable pursuant to options that are exercisable within 60 days of December 31, 2018 (of which all would be vested).

(11) Consists of (a) 112,251 shares and (b) 75,621 shares issuable pursuant to options that are exercisable within 60 days of December 31, 2018 (of which all would be vested).

(12) Consists of (a) 290,880 shares and (b) 109,630 shares issuable pursuant to options that are exercisable within 60 days of December 31, 2018 (of which all would be vested).

(13) Consists of (a) 422,622 shares (of which 13,320 were issued pursuant to options that were early exercised and are subject to repurchase), (b) a warrant to purchase 41,115 shares of our common stock that is currently exercisable and which this table assumes will be net exercised into 35,095 shares of our common stock immediately prior to the completion of this offering and (c) 12,551 shares issuable pursuant to options that are exercisable within 60 days of December 31, 2018 (of which all would be vested). Dr. Brinton resigned as a director of the company, effective as of January 1, 2019.

(14) Mr. Marcotte will resign from our board of directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. As Mr. Marcotte is a partner at Sectoral Asset Management Inc., the firmâ€™s policy prohibits Mr. Marcotte from serving on the board of directors of a public company of the firmâ€™s portfolio companies.

(15) Mr. Larkin and Ms. Francis were appointed to our Board in January 2019.

(16) Consists of (a) 6,825,912 shares held by all current executive officers and directors as a group (of which 13,320 were issued pursuant to options that were early exercised and are subject to repurchase), which includes 41,115 shares issuable pursuant to warrants that are currently exercisable and which this table assumes will be net exercised into 35,095 shares of our common stock immediately prior to the completion of this offering, and 865,824 shares issuable pursuant to options that are exercisable within 60 days of December 31, 2018 (of which all would be vested).

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our amended and restated certificate of incorporation, amended and restated bylaws, the amended and restated investor rights agreement to which we and certain of our stockholders are parties and of the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and amended and restated investor rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is part.

General

Following this offering and after giving effect to the conversion into common stock and retirement of all outstanding shares of our convertible preferred stock, our authorized capital stock will consist 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. In February 2019, our board of directors approved the retirement, upon the conversion of all shares of outstanding convertible preferred stock into common stock in connection with the closing of this offering, of all such shares of convertible preferred stock such that they will be cancelled and will not be subject to future reissuance.

Based on 1,824,807 shares of common stock outstanding as of December 31, 2018, and after giving effect to the (i) automatic conversion of all of our outstanding convertible preferred stock into an aggregate of 18,670,259 shares of common stock, (ii) net exercise of warrants to purchase 141,777 shares of our common stock into 123,461 shares of our common stock upon the completion of this offering, (iii) the issuance of shares of common stock in the Concurrent Private Placement and (iv) the issuance of shares of common stock in this offering, there will be 26,906,762 shares of common stock outstanding upon the closing of this offering. As of December 31, 2018, we had 153 stockholders of record. As of December 31, 2018, there were 3,636,224 shares of common stock subject to outstanding options. As of December 31, 2018, there were 176,217 shares of common stock subject to outstanding warrants (of which 141,777 will net exercise as described above), with a weighted-average exercise price of $2.55 per share. As of December 31, 2018, we had outstanding warrants to purchase up to an aggregate of 54,903 shares of our Series A-1 preferred stock with an exercise price of $3.09636 per share.

Common Stock

Common stock outstanding. As of December 31, 2018 there were 1,824,807 shares of common stock outstanding which were held of record by 84 stockholders. There will be 26,906,762 shares of common stock outstanding, assuming no exercise of the underwritersâ€™ over-allotment option and no exercise of outstanding options, after giving effect to the sale of the shares of common stock offered hereby and in the Concurrent Private Placement. All outstanding shares of common stock are fully paid and non-assessable, and the shares of common stock to be issued upon completion of this offering will be 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. See the section titled â€œDividend Policy.â€

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

Effective immediately upon closing of this offering, there will be no shares of preferred stock outstanding because all our outstanding shares of preferred stock will have been automatically converted into an aggregate of 18,670,259 shares of common stock at such time. Immediately upon the completion of this offering, our amended and restated certificate of incorporation will be restated to reflect the conversion and retirement of such shares of preferred stock. Upon the consummation of this offering and after giving effect to the conversion and retirement of all outstanding shares of preferred stock, 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 Warrants

As of December 31, 2018, we had common stock warrants exercisable for an aggregate of 176,217 shares of our common stock, with a weighted-average exercise price of $2.55 per share. Of these, warrants to purchase 141,777 shares of our common stock, with an exercise price of $2.196 per share, expire in May 2025, but would also expire earlier upon (i) certain transactions involving the merger of our company with or into another organization or the sale or disposition of all or substantially all of our assets and (ii) the closing of a firm commitment underwritten initial public offering pursuant to an effective registration statement filed under the Securities Act covering the offering and sale of the companyâ€™s common stock. The remaining warrants to purchase 34,440 shares of our common stock, with an exercise price of $4.026 per share, expire in February 2028, but would also expire earlier upon certain transactions involving the merger of our company with or into another organization or the sale or disposition of all or substantially all of our assets. The warrants contain provisions for adjustment of the exercise price and number of shares issuable upon the exercise of the warrants in the event of reclassification of shares, certain stock dividends, subdivisions and stock splits or combinations. The warrants have a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our stock at the time of exercise of the warrant after deduction of the aggregate exercise price.

Preferred Stock Warrants

As of December 31, 2018, we had outstanding a convertible preferred stock warrant to purchase up to an aggregate of 54,903 shares of our Series A-1 preferred stock, with an exercise price of $3.09636 per share. Upon the closing of this offering, the warrants will automatically convert into warrants to purchase 54,903 shares of our common stock with an exercise price of $3.09636 per share, and, unless exercised earlier, will expire in June 2024.

The warrants contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the applicable warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations.

Common Stock Options

As of December 31, 2018, we had outstanding options to purchase an aggregate of 3,636,224 shares of our common stock, with a weighted-average exercise price of $3.50 per share, under our 2009 Plan. After

December 31, 2018, we issued options to purchase an aggregate of 119,667 shares of our common stock, with an exercise price of $6.59 per share, under our 2009 Plan.

Registration Rights

After the closing of this offering, certain holders of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act pursuant to the IRA as described in additional detail below. 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. In connection with this offering, each stockholder that has registration rights agreed not to sell or otherwise dispose of any securities without the prior written consent of the underwriters for a period of 180 days after the date of this prospectus, subject to certain terms and conditions. For more information regarding such restrictions, see the section captioned â€œUnderwriting.â€

Demand Registration Rights

Beginning the earlier of either 180 days following the completion of this offering or the third anniversary of the date of the initial sale of shares of our Series D convertible preferred stock, the holders of approximately 19,258,494 shares of our common stock will be 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

After the closing of this offering, 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 19,258,494 shares of our common stock will be entitled to certain â€œpiggybackâ€ 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

After the closing of this offering, 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 registrable securities 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

The IRA 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 after the completion of this offering 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 this 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.

Northgate Right of Participation

As part of the Exclusive License Agreement, Northgate has the right to participate in future financings by the company in a proportion equal to its percentage ownership of the company as of immediately prior to each such financing on a fully diluted basis, subject to various exclusions, including exclusions for the issuance of shares of common stock to employees and consultants or in a firmly underwritten public offering (including this offering) and for specified strategic transaction purposes. Northgate waived its right to participate in the Concurrent Private Placement.

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

Election and Removal of Directors

Immediately upon the completion of this offering, our board of directors will consist of seven 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

Upon the closing of this offering, our board of directors will be will be 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 amended and 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 amended and 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 amended and restated certificate of incorporation and bylaws will specifically deny any power of any other person to call a special meeting.

Amendment of Certificate of Incorporation

The provisions of our amended and restated certificate of incorporation described under â€œElection and Removal of Directors,â€ â€œStockholder Meetingsâ€ and â€œLimits on Written Consentsâ€ 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 will generally be required to amend other provisions of our amended and 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:

- â€¢ 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
- â€¢ 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 will also impose some procedural requirements on stockholders who wish to:

- â€¢ make nominations in the election of directors;
- â€¢ propose that a director be removed;
- â€¢ propose any repeal or change in our bylaws; or
- â€¢ 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:

- â€¢ a description of the business or nomination to be brought before the meeting and the reasons for conducting such business at the meeting;
- â€¢ the stockholderâ€™s name and address;
- â€¢ any material interest of the stockholder in the proposal;
- â€¢ the number of shares beneficially owned by the stockholder and evidence of such ownership; and

- â€¢ 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:

- â€¢ 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
- â€¢ 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 daysâ€™ 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 stockholderâ€™s proposal or nominee will be ineligible and will not be voted on by our stockholders.

Limitation of Liability of Directors and Officers

Our amended and restated certificate of incorporation to be in effect upon the completion of this offering will provide that we may indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. For information regarding the limitation of liability of our directors and officers, please refer to the section titled â€œManagementâ€”Limitations on Liability and Indemnification of Directors and Officers.â€

Forum Selection

The Court of Chancery of the State of Delaware will be 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 companyâ€™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 Exchange Act. In addition, our amended and restated bylaws will also provide 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 will elect to be subject to Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. Section 203 prevents an â€œinterested stockholder,â€ which is defined generally as a person owning 15% or more of a corporationâ€™s voting stock, or any affiliate or associate of that person, from engaging in

a broad range of â€œbusiness combinationsâ€ with the corporation for three years after becoming an interested stockholder unless:

- â€¢ the board of directors of the corporation had previously approved either the business combination or the transaction that resulted in the stockholderâ€™s becoming an interested stockholder;
- â€¢ upon completion of the transaction that resulted in the stockholderâ€™s becoming an interested stockholder, that person owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, other than statutorily excluded shares; or
- â€¢ 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 corporationâ€™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 amended and restated certificate of incorporation and bylaws could make the following more difficult:

- â€¢ acquisition of control of us by means of a proxy contest or otherwise, or
- â€¢ 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

We have been approved to list our common stock on the Nasdaq Global Select Market under the symbol â€œSWAV.â€

Transfer Agent and Registrar

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

MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES FOR NON-U.S. HOLDERS OF COMMON STOCK

The following are the material U.S. federal income and estate tax consequences of the ownership and disposition of our common stock acquired in this offering by a â€œNon-U.S. Holderâ€ that does not own, and has not owned, actually or constructively, more than 5% of our common stock. You are a Non-U.S. Holder if for U.S. federal income tax purposes you are a beneficial owner of our common stock that is:

- a nonresident alien individual;
- a foreign corporation; or
- a foreign estate or trust.

You are not a Non-U.S. Holder if you are a nonresident alien individual present in the United States for 183 days or more in the taxable year of disposition, or if you are a former citizen or former resident of the United States for U.S. federal income tax purposes. If you are such a person, you should consult your tax adviser regarding the U.S. federal income tax consequences of the ownership and disposition of our common stock.

If you are a partnership for U.S. federal income tax purposes, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and your activities.

This discussion is based on the Internal Revenue Code of 1986, as amended to the date hereof (the â€œCodeâ€), administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations, changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein, possibly with retroactive effect. This discussion does not describe all of the tax consequences that may be relevant to you in light of your particular circumstances, including alternative minimum tax and Medicare contribution tax consequences and does not address any aspect of state, local or non-U.S. taxation, or any taxes other than income and estate taxes. You should consult your tax adviser with regard to the application of the U.S. federal tax laws to your particular situation, as well as any tax consequences arising under the laws of any state, local or non-U.S. taxing jurisdiction.

Dividends

As discussed under â€œDividend Policyâ€ above, we do not currently expect to make distributions on our common stock. In the event that we do make distributions of cash or other property, those distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed our current and accumulated earnings and profits, they will constitute a return of capital, which will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of our common stock, as described below under â€œâ€”Gain on Disposition of Our Common Stock.â€

Dividends paid to you generally will be subject to withholding tax at a 30% rate or a reduced rate specified by an applicable income tax treaty. In order to obtain a reduced rate of withholding (subject to the discussion below under â€œâ€”FATCAâ€), you will be required to provide a properly executed applicable Internal Revenue Service (â€œIRSâ€) Form W-8 certifying your entitlement to benefits under a treaty.

If dividends paid to you are effectively connected with your conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base maintained by you in the United States), you will generally be taxed on the dividends in the same manner as a U.S. person. In this case, you will be exempt from the withholding tax discussed in the preceding paragraph, although you will be required to provide a properly executed IRS Form W-8ECI in order to claim an exemption from withholding. You should consult your tax adviser with respect to other U.S. tax consequences of the ownership and disposition of our common stock, including the possible imposition of a branch profits tax at a rate of 30% (or a lower treaty rate) if you are a corporation.

Gain on Disposition of Our Common Stock

Subject to the discussions below under â€œâ€”Information Reporting and Backup Withholdingâ€ and â€œâ€”FATCA,â€ you generally will not be subject to U.S. federal income or withholding tax on gain realized on a sale or other taxable disposition of our common stock unless:

- â€¢ the gain is effectively connected with your conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by you in the United States), or
- â€¢ we are or have been a â€œUnited States real property holding corporation,â€ as defined in the Code, at any time within the five-year period preceding the disposition or your holding period, whichever period is shorter, and our common stock has ceased to be regularly traded on an established securities market prior to the beginning of the calendar year in which the sale or disposition occurs.

We believe that we are not, and do not anticipate becoming, a United States real property holding corporation.

If you recognize gain on a sale or other disposition of our common stock that is effectively connected with your conduct of a trade or business in the United States (and if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by you in the United States), you will generally be taxed on such gain in the same manner as a U.S. person. You should consult your tax adviser with respect to other U.S. tax consequences of the ownership and disposition of our common stock, including the possible imposition of a branch profits tax at a rate of 30% (or a lower treaty rate) if you are a corporation.

Information Reporting and Backup Withholding

Information returns are required to be filed with the IRS in connection with payments of dividends on our common stock. Unless you comply with certification procedures to establish that you are not a U.S. person, information returns may also be filed with the IRS in connection with the proceeds from a sale or other disposition of our common stock. You may be subject to backup withholding on payments on our common stock or on the proceeds from a sale or other disposition of our common stock unless you comply with certification procedures to establish that you are not a U.S. person or otherwise establish an exemption. Your provision of a properly executed applicable IRS Form W-8 certifying your non-U.S. status will permit you to avoid backup withholding. Amounts withheld under the backup withholding rules are not additional taxes and may be refunded or credited against your U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

FATCA

Provisions of the Code commonly referred to as â€œFATCAâ€ require withholding of 30% on payments of dividends on our common stock, as well as, subject to the discussion of certain proposed U.S. Treasury regulations below, of gross proceeds of dispositions occurring after December 31, 2018 of our common stock, to â€œforeign financial institutionsâ€ (which is broadly defined for this purpose and in general includes investment vehicles) and certain other non-U.S. entities unless various U.S. information reporting and due diligence requirements (generally relating to ownership by U.S. persons of interests in or accounts with those entities) have been satisfied, or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. If FATCA withholding is imposed, a beneficial owner that is not a foreign financial institution generally may obtain a refund of any amounts withheld by filing a U.S. federal income tax return (which may entail significant administrative burden). The U.S. Treasury recently released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock. In its preamble to such proposed regulations, the U.S. Treasury stated that taxpayers may generally rely on the proposed regulations

until final regulations are issued. You should consult your tax adviser regarding the effects of FATCA on your investment in our common stock, and the possible impact of these rules on the entities through which you hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of this 30% withholding tax.

Federal Estate Tax

Individual Non-U.S. Holders and entities the property of which is potentially includible in such an individualâ€™s gross estate for U.S. federal estate tax purposes (for example, a trust funded by such an individual and with respect to which the individual has retained certain interests or powers), should note that, absent an applicable treaty exemption, our common stock will be treated as U.S.-situs property subject to U.S. federal estate tax.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our common stock. Future sales of substantial amounts of our common stock in the public market could adversely affect market prices prevailing from time to time. Furthermore, because only a limited number of shares will be available for sale shortly after this offering due to existing contractual and legal restrictions on resale as described below, there may be sales of substantial amounts of our common stock in the public market after the restrictions lapse. This may adversely affect the prevailing market price and our ability to raise equity capital in the future.

Upon completion of this offering, we will have 26,906,762 shares of common stock outstanding assuming the conversion of all outstanding shares of preferred stock and no exercise of any options and warrants outstanding as of December 31, 2018 (other than the assumed net exercise of certain of our common stock warrants into shares of our common stock that would otherwise expire upon completion of this offering), or 27,761,762 shares assuming the exercise of the underwritersâ€™ over-allotment option. Of these shares, 5,700,000 shares, or 6,555,000 shares if the underwriters exercise their option in full, sold in this offering will be freely transferable without restriction or registration under the Securities Act, except for any shares purchased by one of our existing â€œaffiliates,â€ as that term is defined in Rule 144 under the Securities Act. The remaining 21,206,762 shares of common stock existing are â€œrestricted sharesâ€ as defined in Rule 144. Restricted shares may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 of the Securities Act. As a result of the contractual 180-day lock-up period described below and the provisions of Rules 144 and 701, these shares will be available for sale in the public market as follows:

Number of Shares	Date
0	On the date of this prospectus.
21,206,762	At various times after 180 days from the date of this prospectus (subject, in some cases, to volume limitations).

Rule 144

In general, a person who has beneficially owned restricted shares of our common stock for at least six months would be entitled to sell such securities, provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares of our common stock for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three month period only a number of securities that does not exceed the greater of either of the following:

- â€¢ 1% of the number of shares of our common stock then outstanding, which will equal approximately 269,068 shares immediately after this offering, assuming no exercise of the underwritersâ€™ over-allotment option; or
- â€¢ the average weekly trading volume of our common stock on the Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144 to the extent applicable.

Rule 701

In general, under Rule 701, any of our employees, directors, officers, consultants or advisors who purchases shares from us in connection with a compensatory stock or option plan or other written agreement before the

effective date of this offering is entitled to resell such shares 90 days after the effective date of this offering in reliance on Rule 144, without having to comply with the holding period requirements or other restrictions contained in Rule 701.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after the date of this prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual restrictions described above, beginning 90 days after the date of this prospectus, may be sold by persons other than â€œaffiliates,â€ as defined in Rule 144, subject only to the manner of sale provisions of Rule 144 and by â€œaffiliatesâ€ under Rule 144 without compliance with its one-year minimum holding period requirement.

Registration Rights

Upon completion of this offering, the holders of 19,258,494 shares of common stock will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates.

Warrants

As of December 31, 2018, warrants to purchase an aggregate of 176,217 shares of our common stock with a weighted-average exercise price of $2.55 per share were outstanding. See the section of this prospectus titled â€œDescription of Capital Stockâ€”Warrantsâ€ for additional information. Such shares issued upon exercise of the warrants may be able to be sold after the expiration of the lock-up period described above subject to the requirements of Rule 144 described above.

Stock Options

As of December 31, 2018, options to purchase a total of 3,636,224 shares of common stock were outstanding. All of the shares subject to options are subject to lock-up agreements. All of the shares subject to options are subject to lock-up agreements. An additional 392,299 shares of common stock were available for future grants under our stock plans. As of the effective date of the registration statement of which this prospectus forms a part, these shares will cease to be available for issue. Shares have been reserved under our 2019 Plan for stock options and other equity awards granted after this date.

Upon completion of this offering, we intend to file a registration statement under the Securities Act covering all shares of common stock subject to outstanding options or issuable pursuant to our 2019 Plan. Subject to Rule 144 volume limitations applicable to affiliates, shares registered under any registration statements will be available for sale in the open market, beginning 90 days after the date of the prospectus, except to the extent that the shares are subject to vesting restrictions with us or the contractual restrictions described below.

Lock-up Agreements

All of our directors, executive officers and substantially all of the other holders of our equity securities have agreed, subject to certain exceptions, not to offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock for a period of 180 days after the date of this prospectus, without the prior written consent of the representatives of the underwriters. See the section titled â€œUnderwritingâ€ for more information.

UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

Name	Number of Shares
Morgan Stanley & Co. LLC	2,280,000
Merrill Lynch, Pierce, Fenner & Smith Incorporated	2,280,000
Wells Fargo Securities, LLC	570,000
Canaccord Genuity LLC	570,000
Total:	5,700,000

The underwriters and the representatives are collectively referred to as the â€œunderwritersâ€ and the â€œrepresentatives,â€ respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwritersâ€™ over-allotment option described below. The offering of the shares of common stock by the underwriters is subject to receipt and acceptance and subject to the underwritersâ€™ right to reject any order in whole or in part.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 855,000 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriterâ€™s name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

At our request, the underwriters have reserved for sale, at the initial public offering price, up to approximately 3% of the shares offered hereby for our directors, officers and certain employees and other persons with whom we have a relationship who have expressed an interest in purchasing common stock in the offering. The number of shares available for sale to the general public in the offering will be reduced to the extent these persons purchase the reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares. Shares offered in the directed share program will not be subject to lock-up agreements, with the exception of the shares to be issued to directors, officers and certain existing stockholders who are already subject to lock-up agreements, as described below.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwritersâ€™ over-allotment option.

		Total	
	Per Share	No Exercise	Full Exercise
Public offering price	$ 17.00	$96,900,000	$111,435,000
Underwriting discounts and commissions to be paid by us	$ 1.19	$ 6,783,000	$ 7,800,450
Proceeds, before expenses, to us	$ 15.81	$90,117,000	$103,634,550

Perella Weinberg Partners LP (â€œPerella Weinbergâ€), a Financial Industry Regulatory Association, Inc. (â€œFINRAâ€) member, is acting as our financial advisor in connection with the offering. We expect to pay Perella Weinberg, upon the successful completion of this offering, a fee of up to $735,000 for its services. The services provided to us by Perella Weinberg include, among other things, an independent financial valuation analysis; assisting in drafting our positioning and investment thesis; assisting us in our interactions with the underwriters; and assisting us in crafting an appropriate aftermarket trading and investor relations strategy. Apart from Perella Weinbergâ€™s role as financial advisor in connection with this offering, Perella Weinberg has had no other relationships with the company. Perella Weinberg will not sell or offer to sell any securities in this offering and will not identify, solicit or engage directly with potential investors in this offering. In addition, Perella Weinberg will not purchase any of the offered shares of common stock.

The estimated offering expenses payable by us, including the fees of Perella Weinberg but exclusive of the underwriting discounts and commissions, are approximately $3.9 million. We have also agreed to reimburse the underwriters for expense relating to clearance of this offering with FINRA up to $40,000. The underwriters have agreed to reimburse us for certain expenses we incur in connection with this offering up to $735,000.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

We have been approved to list our common stock on the Nasdaq Global Select Market under the symbol â€œSWAV.â€

We and all of our directors and officers and the holders of all of our outstanding securities have agreed that, without the prior written consent of Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated on behalf of the underwriters, we and they will not, during the period ending 180 days after the date of this prospectus (the â€œrestricted periodâ€):

- â€¢ offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;
- â€¢ file any registration statement with the SEC relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- â€¢ enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock;

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person have agreed that, without the prior written consent of Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph do not apply to our directors, officers and securityholders with respect to, among other things:

(a) transactions relating to shares of common stock or other securities acquired in open market transactions after the completion of this offering, provided that no filing under Section 16(a) of the Exchange Act or other public announcement shall be required or shall be voluntarily made in connection with subsequent sales of common stock or other securities acquired in such open market transactions during the restricted period;

(b) transfers of securities to us in connection with the conversion of our outstanding preferred stock or warrants into shares of common stock or warrants to acquire shares of common stock in connection with the consummation of this offering, which conversion is described in this prospectus, it being understood that any such shares of common stock or warrants received by the securityholder upon such conversion shall be subject to the restrictions on transfer set forth in the lock-up agreement;

(c) transfers of shares of common stock or any security convertible into common stock (i) as a bona fide gift, (ii) to an immediate family member or a trust for the direct or indirect benefit of the securityholder or such immediate family member of the securityholder, (iii) if the securityholder is a trust, to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust, (iv) if the secuirtyholder is a corporation, partnership, limited liability company, investment fund or other entity, distributions of shares of common stock or any security convertible into shares of common stock to stockholders, limited partners, members or affiliates or to any other entity that is controlled or managed by, or under common control or management with, the securityholder or (v) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the securityholder; provided that in the case of any transfer or distribution pursuant to this clause, (i) each donee or distributee shall sign and deliver a lock-up agreement, (ii) no filing under Section 16(a) of the Exchange Act or other public announcement, reporting a reduction in beneficial ownership of shares of common stock, shall be required or shall be voluntarily made during the restricted period and (iii) such transfer shall not involve a disposition for value;

(d) transfers of shares of common stock or any securities convertible into or exercisable or exchangeable for common stock that occur by operation of law pursuant to a qualified domestic order or in connection with a divorce settlement, provided that (i) each transferee shall sign and deliver a lock-up agreement, (ii) any public report or filing required to be made under Section 16(a) of the Exchange Act shall clearly indicate in the footnotes thereto that such transfer is pursuant to a qualified domestic order or in connection with a divorce settlement and (iii) such transfer shall not involve a disposition for value, and provided, further that no other public announcement shall be required or shall be made voluntarily in connection with such transfer;

(e) transfers of shares of common stock or any securities convertible into or exercisable or exchangeable for common stock to us pursuant to agreements entered into pursuant to a stock incentive plan disclosed in this prospectus and in effect on the date of this prospectus under which we have the option to repurchase such shares or securities upon termination of service of the securityholder, provided that no public report or filing required to be made under Section 16(a) of the Exchange Act or other public filing, report or announcement shall be required or shall be voluntarily made during the period beginning on the date hereof and continuing to and including the date that is 30 days after the date of this prospectus (the â€œ30 Day Periodâ€), and after such 30th day, if the securityholder is required to file a report under Section 16(a) of the Exchange Act during the restricted period, the securityholder shall clearly indicate in the footnotes thereto that such transfer is pursuant to the circumstances described in this clause, and provided, further that no other public announcement shall be made voluntarily in connection with such transfer;

(f) the exercise of outstanding warrants by the securityholder described in this prospectus or any stock option by the securityholder that was granted under a stock incentive plan or stock purchase plan described in this prospectus, provided that the shares received upon exercise shall continue to be

subject to the restrictions on transfer set forth in the lock-up agreement and provided, further that no public report or filing required to be made under Section 16(a) of the Exchange Act or other public filing, report or announcement shall be required or shall be voluntarily made during the 30 Day Period, and after the 30 Day Period, if the securityholder is required to file a report under Section 16(a) of the Exchange Act during the restricted period, the securityholder shall clearly indicate in the footnotes thereto that the filing relates to the exercise of a stock option or warrant, that no shares were sold by the reporting person and that the shares received upon exercise of the stock option or warrant are subject to a lock-up agreement, and provided, further that no other public announcement shall be made voluntarily in connection with such exercise;

(g) the transfer of shares of common stock or any security convertible into common stock to us upon the exercise of options or warrants to purchase our securities outstanding or pursuant to a stock incentive plan or stock purchase plan described in this prospectus, on a â€œcashlessâ€ or â€œnet exerciseâ€ basis, provided that the shares received upon exercise shall continue to be subject to the restrictions on transfer set forth in the lock-up agreement and provided, further that no public report or filing required to be made under Section 16(a) of the Exchange Act or other public filing, report or announcement shall be required or shall be voluntarily made during the period beginning on the date of the lock-up agreement and continuing to and including the 30 Day Period, and after the 30 Day Period, if the securityholder is required to file a report under Section 16(a) of the Exchange Act during the restricted period, the securityholder shall clearly indicate in the footnotes thereto that the filing relates to the â€œcashlessâ€ or â€œnetâ€ exercise of a stock option or warrant, that no shares were sold by the reporting person and that the shares received upon exercise of the stock option or warrant are subject to a lock-up agreement, and provided, further that no other public announcement shall be made voluntarily in connection with such transfer;

(h) the transfer of shares of common stock or any security convertible into common stock to us, or the withholding of shares of common stock by us, in connection with a vesting event of our securities granted pursuant to a stock incentive plan or stock purchase plan described in this prospectus, to cover tax withholding obligations or the payment of taxes due in connection with the vesting event, provided that no public report or filing required to be made under Section 16(a) of the Exchange Act or other public filing, report or announcement shall be required or shall be voluntarily made during the period beginning on the date of the lock-up agreement and continuing to and including the 30 Day Period, and after the 30 Day Period, if the securityholder is required to file a report under Section 16(a) of the Exchange Act during the restricted period, the securityholder shall clearly indicate in the footnotes thereto that the purpose of such transfer is to cover such tax withholding obligations or the payment of taxes due in connection with the vesting event, and provided, further that no other public announcement shall be made voluntarily in connection with such transfer;

(i) a merger, consolidation or other similar transaction involving a change of control of our company after the closing of this offering and approved by our board of directors, provided that in the event that such change of control is not completed, the securityholderâ€™s shares shall remain subject to the restrictions contained in the lock-up agreement and title to the securityholderâ€™s shares shall remain with the securityholder; and

(j) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the securityholder or us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Common Stock may be made under such plan during the restricted period.

In our case, such restrictions shall not apply to:

(a) the shares of our common stock to be sold in this offering;

(b) any shares of our common stock issued upon the exercise of options or warrants or the conversion of a security outstanding on the date of the underwriting agreement of which Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated have been advised in writing;

(c) the grant of options or the issuance of shares of common stock by us to our employees, officers, directors, advisors or consultants pursuant to employee benefit plans in effect on the date of the underwriting agreement and as described herein;

(d) the filing by us of a registration statement with the SEC on Form S-8 in respect of any shares issued under or the grant of any award pursuant to an employee benefit plan described herein;

(e) shares of common stock to be sold in the Concurrent Private Placement; or

(f) the sale or issuance of or entry into an agreement to sell or issue shares of our common stock or securities convertible into or exercisable or exchangeable for our common stock in connection with any (1) mergers, (2) acquisition of securities, businesses, property or other assets, (3) joint ventures, (4) strategic alliances, (5) partnerships with experts or other talent to develop or provide content, (6) equipment leasing arrangements or (7) debt financing, provided that the aggregate number of shares of our common stock or securities convertible into or exercisable for common stock (on an as-converted or as-exercised basis, as the case may be) that we may sell or issue or agree to sell or issue as described in this bullet point shall not exceed 5% of the total number of shares of our common stock issued and outstanding immediately following the completion of this offering, and provided, further, that each recipient of shares of our common stock or securities convertible into or exercisable for our common stock pursuant to this bullet point shall execute and deliver to Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated a lock-up agreement.

Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging. financing and brokerage activities. Certain of the underwriters and their respective affiliates may in the future perform, various financial advisory and investment banking services for us, for which they will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Pricing of the Offering

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

Selling Restrictions

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a â€œRelevant Member Stateâ€) an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an â€œoffer to the publicâ€ in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression â€œProspectus Directiveâ€ means Directive 2003/71/EC (as amended), including by Directive 2010/73/EU, and includes any relevant implementing measure in the Relevant Member State.

This European Economic Area selling restriction is in addition to any other selling restrictions set out below.

United Kingdom

Each underwriter has represented and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 or the â€œFSMAâ€ received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus supplement or the accompanying prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaserâ€™s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaserâ€™s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Russia

Under Russian law, shares of common stock may be considered securities of a foreign issuer. Neither we, nor this prospectus, nor shares of our common stock have been, or are intended to be, registered with the Central Bank of the Russian Federation under the Federal Law No. 39-FZ â€œOn Securities Marketâ€ dated April 22, 1996 (as amended, the â€œRussian Securities Lawâ€), and none of the shares of our common stock are intended to be, or may be offered, sold or delivered, directly or indirectly, or offered or sold to any person for reoffering or re-sale, directly or indirectly, in the territory of the Russian Federation or to any resident of the Russian Federation, except pursuant to the applicable laws and regulations of the Russian Federation.

The information provided in this prospectus does not constitute any representation with respect to the eligibility of any recipients of this prospectus to acquire shares of our common stock under the laws of the Russian Federation, including, without limitation, the Russian Securities Law and other applicable legislation.

This prospectus is not to be distributed or reproduced (in whole or in part) in the Russian Federation by the recipients of this prospectus. Recipients of this prospectus undertake not to offer, sell or deliver, directly or indirectly, or offer or sell to any person for reoffering or re-sale, directly or indirectly, shares of our common stock in the territory of the Russian Federation or to any resident of the Russian Federation, except pursuant to the applicable laws and regulations of the Russian Federation.

Recipients of this prospectus understand that respective receipt/acquisition of shares of our common stock is subject to restrictions and regulations applicable from the Russian law perspective.

Switzerland

The shares of common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland. Neither this document nor any other offering or marketing material relating to the offering, us, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or the Exempt Investors, who are â€œsophisticated investorsâ€ (within the meaning of section 708(8) of the Corporations Act), â€œprofessional investorsâ€ (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take into account the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities

recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate for their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

New Zealand

The shares of common stock offered hereby have not been offered or sold, and will not be offered or sold, directly or indirectly in New Zealand and no offering materials or advertisements have been or will be distributed in relation to any offer of shares in New Zealand, in each case other than:

(a) to persons whose principal business is the investment of money or who, in the course of and for the purposes of their business, habitually invest money; or

(b) to persons who in all the circumstances can properly be regarded as having been selected otherwise than as members of the public; or

(c) to persons who are each required to pay a minimum subscription price of at least NZ$500,000 for the shares before the allotment of those shares (disregarding any amounts payable, or paid, out of money lent by the issuer or any associated person of the issuer); or

(d) in other circumstances where there is no contravention of the Securities Act 1978 of New Zealand (or any statutory modification or re-enactment of, or statutory substitution for, the Securities Act 1978 of New Zealand).

Hong Kong

The shares of common stock have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (i) to â€œprofessional investorsâ€ as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (ii) in other circumstances which do not result in the document being a â€œprospectusâ€ as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares of common stock has been or may be issued or has been or may be in the possession of any person for the purposes of issuance, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares of common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to â€œprofessional investorsâ€ as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Japan

No registration pursuant to Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended), or the FIEL, has been made or will be made with respect to the solicitation of the application for the acquisition of the shares of common stock.

Accordingly, the shares of common stock have not been, directly or indirectly, offered or sold and will not be, directly or indirectly, offered or sold in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan) or to others for re-offering or re-sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan except pursuant to an exemption from the registration requirements, and otherwise in compliance with, the FIEL and the other applicable laws and regulations of Japan.

For Qualified Institutional Investors, or QII

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a â€œQII only private placementâ€

or a â€œQII only secondary distributionâ€ (each as described in Paragraph 1, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred to QIIs.

For Non-QII Investors

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a â€œsmall number private placementâ€ or a â€œsmall number private secondary distributionâ€ (each as is described in Paragraph 4, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred en bloc without subdivision to a single investor.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares of common stock were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares of common stock, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the â€œSFAâ€)) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(a) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiariesâ€™ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of common stock pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law; or

(d) as specified in Section 276(7) of the SFA.

In connection with Section 309B of the SFA and the Capital Markets Products (the â€œCMPâ€) Regulations 2018, the shares of common stock are prescribed capital markets products (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in Monetary Authority of Singapore Notice SFA 04-N12: Notice on the Sale of Investment Products and Monetary Authority of Singapore Notice FAA-N16: Notice on Recommendations on Investment Products).

LEGAL MATTERS

The validity of the issuance of the shares of common stock offered hereby will be passed upon for us by Davis Polk & Wardwell LLP, Menlo Park, California. Cooley LLP, San Diego, California, is representing the underwriters.

EXPERTS

The consolidated financial statements of ShockWave Medical, Inc. (the â€œCompanyâ€) as of December 31, 2017 and 2018, and for the years then ended, included in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Companyâ€™s ability to continue as a going concern as described in Note 1 to the consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the common stock offered hereby. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. For further information with respect to the company and its common stock, reference is made to the registration statement and the exhibits and any schedules filed therewith. Statements contained in this prospectus as to the contents of any contract or other document referred to are not necessarily complete and in each instance, if such contract or document is filed as an exhibit, reference is made to the copy of such contract or other document filed as an exhibit to the registration statement, each statement being qualified in all respects by such reference. A copy of the registration statement, including the exhibits and schedules thereto, may be read and copied at the SECâ€™s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site at www.sec.gov, from which interested persons can electronically access the registration statement, including the exhibits and any schedules thereto.

As a result of the offering, we will be required to file periodic reports and other information with the SEC. We also maintain an Internet site at www.Shockwavemedical.com. Our website and the information contained therein or accessible therefrom shall not be deemed to be incorporated into this prospectus or the registration statement of which it forms a part.

SHOCKWAVE MEDICAL, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2017 and 2018

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 â€œCompanyâ€) as of December 31, 2017 and 2018, the related consolidated statements of operations and comprehensive loss, stockholdersâ€™ deficit and cash flows for the years then ended, and the related notes (collectively referred to as the â€œconsolidated financial statementsâ€). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

The Companyâ€™s Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred significant losses and has negative cash flows from operations, and has stated that substantial doubt exists about the Companyâ€™s ability to continue as a going concern. Managementâ€™s evaluation of the events and conditions and managementâ€™s plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Companyâ€™s management. Our responsibility is to express an opinion on the Companyâ€™s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (â€œPCAOBâ€) 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 audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Companyâ€™s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Companyâ€™s auditor since 2016.

San Jose, California
February 8, 2019,
except for Note 14, as to which the date is
February 22, 2019

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

	December 31,		Pro Forma December 31, 2018
	2017	2018	(unaudited)
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	$ 51,923	$ 39,643	
Short-term investments	1,806	â€”	
Accounts receivable, net	639	2,850	
Inventory	2,523	5,131	
Prepaid expenses and other current assets	968	1,112	
Total current assets	57,859	48,736	
Property and equipment, net	1,372	2,619	
Other assets	73	2,066	
TOTAL ASSETS	$ 59,304	$ 53,421	
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERSâ€™ EQUITY (DEFICIT)			
CURRENT LIABILITIES:			
Accounts payable	$ 1,148	$ 1,487	
Term notes, current portion	â€”	1,667	
Accrued liabilities	3,393	6,217	
Total current liabilities	4,541	9,371	
Term notes, noncurrent portion	â€”	13,383	
Convertible preferred stock warrant liability	577	313	$ â€”
Other liabilities	9	136	
TOTAL LIABILITIES	5,127	23,203	
Commitments and contingencies (Note 6)			
Convertible preferred stock, $0.001 par value; 216,079,811 and 229,098,987 shares authorized as of December 31, 2017 and 2018; 17,510,045 and 18,670,328 shares issued and outstanding as of December 31, 2017 and 2018, actual; aggregate liquidation preference of $152.5 million as of December 31, 2018; no shares issued and outstanding, as of December 31, 2018, pro forma (unaudited)	137,469	152,806	â€”
STOCKHOLDERSâ€™ EQUITY (DEFICIT):			
Common stock, $0.001 par value; 325,000,000 shares authorized as of December 31, 2017 and 2018; 1,627,032 and 1,824,852 shares as of December 31, 2017 and 2018 issued and outstanding; 20,618,527 shares issued and outstanding as of December 31, 2018, pro forma (unaudited)	2	2	21
Additional paid-in capital	2,470	4,275	157,375
Accumulated other comprehensive loss	(1)	â€”	â€”
Accumulated deficit	(85,763)	(126,865)	(126,865)
TOTAL STOCKHOLDERSâ€™ EQUITY (DEFICIT)	(83,292)	(122,588)	$ 30,531
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERSâ€™ EQUITY (DEFICIT)	$ 59,304	$ 53,421	

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,	
	2017	2018
Revenue:		
Product revenue	$ 1,719	$ 12,263
Operating expenses:		
Cost of product revenue	2,836	7,250
Research and development	17,963	22,698
Sales and marketing	6,363	17,536
General and administrative	5,422	5,979
Total operating expenses	32,584	53,463
Loss from operations	(30,865)	(41,200)
Interest expense	(58)	(401)
Change in fair value of warrant liability	(32)	(52)
Other income, net	366	589
Net loss before taxes	(30,589)	(41,064)
Income tax provision	26	38
Net loss	$ (30,615)	$ (41,102)
Unrealized (loss) gain on available-for-sale securities	(1)	1
Total comprehensive loss	$ (30,616)	$ (41,101)
Net loss per share, basic and diluted	$ (19.71)	$ (23.39)
Shares used in computing net loss per share, basic and diluted	1,553,365	1,757,102
Pro forma net loss per share, basic and diluted (unaudited)		$ (2.10)
Shares used in computing pro forma net loss per share, basic and diluted (unaudited)		19,528,258

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

SHOCKWAVE MEDICAL, INC.
Consolidated Statements of Convertible Preferred Stock and Stockholdersâ€™ Deficit
(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholdersâ€™ Deficit
	Shares	Amount	Shares	Amount				
Balanceâ€”December 31, 2016	14,605,589	$ 102,180	1,555,510	$ 2	$ 1,315	$ â€”	$ (55,148)	$ (53,831)
Issuance of Series C convertible preferred stock, net of issuance costs of $93	2,840,504	34,907	â€”	â€”	â€”	â€”	â€”	â€”
Exercise of Series A-1 warrants	63,952	382	â€”	â€”	â€”	â€”	â€”	â€”
Exercise of stock options	â€”	â€”	71,522	â€”	139	â€”	â€”	139
Unrealized loss on available-for-sale securities	â€”	â€”	â€”	â€”	â€”	(1)	â€”	(1)
Vesting of early exercised options	â€”	â€”	â€”	â€”	51	â€”	â€”	51
Stock-based compensation	â€”	â€”	â€”	â€”	965	â€”	â€”	965
Net loss	â€”	â€”	â€”	â€”	â€”	â€”	(30,615)	(30,615)
Balanceâ€”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	â€”	â€”	â€”	â€”	â€”	â€”
Exercise of Series A-1 warrants	69,675	417	â€”	â€”	â€”	â€”	â€”	â€”
Issuance of common stock warrants	â€”	â€”	â€”	â€”	104	â€”	â€”	104
Exercise of stock options	â€”	â€”	197,820	â€”	326	â€”	â€”	326
Unrealized gain on available-for-sale securities	â€”	â€”	â€”	â€”	â€”	1	â€”	1
Vesting of early exercised options	â€”	â€”	â€”	â€”	78	â€”	â€”	78
Stock-based compensation	â€”	â€”	â€”	â€”	1,297	â€”	â€”	1,297
Net loss	â€”	â€”	â€”	â€”	â€”	â€”	(41,102)	(41,102)
Balanceâ€”December 31, 2018	18,670,328	$ 152,806	1,824,852	$ 2	$ 4,275	$ â€”	$ (126,865)	$ (122,588)

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,	
	2017	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(30,615)	$(41,102)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	468	700
Stock-based compensation	965	1,297
Loss on write down of fixed assets	38	31
Change in fair value of warrant liability	32	52
Amortization of debt issuance costs	18	206
Changes in operating assets and liabilities:		
Accounts receivable	(594)	(2,211)
Inventory	(1,863)	(2,608)
Prepaid expenses and other current assets	(373)	(144)
Other assets	â€”	(917)
Accounts payable	249	360
Accrued and other current liabilities	1,328	2,773
Other liabilities	â€”	98
Net cash used in operating activities	(30,347)	(41,465)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of available-for-sale securities	(17,707)	â€”
Proceeds from maturities of available-for-sale securities	15,900	1,807
Purchase of property and equipment	(425)	(1,981)
Net cash used in investing activities	(2,232)	(174)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of convertible preferred stock, net of issuance costs	34,907	14,920
Proceeds from term notes	â€”	14,988
Payments of deferred offering costs	â€”	(626)
Proceeds from stock option exercises including early exercised options	139	426
Proceeds from warrant exercises	198	101
Principal payment of term loan	(1,557)	â€”
Net cash provided by financing activities	33,687	29,809
Net increase (decrease) in cash, cash equivalents and restricted cash	1,108	(11,830)
Cash, cash equivalents and restricted cash at beginning of period	50,815	51,923
Cash, cash equivalents and restricted cash equivalents at end of period	$ 51,923	$ 40,093
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	$ 40	$ 156
Income tax paid	$ â€”	$ 5
NON-CASH FINANCING ACTIVITIES:		
Property and equipment purchases included in accounts payable	$ 58	$ 55
Issuance of common stock warrants in connection with debt financing	$ â€”	$ 104
Deferred offering costs included in accounts payable and accrued liabilities	$ â€”	$ 893
Issuance of Series A-1 convertible preferred stock on net exercise of warrants	$ â€”	$ 316

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

ShockWave Medical, Inc.
Notes to Consolidated Financial Statements

1. Organization and Basis of Presentation

ShockWave Medical, Inc. (the â€œCompanyâ€) was incorporated on June 17, 2009. The Company is primarily engaged in the development of Intravascular Lithotripsy (â€œIVLâ€) 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 Companyâ€™s headquarters are in Santa Clara, California. The Company is located and operates primarily in the United States and has a subsidiary in Germany.

Going Concern

The Company has incurred significant losses and has negative cash flows from operations. As of December 31, 2018, the Company had an accumulated deficit of $126.9 million. Management expects to continue to incur additional substantial losses in the foreseeable future.

As of December 31, 2018, the Company had cash and cash equivalents of $39.6 million, which are available to fund future operations. The Company will need to raise additional capital to support the commercialization of its products and research and development activities. The Companyâ€™s activities are subject to significant risks and uncertainties, including the market acceptance of the Companyâ€™s products and the timing and extent of spending on research and development.

The Company believes that its cash and cash equivalents as of December 31, 2018, together with available borrowings under a revolving line of credit, will not be sufficient for the Company to continue as a going concern for at least one year from the issuance date of its consolidated financial statements. The Company believes that this raises substantial doubt about its ability to continue as a going concern. As a result, the Company will be required to raise additional capital from the sale of common stock or convertible preferred stock or the issuance of debt. However, no assurance can be given as to whether additional needed financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, the Company may be required to curtail planned activities to significantly reduce its operating expenses. Failure to manage discretionary spending or raise additional financing, as needed, may adversely impact the Companyâ€™s ability to achieve its intended business objectives and have an adverse effect on its results of operations and future prospects.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying consolidated financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Principles of Consolidation

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

ShockWave Medical, Inc.
Notes to Consolidated Financial Statements

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (â€œU.S. GAAPâ€) 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 expense 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 fair value of common stock, the fair value of preferred stock warrant liabilities, the fair value of stock options, recoverability of the Companyâ€™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.

Unaudited Pro Forma Financial Information

The unaudited pro forma consolidated balance sheet information as of December 31, 2018 reflects: (i) the automatic conversion of all outstanding shares of the Companyâ€™s convertible preferred stock into an aggregate of 18,670,328 shares of common stock immediately prior to the completion of the Companyâ€™s planned initial public offering (â€œIPOâ€); (ii) the reclassification of the convertible preferred stock warrant liability to additional paid-in capital due to the warrants converting to warrants to purchase common stock; and (iii) the net exercise of certain outstanding common stock warrants that would otherwise expire upon completion of an IPO into 123,461 shares of common stock, based on an assumed IPO price of $17.00 per share. The shares of common stock issuable and the proceeds expected to be received in the IPO are excluded from such pro forma financial information.

Pro forma basic and diluted net loss per share has been computed to give effect to the conversion of all outstanding convertible preferred stock into shares of common stock and the net exercise of certain stock warrants. Also, the numerator in the pro forma basic and diluted net loss per share calculation has been adjusted to remove gains or losses resulting from the remeasurement of the convertible preferred stock warrant liability. The unaudited pro forma net loss per share does not include the shares expected to be sold and related proceeds to be received from the IPO. The unaudited pro forma net loss per share for the year ended December 31, 2018 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of convertible preferred stock into shares of common stock and the net exercise of certain convertible preferred stock warrants and common stock warrants, as if such conversion or net exercise had occurred at the beginning of the period, or their issuance dates if later.

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.

ShockWave Medical, Inc.
Notes to Consolidated Financial Statements

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,	
	2017	2018
	(in thousands)	
Cash and cash equivalents	$51,923	$39,643
Restricted cash	â€”	450
Total cash, cash equivalents, and restricted cash	$51,923	$40,093

Restricted cash as of December 31, 2018 relates to a letter of credit established for a lease entered into in May 2018 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.

Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. The Company periodically evaluates whether declines in fair values of its marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Companyâ€™s ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis. Realized gains and losses and declines in fair value judged to be other than temporary, 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 Companyâ€™s investments have investment grade ratings when purchased. The Company performs ongoing evaluations of its customers and generally does not require collateral.

Concentration of Customers

For the year ended December 31, 2017, one customer accounted for 19% of the Companyâ€™s revenue. For the year ended December 31, 2108, there were no customers which accounted for more than 10% of the Companyâ€™s revenue. There were no customers which accounted for more than 10% of the Companyâ€™s accounts receivable as of December 31, 2017 and 2018.

Fair Value of Financial Instruments

The Companyâ€™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 â€“ Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2 â€“ 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 â€“ Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are recorded at invoice value, net of any allowance for doubtful accounts. Estimates of the allowance for doubtful accounts are determined based on existing contractual payment terms, historical payment patterns of customers and individual customer circumstances. The allowance for doubtful accounts was $76,000 as of December 31, 2018 and the Company recognized accounts receivable write-offs in the amount of $1,000 for the year ended December 31, 2018. There was no allowance for doubtful accounts recorded and no accounts receivable write-offs recognized as of and for the year ended December 31, 2017.

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.

Convertible Preferred Stock Warrant Liability

The Company has accounted for its freestanding warrants to purchase shares of the Companyâ€™s convertible preferred stock as liabilities at fair value upon issuance primarily because the shares underlying the warrants contain contingent redemption features outside the control of the Company. The warrants are subject to re-measurement at each balance sheet date and any change in fair value is recognized as the change in fair value of warrant liability. The carrying value of the warrants will continue to be adjusted until such time as these instruments are exercised, expire or convert into warrants to purchase shares of the Companyâ€™s common stock. At that time, the liabilities will be reclassified to additional paid-in capital, a component of stockholdersâ€™ equity (deficit).

Revenue

The Company adopted Accounting Standards Codification (â€œASCâ€) 606, *Revenue from Contracts with Customers*, effective January 1, 2018 using the modified retrospective method. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under ASC 605, *Revenue Recognition*. The adoption of this standard did not have a cumulative effect on opening accumulated deficit as of January 1, 2018, as the timing and measurement of revenue recognition is materially the same under ASC 606 as it was under the prior guidance.

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 Companyâ€™s revenue is generated through a consignment model under which inventory is maintained at hospitals.

Under ASC 605, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price to the customer is fixed or determinable, and collectability is reasonably assured. For products sold through direct sales representatives, revenue is recognized upon delivery to customers. For products sold to distributors, revenue is recognized upon transfer of title and risk of loss to the distributor. For consignment inventory, revenue is recognized at the time the catheters are consumed in a procedure.

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.

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 customerâ€™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 generally provides 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 daysâ€™ 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 Companyâ€™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.

Deferred Offering Costs

Offering costs, consisting of legal, accounting, printer and filing fees related to the IPO, are deferred and will be offset against proceeds from the IPO upon the effectiveness of the offering. In the event the offering is terminated, all deferred offering costs will be expensed. As of December 31, 2018, $1.5 million of deferred offering costs were recorded as other assets on the consolidated balance sheet. There were no deferred offering costs recorded as of December 31, 2017.

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 but has not made such contributions for the years ended December 31, 2017 and 2018.

ShockWave Medical, Inc.
Notes to Consolidated Financial Statements

Comprehensive Loss

Comprehensive loss is comprised of net loss and changes in unrealized gains and losses on the Companyâ€™s available-for-sale investments.

Foreign Currency

The functional currency of the Companyâ€™s foreign subsidiary 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 $36,000 for the year ended December 31, 2017 and net foreign currency transaction losses of $46,000 for the year ended December 31, 2018.

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 holdersâ€™ continued service to the Company. Since 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 Companyâ€™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 Companyâ€™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 (â€œCODMâ€) in deciding how to allocate resources to an individual segment and in assessing performance. The Companyâ€™s CODM is its Chief Executive Officer. The Company has determined it operates in one segment.

Recently Issued and Adopted Accounting Pronouncements

In June 2018, the Financial Accounting Standards Board (â€œFASBâ€) issued Accounting Standards Update (â€œASUâ€) No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. ASU 2018-07

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simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company early adopted this guidance as of January 1, 2018. Adoption of this guidance did not have a material impact on the Companyâ€™s consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash*, which amends the classification and presentation of changes in restricted cash or restricted cash equivalents in the consolidated statements of cash flows. The Company adopted this guidance as of January 1, 2018. Adoption of this guidance did not have a material impact on the Companyâ€™s consolidated financial statements.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. This new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. The Company plans to adopt this accounting standard as of January 1, 2019 using the adoption method defined in ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, in which the new leases standard is not applied in comparative periods presented in the year of adoption. The Company plans to apply a practical expedient to combine lease and non-lease components. The Company is currently in the process of evaluating the impact of the adoption of this new standard on the Companyâ€™s consolidated financial statements. We expect that the adoption of this standard will result in the recognition of a right-of-use asset for leased facilities and recognition of a liability for the lease payments remaining on the lease. These changes will be reflected on the consolidated balance sheets.

3. Financial Instruments and Fair Value Measurements

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

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Money market funds	$26,379	$ â€”	$ â€”	$26,379
U.S. treasury note	1,806	â€”	â€”	1,806
Total assets	$28,185	$ â€”	$ â€”	$28,185
Liabilities:				
Convertible preferred stock warrant liability	$ â€”	$ â€”	$ 577	$ 577
Total liabilities	$ â€”	$ â€”	$ 577	$ 577

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	December 31, 2018			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Money market funds	$21,680	$ â€”	$ â€”	$21,680
Total assets	$21,680	$ â€”	$ â€”	$21,680
Liabilities:				
Convertible preferred stock warrant liability	$ â€”	$ â€”	$ 313	$ 313
Total liabilities	$ â€”	$ â€”	$ 313	$ 313

The change in the fair value of the warrant liability is summarized below:

	Year Ended December 31,	
	2017	2018
	(in thousands)	
Beginning balance	$ 729	$ 577
Exercise of warrants	(184)	(316)
Expiration of warrants, included in change in fair value of warrant liability	â€”	(133)
Change in fair value of warrant liability	32	185
Ending balance	$ 577	$ 313

The valuation of the Companyâ€™s convertible preferred stock warrant liability contains unobservable inputs that reflect the Companyâ€™s own assumptions for which there is little, if any, market activity for at the measurement date. Accordingly, the Companyâ€™s convertible preferred stock warrant liability is measured at fair value on a recurring basis using unobservable inputs and are classified as Level 3 inputs, and any change in fair value is recognized as change in fair value of warrant liability in the consolidated statements of operations and comprehensive loss. Refer to Note 9 for the valuation technique and assumptions used in estimating the fair value of the warrants.

There were no transfers between Levels 1, 2 or 3 for the periods presented.

4. Cash Equivalents and Short-Term Investments

The following is a summary of the Companyâ€™s cash equivalents and short-term investments:

	December 31, 2017			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Money market funds	$ 26,379	$ â€”	$ â€”	$ 26,379
U.S. treasury note	1,807	â€”	(1)	1,806
Total	$ 28,186	$ â€”	$ (1)	$ 28,185
Reported as:				
Cash equivalents				$ 26,379
Short-term investments				1,806
Total				$ 28,185

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	December 31, 2018			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Money market funds	$ 21,680	$ â€”	$ â€”	$ 21,680
Total	$ 21,680	$ â€”	$ â€”	$ 21,680
Reported as:				
Cash equivalents				$ 21,680
Total				$ 21,680

For the years ended December 31, 2017 and 2018, the Company recognized no material realized gains or losses on cash equivalents and short-term investments.

5. Balance Sheet Components

Inventory

Inventory consists of the following:

	December 31,	
	2017	2018
	(in thousands)	
Raw material	$ 478	$1,084
Work in progress	198	634
Finished goods	1,041	2,313
Consigned inventory	806	1,100
Total inventory	$2,523	$5,131

Property and Equipment, Net

Property and equipment, net consists of the following:

	December 31,	
	2017	2018
	(in thousands)	
Equipment	$1,298	$ 2,321
Equipment on loan to customers	263	786
Office furniture	68	90
Software	76	76
Leasehold improvements	366	764
Construction in progress	258	236
Property and equipment, gross	2,329	4,273
Less accumulated depreciation and amortization	(957)	(1,654)
Total property and equipment, net	$1,372	$ 2,619

Depreciation and amortization expense was $0.5 million and $0.7 million for the years ended December 31, 2017 and 2018, respectively.

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Other Assets

Other assets consist of the following:

	December 31, 2017	December 31, 2018
	(in thousands)	
Deferred offering costs	$â€”	$1,519
Restricted cash	â€”	450
Other	73	97
Total other assets	$ 73	$2,066

Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2017	December 31, 2018
	(in thousands)	
Accrued employee compensation	$2,072	$3,135
Accrued research and development costs	507	1,115
Accrued professional services	348	1,391
Other	466	576
Total accrued liabilities	$3,393	$6,217

6. Commitments and Contingencies

Operating Leases

In August 2012, the Company entered into a lease for office space located in Fremont, California. In October 2018, the Company extended the term of the lease to June 30, 2019. The Company is using the facility for office, manufacturing and research and development purposes.

In May 2018, the Company entered into a new lease agreement for office and laboratory space which consist of approximately 35,000 square feet located in Santa Clara, California. The lease term commenced in September 2018 and ends in August 2022. In connection with the 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.

The following are minimum future rental payments owed under these agreements:

Year ending December 31:	(in thousands)
2019	$ 940
2020	830
2021	855
2022	582
Total	$ 3,207

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Rent expense for the years ended December 31, 2017 and 2018 was $0.4 million and $0.8 million, respectively.

7. Term Notes

2014 Loan and Security Agreement

In June 2014, the Company entered into a Loan and Security Agreement with Silicon Valley Bank (the â€œ2014 Loan and Security Agreementâ€), under which a total of $4.0 million was borrowed. The Company made monthly payments of principal and interest through the maturity date of October 1, 2017, and a one-time payment of $0.2 million on the maturity date of the loan. All the borrowings under the 2014 Loan and Security Agreement were fully repaid as of December 31, 2017.

In connection with the 2014 Loan and Security Agreement, the Company issued warrants to purchase shares of the Companyâ€™s Series A-1 convertible preferred stock. Upon issuance, the fair value of the warrants was recorded as a debt discount. The debt discount was amortized to interest expense, net over the repayment period of the loan. During the year ended December 31, 2017, amortization of debt discount was $0.1 million.

2018 Loan and Security Agreement

In February 2018, the Company entered into a Loan and Security Agreement with Silicon Valley Bank (the â€œ2018 Loan and Security Agreementâ€). The terms of the 2018 Loan and Security Agreement include 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 Company has not drawn down on its revolving line of credit as of December 31, 2018.

The term loan matures in December 2021, with interest-only monthly payments until September 2019. The interest-only period will extend through December 2019 if certain financing milestones are met. The term loan accrues interest at a floating per annum rate equal to the greater of the Wall Street Journal prime rate minus 1.75% and 2.75% (3.75% as of December 31, 2018). There is a final payment equal to 6.75% of the original aggregate principal amount, or $1.0 million, of the term loan advances, which will be accrued over the term of the loan using the effective-interest method.

The line of credit matures in February 2021 and accrues interest at the Wall Street Journal prime rate.

In connection with the execution of the 2018 Loan and Security Agreement, the Company issued warrants to purchase 34,440 shares of the Companyâ€™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 repayment period of the loan.

During the year ended December 31, 2018, the Company recorded interest expense related to the 2018 Loan and Security Agreement and amortization of debt discount of $0.2 million and $0.2 million, respectively.

The term loan is secured by all of the Companyâ€™s assets, excluding intellectual property and certain other assets. The loan contains customary affirmative and restrictive covenants, including with respect to the Companyâ€™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 Companyâ€™s affiliates, but does not include any financial covenants.

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

	December 31, 2018 (in thousands)
Face value of term note	$ 15,000
Net premium associated with accretion of final payment, issuance of common stock warrants, and other debt issuance costs	50
Term note, current and noncurrent	15,050
Less term note, current portion	(1,667)
Term note, noncurrent portion	$ 13,383

Future minimum payments of principal and estimated payments of interest on the Companyâ€™s outstanding variable rate borrowings as of December 31, 2018 are as follows:

Year ending December 31:	(in thousands)
2019	$ 2,243
2020	7,079
2021	7,816
Total future payments	17,138
Less amounts representing interest	(1,125)
Less final payment	(1,013)
Total principal amount of term note payments	$ 15,000

8. Convertible Preferred Stock

In September 2017, the Company issued 2,840,504 shares of its Series C convertible preferred stock at a price per share of $12.32176 for net proceeds of $34.9 million.

In December 2018, the Company issued 1,090,608 shares of its Series D convertible preferred stock at a price per share of $13.75379 for gross proceeds of $15.0 million. The Series D investor has the option to purchase up to $10.0 million in common stock in a concurrent private placement at a price per share equal to the price per share of the common stock to the public in an initial public offering.

During 2018, the Company issued 69,675 shares of its Series A-1 convertible preferred stock at the fair value of $5.978 per share, of which 32,498 shares were issued for gross cash proceeds of $0.1 million in connection with the cash exercise of Series A-1 warrants and 37,177 shares were issued in connection with the net exercise of 49,655 shares of Series A-1 warrants.

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Convertible preferred stock consists of the following:

	December 31, 2017			
	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Aggregate Liquidation Preference
	(in thousands, except share amounts)			
Series A	19,280,722	1,580,387	$ 4,226	$ 4,473
Series A-1	52,589,632	4,127,463	13,637	12,780
Series B	65,000,000	5,309,617	39,877	40,000
Series C	79,209,457	6,492,578	79,729	80,000
	216,079,811	17,510,045	$ 137,469	$ 137,253

	December 31, 2018			
	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Aggregate Liquidation Preference
	(in thousands, except share amounts)			
Series A	19,280,722	1,580,387	$ 4,226	$ 4,473
Series A-1	51,874,893	4,197,138	14,054	12,996
Series B	64,777,331	5,309,617	39,877	40,000
Series C	79,209,457	6,492,578	79,729	80,000
Series D	13,956,584	1,090,608	14,920	15,000
	229,098,987	18,670,328	$ 152,806	$ 152,469

The Company recorded its convertible preferred stock at fair value on the dates of issuance, net of issuance costs. As of December 31, 2017 and 2018, the Company classified its Series A, Series A-1, Series B, Series C, and Series D convertible preferred stock outside of stockholdersâ€™ deficit in temporary equity because, in the event of certain â€œliquidation eventsâ€ that are not solely within the control of the Company (including liquidation, sale or transfer of control of the Company), the shares would become redeemable at the option of the holders. As of December 31, 2017 and 2018, the Company did not adjust the carrying values of the Series A, Series A-1, Series B, Series C and Series D convertible preferred stock to the deemed liquidation values of such shares since a liquidation event was not probable at the consolidated balance sheet dates. Subsequent adjustments to increase or decrease the carrying values to the ultimate liquidation values will be made if and when it becomes probable that such a liquidation event will occur.

The holders of the Convertible Preferred Stock have the following rights, privileges and preferences:

Optional Conversion Rights

Each share of Series A, Series A-1, Series B, Series C and Series D convertible preferred stock is convertible at the option of the holder into the number of shares of common stock determined by dividing the original issue price by the applicable conversion price. The original issue price per share and initial conversion price per share is $2.8304 for Series A, $3.09636 for Series A-1, $7.5335 for Series B, $12.32176 for Series C and $13.75379 for Series D convertible preferred stock. As of December 31, 2018, at the current conversion ratios, each share of Series A, Series A-1, Series B, Series C and Series D convertible preferred stock will convert on a one-for-one basis into common stock. The conversion price per share for the convertible preferred stock shall be adjusted for certain recapitalizations, splits, combinations, common stock dividends or as set forth in the Companyâ€™s amended and restated certificate of incorporation. At December 31, 2017 and 2018, none of

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the Series A, Series A-1, Series B, Series C and Series D convertible preferred stock has been converted to common stock.

Automatic Conversion Rights

Each share of convertible preferred stock shall automatically be converted into shares of common stock at the then effective conversion rate for such share (i) immediately prior to the closing of a firm commitment underwritten initial public offering pursuant to an effective registration statement filed under the Securities Act of 1933, as amended (the â€œSecurities Actâ€), covering the offer and sale of the Companyâ€™s common stock, provided that the offering price per share is not less than $15.067 (as adjusted for recapitalizations) and the aggregate gross proceeds to the Company are not less than $30.0 million, or (ii) upon the receipt by the Company of a written request for such conversion from the preferred requisite majority, or, if later, the effective date for conversion specified in such requests. The conversion prices and rates for each series of convertible preferred stock are the same in the event of an automatic conversion as they would be in the event of an optional conversion.

Voting Rights

Each share of convertible preferred stock has a number of votes equal to the number of shares of common stock into which it is convertible. The holders of the Series A, Series A-1 and Series B convertible preferred stock, voting as separate classes, each have the right to elect one director to the Companyâ€™s board of directors (the â€œBoardâ€). The holders of the Series C and Series D convertible preferred stock, voting together as a separate class, have the right to elect one director to the Companyâ€™s Board. The holders of the common stock, voting as a separate class, have the right to elect two members to the Board. Any other members of the Companyâ€™s Board shall be elected by both (i) the holders of convertible preferred stock, voting as a separate class and on an as-converted basis, and (ii) the holders of common stock, voting as a separate class.

Liquidation Rights

In the event of any liquidation, dissolution or winding-up of the Company, the holders of the Series A, Series A-1, Series B, Series C and Series D convertible preferred stock are entitled to liquidation preferences in the amount of $2.8304 per share for the Series A, $3.09636 per share for the Series A-1, $7.5335 per share for the Series B, $12.32176 per share for the Series C and $13.75379 for the Series D convertible preferred stock (each subject to adjustment for recapitalizations), plus all declared but unpaid dividends. After the payment or setting aside for payment to the holders of the Series A, Series A-1, Series B, Series C and Series D convertible preferred stock of their full liquidation preference amounts, the entire remaining assets of the Company legally available for distribution shall be distributed pro rata to the holders of common stock in proportion to the number of shares of common stock held by them.

If upon the liquidation, dissolution or winding up of the Company the assets of the Company legally available for distribution to the holders of the Series A, Series A-1, Series B, Series C and Series D convertible preferred stock are insufficient to permit the payment to such holders of the full liquidation preferences to which they are entitled, then the holders of the Companyâ€™s common stock will receive nothing in respect of their equity holdings in the Company. Upon such an event, the assets of the Company legally available for distribution shall satisfy the respective liquidation preferences in the order of: first, the Series D and C convertible preferred stock, which would be treated with equal priority, then the Series B convertible preferred stock, then the Series A-1 convertible preferred stock and then, finally, the Series A convertible preferred stock.

A Liquidation Event is defined as including (i) the acquisition of the corporation by another entity by means of any transaction or series of related transactions to which the corporation is party other than a transaction or

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series of transactions in which the holders of the voting securing of the corporation outstanding immediately prior to such transaction retain, immediately after such transaction or series of transactions, as a result of shares in the corporation held by such holders prior to such transaction, at least a majority of the total voting power represented by the outstanding voting securities of the corporation or such other surviving or resulting entity; (ii) a sale, lease or other disposition (excluding by exclusive license) of all or substantially all of the assets of the corporation; or (iii) any liquidation, dissolution or winding up of the corporation whether voluntary or involuntary.

Dividend Rights

The convertible preferred stockholders are entitled to receive dividends at an annual rate of $0.22643 per share of Series A, $0.24766 per share of Series A-1, $0.60268 per share of Series B, $0.98576 per share of Series C and $1.10044 per share of Series D (each adjusted to reflect recapitalizations). Such dividends are payable out of funds legally available, are payable only when and if declared by the Board and are noncumulative. No dividends may be paid on the common stock during any fiscal year until the Series A, Series A-1, Series B, Series C and Series D convertible preferred stockholders have received their dividend preference for that fiscal year. After the payment of these dividends, any dividends declared by the Companyâ€™s Board out of funds legally available shall be shared equally among all outstanding shares on an as-converted basis. No dividends have been declared to date.

Redemption Rights

There are no redemption rights afforded to the holders of convertible preferred stock. Upon certain change in control events that are outside of the Companyâ€™s control, including liquidation, sale or transfer of control of the Company, the convertible preferred stock is contingently redeemable.

9. Warrant Liability

The key terms of the outstanding convertible preferred stock warrants are summarized in the following table:

	Warrants Outstanding			
	Warrants Outstanding December 31, 2017	Warrants Outstanding December 31, 2018	Exercise Price	Expiration
Series A-1 convertible preferred stock warrants	128,259	â€”	$ 3.09636	Various dates in 2018
Series A-1 convertible preferred stock warrants	54,903	54,903	$ 3.09636	June 2024
Total convertible preferred stock warrants	183,162	54,903		

As discussed in Note 8, during 2018, the Company issued 69,675 shares of its Series A-1 convertible preferred stock at the fair value of $5.978 per share upon the exercise of its warrants; 12,478 warrants were cancelled as payment for the net exercise of warrants pursuant to these issuances. During the year ended December 31, 2018, 46,106 Series A-1 convertible preferred stock warrants expired unexercised.

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The fair value of the warrants was determined using the Black-Scholes option pricing model and the following assumptions:

	December 31,	
	2017	2018
Expected term (in years)	0-6.5	5.5
Expected volatility	19.8%-42.3%	42.8%
Risk-free interest rate	1.1%-1.8%	2.9%
Expected dividend yield	0%	0%

10. Stock-Based Compensation

Total stock-based compensation was as follows:

	Year Ended December 31,	
	2017	2018
	(in thousands)	
Cost of product revenue	$ 46	$ 67
Research and development	185	235
Sales and marketing	130	294
General and administrative	604	701
Total stock-based compensation	$965	$1,297

Determination of Fair Value

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

	December 31,	
	2017	2018
Expected term (in years)	6.08	6.08
Expected volatility	45.6%	40.8%-41.9%
Risk-free interest rate	1.9%-2.2%	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 Termâ€"*The expected term represents the period that stock-based awards are expected to be outstanding. The Companyâ€™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 Volatilityâ€"*The expected volatility was derived from the historical stock volatilities of comparable peer public companies within the Companyâ€™s industry that are considered to be comparable to the Companyâ€™s business over a period equivalent to the expected term of the stock-based awards since there has been no trading history of the Companyâ€™s common stock.

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*Risk-Free Interest Rateâ€"*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 awardsâ€™ expected term.

*Expected Dividend Yieldâ€"*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.

Equity Incentive Plan

On June 17, 2009, the Company adopted the 2009 Equity Incentive Plan (the â€œPlanâ€) under which the Board may issue stock options to employees, directors and consultants. 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, 2018, the Company had reserved 5,057,744 shares of common stock for issuance under the Plan.

Activity under the 2009 Plan is set forth below:

	Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance, December 31, 2016	887,885	1,365,934	$ 1.95		$ 2,011
Awards authorized	1,352,677	â€"			
Options granted	(1,974,589)	1,974,589	3.42		
Options exercised	â€"	(71,522)	1.95		
Options cancelled	160,397	(160,397)	2.44		
Balance, December 31, 2017	426,370	3,108,604	$ 2.81	8.03	$ 3,647
Awards authorized	691,503	â€"			
Options granted	(1,015,963)	1,015,963	5.25		
Options exercised	â€"	(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
Vested and exercisable, December 31, 2018		1,585,273	$ 2.68	6.50	$ 6,249
Vested and expected to vest, December 31, 2018		3,636,358	$ 3.54	7.79	$ 11,267

The weighted-average grant date fair value of options granted during the years ended December 31, 2017 and 2018 was $1.59 and $2.56 per share, respectively. The total grant date fair value of options vested was $0.9 million and $1.6 million for the years ended December 31, 2017 and 2018, respectively.

The aggregate intrinsic values of options outstanding, vested and exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of the Companyâ€™s common stock, as determined by the Board, as of December 31, 2018. The aggregate intrinsic value

of options exercised was $0.1 million and $0.5 million for the years ended December 31, 2017 and 2018, respectively.

As of December 31, 2018, total unrecognized stock-based compensation related to unvested stock options was $3.8 million, which the Company expects to recognize over a remaining weighted-average period of 2.72 years.

Early Exercise of Options

Certain stock options granted under the Companyâ€™s stock option Plan provide option holders the right to elect to exercise unvested options in exchange for restricted common stock. A summary of the restricted stock shares issued under the Companyâ€™s Plan is as follows:

	Number of Shares	Weighted-Average Exercise Price
Outstanding and unvested at December 31, 2016	94,610	$ 0.61
Vested	83,007	$ 0.61
Outstanding and unvested at December 31, 2017	11,603	$ 0.61
Exercised	45,287	$ 2.20
Vested	(43,468)	$ 1.83
Outstanding and unvested at December 31, 2018	13,422	$ 2.20

Terms of the Plan permit certain option holders to exercise options before their options are vested, subject to certain limitations. Upon early exercise, the awards become subject to a restricted stock agreement. The shares of restricted stock granted upon early exercise of the options are subject to the same vesting provisions in the original stock option awards. Common stock outstanding in these consolidated financial statements includes restricted stock subject to repurchase. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaserâ€™s employment, at the price paid by the purchaser, and are not deemed to be issued for accounting purposes until those related shares vest. The liability is reclassified into common stock and additional paid-in capital as the shares vest and the repurchase right lapses. Accordingly, the Company has recorded the unvested portion of the exercise proceeds of $7,000 and $29,000 as a liability as of December 31, 2017 and 2018, from the early exercise in the accompanying consolidated balance sheets.

Stock-Based Awards Granted Outside of Equity Incentive Plans

Common Stock Warrants

In May 2015, the Company issued warrants to purchase shares of its common stock to the three founders of the Company. In February 2018, in connection with the execution of the 2018 Loan and Security Agreement, the Company issued warrants to purchase shares of the Companyâ€™s common stock. The key terms of the outstanding common stock warrants are summarized in the following table:

	Warrants Outstanding			
	Warrants Outstanding December 31, 2017	Warrants Outstanding December 31, 2018	Exercise Price	Expiration
Related party common stock warrants	141,778	141,778	$ 2.196	May 2025
Common stock warrants issued in connection with the 2018 Loan and Security Agreement	â€”	34,440	$ 4.026	February 2028
Total common stock warrants	141,778	176,218		

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11. Income Taxes

Current income tax provision consists of the following:

	December 31, 2017	December 31, 2018
	(in thousands)	
Domestic	$ 1	$ 3
Foreign	25	35
Total current income tax provision	$ 26	$ 38

The components of the deferred tax assets are as follows:

	December 31, 2017	December 31, 2018
	(in thousands)	
Deferred tax assets:		
Net operating loss carryovers	$ 19,251	$ 28,834
Fixed and intangible assets	664	837
Accruals and reserves	465	761
Stock-based compensation	31	132
Research and development credits	1,858	1,716
Contributions	13	14
Total deferred tax assets	22,282	32,294
Less valuation allowance	(22,282)	(32,294)
Total net deferred tax assets	$ â€”	$ â€”

Reconciliation of the statutory federal income tax to the Companyâ€™s effective tax is as follows:

	December 31, 2017	December 31, 2018
	(in thousands)	
Income tax benefit at federal statutory rate	$(10,404)	$(8,624)
State and local income taxes net of federal tax benefit	1	3
Foreign tax rate differential	(3)	11
Change in valuation allowance	(522)	8,497
Stock-based compensation	309	123
R&D tax credits	(222)	(313)
Other	109	341
Federal rate change (pursuant to the Tax Cuts and Jobs Act of 2017)	10,758	â€”
Total current income tax provision	$ 26	$ 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 $0.6 million and $10.0 million during the years ended December 31, 2017 and 2018, respectively.

As of December 31, 2018, the Company had net operating loss carryforwards available to reduce future federal, California and other state income of $119.5 million, $37.2 million and $19.5 million, respectively. The

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federal net operating loss carryforwards begin expiring in 2030, 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. The net operating loss related deferred tax assets do not include excess tax benefits from employee stock option exercises.

As of December 31, 2018, the Company had research and development credit carryforwards of $1.0 million for federal income tax purposes and $0.9 million for California state income tax purposes available to reduce future taxable income, if any. The federal research and development credit carryforwards expire beginning 2032 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 percentage change limitations 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 Tax Cuts and Jobs Act (â€œTCJAâ€) was enacted on December 22, 2017. The TCJA reduces the top U.S. federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred, changes the rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017, allows for immediate expensing of fixed asset additions beginning after September 27, 2017, and creates new taxes on certain foreign sourced earnings. In 2017, the Company was not subject to a one-time transition tax as no foreign accumulated earnings and profits existed. As a result of the signing of the TCJA, the Company recorded a $10.1 million reduction as of December 31, 2017, due to remeasurement of its deferred tax assets along with a corresponding reduction of its valuation allowance.

Subsequent to the enactment of the TCJA, the SEC staff issued Staff Accounting Bulletin No. 118 (â€œSAB 118â€), which allowed companies to record provisional amounts related to the effects of the TCJA during a measurement period not to extend beyond one year of the enactment date. The accounting for the tax effects of the TCJA has been completed as of December 31, 2018 and was not material to income tax expense for the year then ended.

The Company has adopted the approach of recording the consequences of the global intangible low-taxed income (â€œGILTIâ€) provisions of the TCJA as period costs when incurred effective for periods beginning after December 31, 2017.

Uncertain Tax Positions

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

	December 31,	
	2017	2018
	(in thousands)	
Beginning balance	$ 688	$ 893
Additions based on tax positions related to prior years	â€”	394
Additions based on tax positions related to current years	205	609
Balance at end of year	$ 893	$ 1,896

If recognized, gross unrecognized tax benefits would not have an impact on the Companyâ€™s effective tax rate due to the Companyâ€™s full valuation allowance position. While it is often difficult to predict the final outcome of any particular uncertain tax position, the Company does not believe that the amount of gross

unrecognized tax benefits will change significantly in the next twelve months. The Company is subject to taxation in the United States and in Germany. The Company files federal, California, and various other state income tax returns. The Company is not currently under examination by any income tax authorities. 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.

It is the Companyâ€™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, 2018.

12. 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:

	Year Ended December 31,	
	2017	2018
	(in thousands)	
Convertible preferred stock	17,510,045	18,670,328
Common stock options issued and outstanding	3,108,604	3,636,358
Early exercised options subject to future vesting	11,603	13,422
Convertible preferred stock warrants	183,162	54,903
Common stock warrants	141,778	176,218
Total	20,955,192	22,551,229

Unaudited Pro Forma Net Loss Per Share

The following table sets forth the computation of unaudited pro forma basic and diluted net loss per share:

	Year Ended December 31, 2018
	(unaudited) (in thousands, except share and per share data)
Numerator:	
Net loss	$ (41,102)
Change in fair value of warrant liability	52
Pro forma net loss, basic and diluted	$ (41,050)
Denominator:	
Shares of common stock used in computing net loss per share, basic and diluted	1,757,102
Pro forma adjustment to reflect assumed conversion of convertible preferred stock	17,647,695
Pro forma adjustment to reflect assumed exercise of certain common stock warrants	123,461
Pro forma shares of common stock, basic and diluted	19,528,258
Pro forma net loss per share, basic and diluted	$ (2.10)

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13. Segment and Geographic Information

The following table represents the Companyâ€™s product revenue based on the location to which the product is shipped:

	December 31,	
	2017	2018
	(in thousands)	
United States	$ 969	$ 7,022
Germany	597	1,393
Rest of Europe	143	3,516
All other countries	10	332
Product revenue	$1,719	$12,263

As of December 31, 2017 and 2018, the Companyâ€™s long-lived assets are all held in the United States with exception of certain equipment on loan to customers held internationally, which was not material as of each period end.

14. Subsequent Events

Except as noted below, subsequent events have been evaluated through February 8, 2019, which is the date that the consolidated financial statements were available to be issued.

Reverse Stock Split

The Companyâ€™s board of directors approved a reverse split of shares of the Companyâ€™s common stock and convertible preferred stock on a 12.2-for-one basis (the â€œReverse Stock Splitâ€), which was effected on February 22, 2019. The par value and the number of authorized shares of the convertible preferred stock and common stock were not adjusted in connection with the Reverse Stock Split. All references to common stock, convertible preferred stock, warrants to purchase common stock, warrants to purchase convertible preferred stock, options to purchase common stock, early exercised options, share data, per share data and related information contained in the financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented. The number of shares of the Companyâ€™s common stock contained in the financial statements includes fractional shares resulting from the Reverse Stock Split, aggregating to 45 whole shares of common stock and 69 whole shares of preferred stock for the period presented, which fractional shares will be settled in cash in fiscal 2019.

5,700,000 Shares

Common Stock

Prospectus

Morgan Stanley **BofA Merrill Lynch**

Wells Fargo Securities **Canaccord Genuity**

March 6, 2019