UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

OR

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

For the transition period from _____to _____

Commission File Number: 001-38829

ShockWave Medical, Inc.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of October 31, 2019, the registrant had 28,300,080 shares of common stock, $0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

SHOCKWAVE MEDICAL, INC.
Condensed Consolidated Balance Sheets
(*Unaudited*)
(in thousands)

	September 30, 2019	December 31, 2018
		(1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 39,452	$ 39,643
Short-term investments	74,646	—
Accounts receivable, net	5,551	2,850
Inventory	9,227	5,131
Prepaid expenses and other current assets	2,199	1,112
Total current assets	131,075	48,736
Operating lease right-of-use assets	2,155	—
Property and equipment, net	4,111	2,619
Other assets	548	2,066
TOTAL ASSETS	$ 137,889	$ 53,421
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 2,486	$ 1,487
Term notes, current portion	6,667	1,667
Accrued liabilities	9,496	6,217
Lease liability, current portion	742	—
Total current liabilities	19,391	9,371
Lease liability, noncurrent portion	1,543	—
Term notes, noncurrent portion	8,705	13,383
Convertible preferred stock warrant liability	—	313
Other liabilities	—	136
TOTAL LIABILITIES	29,639	23,203
Commitments and contingencies (Note 6)		
Convertible preferred stock	—	152,806
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock	—	—
Common stock	28	2
Additional paid-in capital	271,394	4,275
Accumulated other comprehensive income	57	—
Accumulated deficit	(163,229)	(126,865)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	108,250	(122,588)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 137,889	$ 53,421

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

(1) The consolidated balance sheet as of December 31, 2018 is derived from the audited consolidated financial statements as of that date.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenue:				
Product revenue	$ 11,333	$ 3,600	$ 28,615	$ 7,201
Operating expenses:				
Cost of product revenue	4,401	1,973	11,606	3,946
Research and development	8,368	5,533	22,778	16,579
Sales and marketing	8,192	4,801	21,023	12,611
General and administrative	3,437	1,369	9,684	4,137
Total operating expenses	24,398	13,676	65,091	37,273
Loss from operations	(13,065)	(10,076)	(36,476)	(30,072)
Interest expense	(251)	(158)	(746)	(216)
Change in fair value of warrant liability	—	(104)	(609)	(53)
Other income, net	385	166	1,518	489
Net loss before taxes	(12,931)	(10,172)	(36,313)	(29,852)
Income tax provision	26	6	51	27
Net loss	$ (12,957)	$ (10,178)	$ (36,364)	$ (29,879)
Unrealized gain (loss) on available-for-sale securities	(18)	—	57	1
Total comprehensive loss	$ (12,975)	$ (10,178)	$ (36,307)	$ (29,878)
Net loss per share, basic and diluted	$ (0.46)	$ (5.73)	$ (1.66)	$ (17.15)
Shares used in computing net loss per share, basic and diluted	28,085,821	1,776,249	21,886,396	1,742,572

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance — December 31, 2018	18,670,328	$ 152,806	1,824,852	$ 2	$ 4,275	$ —	$ (126,865)	$ (122,588)
Exercise of common stock warrants for cash	—	—	50,331	—	110	—	—	110
Issuance of common stock upon net exercise of warrants	—	—	101,744	—	133	—	—	133
Conversion of preferred stock to common stock upon initial public offering	(18,670,328)	(152,806)	18,670,328	18	152,788	—	—	152,806
Conversion of Series A-1 warrants to common stock warrants upon initial public offering	—	—	—	—	789	—	—	789
Issuance of common stock in connection with initial public offering, net of issuance costs of $11.3 million	—	—	6,555,000	7	100,132	—	—	100,139
Issuance of common stock in connection with private placement	—	—	588,235	1	9,999	—	—	10,000
Exercise of stock options	—	—	80,515	—	169	—	—	169
Vesting of early exercised options	—	—	—	—	18	—	—	18
Stock-based compensation	—	—	—	—	412	—	—	412
Adjustment for fractional shares resulting from reverse stock split	—	—	(114)	—	(3)	—	—	(3)
Net loss	—	—	—	—	—	—	(12,799)	(12,799)
Balance — March 31, 2019	—	—	27,870,891	28	268,822	—	(139,664)	129,186
Issuance of common stock upon net exercise of warrants	—	—	79,208	—	—	—	—	—
Exercise of stock options	—	—	73,608	—	148	—	—	148
Vesting of early exercised options	—	—	—	—	9	—	—	9
Stock-based compensation	—	—	—	—	818	—	—	818
Offering costs related to the initial public offering	—	—	—	—	(215)	—	—	(215)
Unrealized gain on available-for-sale securities	—	—	—	—	—	75	—	75
Net loss	—	—	—	—	—	—	(10,608)	(10,608)
Balance — June 30, 2019	—	—	28,023,707	28	269,582	75	(150,272)	119,413
Exercise of stock options	—	—	232,186	—	706	—	—	706
Stock-based compensation	—	—	—	—	1,106	—	—	1,106
Unrealized loss on available-for-sale securities	—	—	—	—	—	(18)	—	(18)
Net loss	—	—	—	—	—	—	(12,957)	(12,957)
Balance — September 30, 2019	—	$ —	28,255,893	$ 28	$ 271,394	$ 57	$ (163,229)	$ 108,250

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance — December 31, 2017	17,510,045	$ 137,469	1,627,032	$ 2	$ 2,470	$ (1)	$ (85,763)	$ (83,292)
Exercise of Series A-1 warrants	52,169	312	—	—	—	—	—	—
Issuance of common stock warrants	—	—	—	—	104	—	—	104
Exercise of stock options	—	—	143,422	—	215	—	—	215
Unrealized gain on available-for-sale securities	—	—	—	—	—	1	—	1
Vesting of early exercised options	—	—	—	—	22	—	—	22
Stock-based compensation	—	—	—	—	273	—	—	273
Net loss	—	—	—	—	—	—	(9,594)	(9,594)
Balance — March 31, 2018	17,562,214	137,781	1,770,454	2	3,084	—	(95,357)	(92,271)
Exercise of Series A-1 warrants	17,506	105	—	—	—	—	—	—
Exercise of stock options	—	—	27,067	—	60	—	—	60
Vesting of early exercised options	—	—	—	—	20	—	—	20
Stock-based compensation	—	—	—	—	312	—	—	312
Net loss	—	—	—	—	—	—	(10,107)	(10,107)
Balance — June 30, 2018	17,579,720	137,886	1,797,521	2	3,476	—	(105,464)	(101,986)
Exercise of stock options	—	—	12,982	—	25	—	—	25
Vesting of early exercised options	—	—	—	—	18	—	—	18
Stock-based compensation	—	—	—	—	289	—	—	289
Net loss	—	—	—	—	—	—	(10,178)	(10,178)
Balance — September 30, 2018	17,579,720	$ 137,886	1,810,503	$ 2	$ 3,808	$ —	$ (115,642)	$ (111,832)

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

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

	Nine Months Ended September 30,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (36,364)	$ (29,879)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	854	466
Stock-based compensation	2,336	874
Amortization of right-of-use assets	739	—
Accretion of discount on available-for-sale securities	(542)	—
Loss on write down of fixed assets	90	25
Change in fair value of warrant liability	609	53
Amortization of debt issuance costs	322	107
Changes in operating assets and liabilities:		
Accounts receivable	(2,701)	(2,016)
Inventory	(4,096)	(2,687)
Prepaid expenses and other current assets	(1,087)	(143)
Other assets	(1)	(9)
Accounts payable	884	(187)
Accrued and other current liabilities	4,169	1,720
Lease liabilities	(749)	—
Other liabilities	—	25
Net cash used in operating activities	(35,537)	(31,651)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of available-for-sale securities	(106,347)	—
Proceeds from maturities of available-for-sale securities	32,300	1,807
Purchase of property and equipment	(2,287)	(1,130)
Net cash (used in) provided by investing activities	(76,334)	677
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon initial public offering, net of issuance costs paid	100,547	—
Proceeds from issuance of common stock in private placement	10,000	—
Proceeds from term loans	—	9,988
Proceeds from stock option exercises	1,023	400
Proceeds from warrant exercises	110	101
Net cash provided by financing activities	111,680	10,489
Net decrease in cash, cash equivalents and restricted cash	(191)	(20,485)
Cash, cash equivalents and restricted cash at beginning of period	40,093	51,923
Cash, cash equivalents and restricted cash equivalents at end of period	$ 39,902	$ 31,438
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	$ 420	$ 68
Income tax paid	$ 120	$ 5
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Common stock issued on conversion of convertible preferred stock	$ 152,806	$ —
Issuance of Series A-1 convertible preferred stock on net exercise of warrants	$ —	$ 316
Common stock issued upon net exercise of warrants	$ 133	$ —
Common stock warrants issued on conversion of preferred stock warrants and the reclassification of the warrant liability	$ 789	$ —
Right-of-use asset obtained in exchange for lease liability	$ 73	$ —
Property and equipment purchases included in accounts payable and accrued liabilities	$ 204	$ 180
Issuance of common stock warrants in connection with debt financing	$ —	$ 104

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

1. Organization and Basis of Presentation

ShockWave Medical, Inc. (the "Company") was incorporated on June 17, 2009. The Company is primarily engaged in the development of Intravascular Lithotripsy ("IVL") technology for the treatment of calcified plaque in patients with peripheral vascular, coronary vascular and heart valve disease. Built on a balloon catheter platform, the IVL technology uses lithotripsy to disrupt both superficial and deep vascular calcium, while minimizing soft tissue injury, and an integrated angioplasty balloon to dilate blockages at low pressures, restoring blood flow.

In 2016, the Company began commercial and manufacturing operations, and began selling catheters based on the IVL technology. The Company's headquarters are in Santa Clara, California. The Company is located and operates primarily in the United States and has a subsidiary in Germany.

Initial Public Offering

On March 11, 2019, the Company completed an initial public offering ("IPO") of its common stock. As part of the IPO, the Company issued and sold 6,555,000 shares of its common stock, which included 855,000 shares sold pursuant to the exercise of the underwriters' over-allotment option, at a public offering price of $17.00 per share. The Company received net proceeds of approximately $99.9 million from the IPO, after deducting underwriters' discounts and commissions of $7.1 million and offering costs of $4.4 million, of which $1.5 million was incurred as of December 31, 2018. Prior to the completion of the IPO, all shares of Series A, A-1, B, C and D convertible preferred stock then outstanding were converted into 18,670,259 shares of common stock on a one-to-one basis.

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

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

Reverse Stock Split

In February 2019, the Company's board of directors approved an amended and restated certificate of incorporation to effect a reverse split of shares of the Company's common stock and convertible preferred stock on a 12.2-for-one basis (the "Reverse Stock Split"). The par values of the common stock and convertible preferred stock were not adjusted as a result of 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 Company'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 as of December 31, 2018, which fractional shares were settled in cash in fiscal 2019.

Need for Additional Capital

The Company has incurred significant losses and has negative cash flows from operations. As of September 30, 2019, the Company had an accumulated deficit of $163.2 million. Management expects to continue to incur additional substantial losses for the foreseeable future.

As of September 30, 2019, the Company had cash, cash equivalents and short-term investments of $114.1 million, which are available to fund future operations. The Company believes that its cash, cash equivalents and short-term investments as of September 30, 2019, will be sufficient for the Company to continue as a going concern for at least 12 months from the date the unaudited condensed consolidated financial statements are filed with the Securities and Exchange Commission ("SEC"). The Company's future capital requirements will depend on many factors, including its growth rate, the timing and extent of its spending to support research and development activities and the timing and cost of establishing additional sales and marketing capabilities.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") and applicable rules and regulations of SEC regarding interim financial reporting.

The interim condensed consolidated financial statements are unaudited. The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's consolidated financial position, results of operations and cash flows. The results of operations for the three and nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2018 included herein was derived from the audited financial statements as of that date. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the prospectus dated March 6, 2019 ("Prospectus") that forms a part of the Company's Registration Statements on Form S-1 (File No. 333-229590), as filed with the SEC pursuant to Rule 424(b)(4) promulgated under the Securities Act of 1933, as amended.

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.

Restricted cash as of September 30, 2019 and 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 condensed consolidated balance sheets.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same amounts shown in the condensed consolidated statements of cash flows:

	September 30, 2019	December 31, 2018
	(in thousands)	
Cash and cash equivalents	$ 39,452	$ 39,643
Restricted cash	450	450
Total cash, cash equivalents, and restricted cash	$ 39,902	$ 40,093

Short-Term Investments

Short-term investments have been classified as available-for-sale and are carried at estimated fair value 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 Company'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.

Fair Value of Financial Instruments

The Company's cash and cash equivalents, restricted cash, short-term investments, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to their short maturities. Management believes that its term notes bear interest at

the prevailing market rates for instruments with similar characteristics; accordingly, the carrying value of this instrument approximates its fair value.

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines the fair value of its financial instruments based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

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

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

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

Leases

The Company adopted Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842)* using the modified retrospective approach with a cumulative-effect adjustment as of January 1, 2019.

Upon adoption of Topic 842, on January 1, 2019, the Company recorded operating right-of-use assets of $2.9 million and operating lease liabilities of $3.0 million and derecognized the deferred rent liability of $0.1 million. Results for the three and nine months ended September 30, 2019 are presented under Topic 842. Prior period amounts have not been adjusted and continue to be reported in accordance with the Company's historical accounting under previous lease guidance, ASC 840: Leases (Topic 840).

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

Rent expense for the operating lease is recognized on a straight-line basis over the lease term and is included in operating expenses on the condensed consolidated statements of operations and comprehensive loss. Variable lease payments include lease operating expenses.

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

Deferred Offering Costs

Offering costs, consisting of legal, accounting, printer and filing fees related to the IPO, were deferred until the completion of the IPO. As of December 31, 2018, $1.5 million of deferred offering costs were recorded as other assets on the condensed consolidated balance sheet. In March 2019, upon the closing of the IPO, the deferred costs were offset against the Company's IPO proceeds.

Convertible Preferred Stock Warrant Liability

The Company has accounted for its freestanding warrants to purchase shares of the Company'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 Company's common stock upon the completion of a liquidation event, including the completion of the IPO, which occurred on March 11, 2019. At that time, the preferred stock warrant liability was reclassified to additional paid-in capital, a component of stockholders' equity (deficit).

Revenue

The Company records product revenue primarily from the sale of its IVL catheters. The Company sells its products to hospitals, primarily through direct sales representatives, as well as through distributors in selected international markets. Additionally, a significant portion of the Company's revenue is generated through a consignment model under which inventory is maintained at hospitals.

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 customer's named location, based on the contractual shipping terms. For consignment inventory, control is transferred at the time the IVL catheters are consumed in a procedure.

The Company 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 days' notice.

3. Financial Instruments and Fair Value Measurements

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

	September 30, 2019			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
U.S. Treasury securities	$ 58,006	$ —	$ —	$ 58,006
Money market funds	19,987	—	—	19,987
Reverse repurchase agreements	—	10,601	—	10,601
Commercial paper	—	8,562	—	8,562
Corporate bonds	—	8,078	—	8,078
Total assets	$ 77,993	$ 27,241	$ —	$ 105,234

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Money market funds	$ 21,680	$ —	$ —	$ 21,680
Total assets	$ 21,680	$ —	$ —	$ 21,680
Liabilities:				
Convertible preferred stock warrant liability	$ —	$ —	$ 313	$ 313
Total liabilities	$ —	$ —	$ 313	$ 313

There were no transfers between Levels 1, 2 or 3 for the periods presented.

The change in the fair value of the warrant liability for the nine months ended September 30, 2019 is summarized below (in thousands):

Balance at December 31, 2018	$	313
Change in fair value of warrant liability		609
Net exercise of warrants		(133)
Conversion of Series A preferred stock warrants to common stock warrants upon the closing of the IPO		(789)
Balance at September 30, 2019	$	—

The change in the fair value of the warrant liability for the nine months ended September 30, 2018 is summarized below (in thousands):

Balance at December 31, 2017	$	577
Exercise of warrants		(316)
Expiration of warrants, included in change in fair value of warrant liability		(133)
Change in fair value of warrant liability		186
Balance at September 30, 2018	$	314

The valuation of the Company's convertible preferred stock warrant liability contains unobservable inputs that reflect the Company's own assumptions for which there is little, if any, market activity for at the measurement date. Accordingly, the Company'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 condensed consolidated statements of operations and comprehensive loss.

The fair value of the warrants, which were converted to common stock warrants upon the closing of the IPO in March 2019, was determined using the Black-Scholes option pricing model and the following assumptions:

	Nine Months Ended September 30,	
	2019	**2018**
Expected term (in years)	5.28	5.71-6.21
Expected volatility	43.9%	42.8%
Risk-free interest rate	2.49%	2.62-2.85%
Expected dividend yield	0%	0%

4. Cash Equivalents and Short-Term Investments

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

	September 30, 2019			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury securities	$ 57,959	$ 47	$ —	$ 58,006
Money market funds	19,987	—	—	19,987
Reverse repurchase agreements	10,601	—	—	10,601
Commercial paper	8,562	—	—	8,562
Corporate bonds	8,068	10	—	8,078
Total	$ 105,177	$ 57	$ —	$ 105,234
Reported as:				
Cash equivalents				$ 30,588
Short-term investments				74,646
Total				$ 105,234

	December 31, 2018			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Money market funds	$ 21,680	$ —	$ —	$ 21,680
Total	$ 21,680	$ —	$ —	$ 21,680
Reported as:				
Cash equivalents				$ 21,680
Total				$ 21,680

The Company recognized no material gains or losses on its cash equivalents and short-term investments in the periods presented.

5. Balance Sheet Components

Inventory

Inventory consists of the following:

	September 30, 2019	December 31, 2018
	(in thousands)	
Raw material	$ 2,169	$ 1,084
Work in progress	850	634
Finished goods	4,451	2,313
Consigned inventory	1,757	1,100
Total inventory	$ 9,227	$ 5,131

Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2019	December 31, 2018
	(in thousands)	
Accrued employee compensation	$ 5,984	$ 3,135
Accrued research and development costs	1,844	1,115
Accrued professional services	856	1,391
Other	812	576
Total accrued liabilities	$ 9,496	$ 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 and in February 2019, the Company exercised the option to extend the lease further until September 30, 2019. The lease expired on September 30, 2019. The Company was 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 in the amount of $0.5 million, which is secured by restricted cash recorded as other assets on the condensed consolidated balance sheets. In connection with the lease, the Company has an operating lease right-of-use asset of $2.2 million as of September 30, 2019 and an aggregate lease liability of $2.2 million on its condensed consolidated balance sheet. The remaining lease term is two years and ten months.

The Company also leases vehicles for use by employees. In connection with the vehicle leases, the Company has an operating lease right-of-use asset of $47,000 as of September 30, 2019 and an aggregate lease liability of $47,000 on its condensed consolidated balance sheet. The weighted average remaining lease term is 8 months.

The weighted average incremental borrowing rate used to measure the operating lease liability is 6.93%.

Rent expense for the three months ended September 30, 2019 and 2018 was $0.3 million and $0.2 million, respectively. Rent expense for the nine months ended September 30, 2019 and 2018 was $0.9 million and $0.5 million, respectively.

Short-term leases are leases having a term of 12 months or less. The Company recognizes short-term leases on a straight-line basis and does not record a related lease asset or liability for such leases.

The following is a maturity analysis of the annual undiscounted cash flows reconciled to the carrying value of the operating lease liabilities as of September 30, 2019:

	(in thousands)
Remainder of 2019	$ 222
2020	861
2021	855
2022	581
Total minimum lease payments	$ 2,519
Less: imputed interest	(234)
Total lease liability	$ 2,285

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

Convertible Preferred Stock

Immediately prior to the closing of the Company's IPO, 18,670,259 shares of outstanding convertible preferred stock converted into 18,670,259 shares of common stock. As discussed in Note 1, the fractional shares resulting from the Reverse Stock Split, aggregating to 45 whole shares of common stock and 69 whole shares of convertible preferred stock were settled in cash in fiscal 2019.

Preferred Stock

The Company's amended and restated certificate of incorporation, which became effective upon the completion of the IPO, authorizes 5,000,000 shares of preferred stock, of which no shares were issued or outstanding as of September 30, 2019.

Preferred Stock Warrants

Upon the closing of the IPO, all of the outstanding convertible preferred stock warrants were converted into 54,903 common stock warrants, which resulted in the reclassification of the convertible preferred stock warrant liability of $0.8 million to additional paid-in capital. In April 2019, all of these common stock warrants were net exercised into 49,321 shares of common stock.

Common Stock Warrants

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

In February 2018, in connection with the execution of a Loan and Security Agreement with Silicon Valley Bank for a term loan and revolving line of credit (the "2018 Loan and Security Agreement"), the Company issued warrants to purchase shares of the Company's common stock. In April 2019, all of these common stock warrants were net exercised into 29,887 shares of common stock.

The key terms of the outstanding common stock warrants are summarized in the following table:

	Warrants Outstanding September 30, 2019	Warrants Outstanding December 31, 2018	Exercise Price	Expiration
Related party common stock warrants	—	141,778	$ 2.196	May 2025
Common stock warrants issued in connection with the 2018 Loan and Security Agreement	—	34,440	$ 4.026	February 2028
Total common stock warrants	—	176,218		

8. Stock-Based Compensation

Total stock-based compensation was as follows:

	Three Months September 30,		Nine Months September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Cost of product revenue	$ 81	$ 7	$ 156	$ 38
Research and development	307	47	582	146
Sales and marketing	288	66	597	185
General and administrative	430	169	1,001	505
Total stock-based compensation	$ 1,106	$ 289	$ 2,336	$ 874

Determination of Fair Value

The Company estimates the grant-date fair value of the Company's option awards using the Black-Scholes option pricing model. The assumptions for the Black-Scholes model for the nine months ended September 30, 2019 and 2018 were as follows:

	Nine Months Ended September 30,	
	2019	**2018**
Expected term (in years)	6.08	6.08
Expected volatility	42.4%-42.9%	40.8%-45.9%
Risk-free interest rate	2.4%-2.6%	1.9%-2.9%
Expected dividend yield	0%	0

2009 Equity Incentive Plan and 2019 Equity Incentive Plan

On June 17, 2009, the Company adopted the 2009 Equity Incentive Plan (the "2009 Plan") under which the Board had the authority to issue stock options to employees, directors and consultants.

In February 2019, the Company adopted the 2019 Stock Option and Incentive Plan (the "2019 Plan"), which became effective in connection with the IPO. As a result, effective as of March 6, 2019, the Company may not grant any additional awards under the 2009 Plan. The 2009 Plan will continue to govern outstanding equity awards granted thereunder. The Company has initially reserved 2,000,430 shares of common stock for the issuance of a variety of awards under the 2019 Plan, including stock options, stock appreciation rights, awards of restricted stock and awards of restricted stock units. In addition, the number of shares of common stock reserved for issuance under the 2019 Plan will automatically increase on the first day of January for a period of up to ten years, commencing on January 1, 2020, in an amount equal to 3% of the total number of shares of the Company's capital stock outstanding on the last day of the preceding year, or a lesser number of shares determined by the Company's board of directors. As of September 30, 2019, there were 1,470,192 shares available for issuance under the 2019 Plan.

Stock Options

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

	Number of Shares	**Weighted-Average Exercise Price Per Share**	**Weighted-Average Remaining Term**	**Aggregate Intrinsic Value**
			(in years)	**(in thousands)**
Balance, December 31, 2018	3,636,358	$ 3.54	7.79	$ 11,267
Options granted	442,858	14.69		
Options exercised	(386,309)	2.65		
Options forfeited	(34,471)	3.49		
Balance, September 30, 2019	3,658,436	$ 4.95	7.52	$ 91,399
Vested and exercisable, September 30, 2019	1,831,368	$ 3.14	6.59	$ 49,068

Restricted Stock Units

Restricted stock units ("RSUs") are share awards that entitle the holder to receive freely tradable shares of the Company's common stock upon vesting. The RSUs cannot be transferred and the awards are subject to forfeiture if the holder's employment terminates prior to the release of the vesting restrictions. The RSUs generally vest over a four-year period with straight-line vesting and a 25% one year cliff or over a three year period in equal amounts on a semi-annual basis, provided the employee remains continuously employed with the Company. The fair value of the RSUs is equal to the closing price of the Company's common stock on the grant date.

RSU activity under the 2019 Plan is set forth below:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance, December 31, 2018	—	$ —
RSUs granted	229,450	38.26
RSUs forfeited	(2,900)	37.51
Balance, September 30, 2019	226,550	$ 38.27

Employee Share Purchase Plan (ESPP)

In February 2019, the Company adopted the 2019 Employee Stock Purchase Plan ("ESPP"), which became effective as of March 6, 2019. The Company has initially reserved 300,650 shares of common stock for purchase under the ESPP. Each offering to the employees to purchase stock under the ESPP will begin on each September 1 and March 1 and will end on the following February 28 or 29 and August 30, respectively. The first offering period began on September 1, 2019 and will end on February 29, 2020. On each purchase date, which falls on the last date of each offering period, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the offering date or (2) the fair market value of the common stock on the purchase date. The occurrence and duration of offering periods under the ESPP are subject to the determinations of the Company's Compensation Committee, in its sole discretion.

The fair value of the ESPP shares is estimated using the Black-Scholes option pricing model. The Company recorded $64,000 of stock-based compensation expense related to the ESPP for the three and nine months ended September 30, 2019.

9. 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 periods presented due to their anti-dilutive effect:

	September 30,	
	2019	2018
	(in thousands)	
Convertible preferred stock on an as-converted basis	—	17,579,720
Common stock options issued and outstanding	3,658,436	3,313,257
Restricted stock units	226,550	—
Early exercised options subject to future vesting	—	21,620
Convertible preferred stock warrants	—	54,903
Common stock warrants	—	176,218
Total	3,884,986	21,145,718

10. Segment and Geographic Information

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
United States	$ 6,246	$ 2,053	$ 15,054	$ 4,476
Germany	873	439	2,389	958
Rest of Europe	3,428	995	9,473	1,597
All other countries	786	113	1,699	170
Product revenue	$ 11,333	$ 3,600	$ 28,615	$ 7,201

As of September 30, 2019 and December 31, 2018, the Company's long-lived assets are all held in the United States with the exception of certain equipment on loan to customers held internationally, which was not material as of each period end.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes thereto for the year ended December 31, 2018, included in our prospectus dated March 6, 2019 (the "Prospectus"), as filed with the Securities and Exchange Commission (the "SEC"), pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, (the "Securities Act"), relating to our Registration Statement on Form S-1 (File No. 333-229590).

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"). In some cases, you can identify these statements by forward-looking words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in this Quarterly Report on Form 10-Q. The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. Except as may be required by law, we assume no obligation to update these forward-looking statements or the reasons that results could differ from these forward-looking statements. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

Overview

We are a medical device company focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. We aim to establish a new standard of care for medical device treatment of atherosclerotic cardiovascular disease through our differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which we refer to as intravascular lithotripsy ("IVL"). Our IVL system (our "IVL System"), which leverages our IVL technology (our "IVL Technology"), is a minimally invasive, easy-to-use and safe way to significantly improve patient outcomes. Our Shockwave M5 IVL catheter ("M5 catheter") was CE-Marked in April 2018 and cleared by the U.S. Food and Drug Administration ("FDA") in July 2018 for use in our IVL System for the treatment of peripheral artery disease ("PAD"). Our Shockwave C2 IVL catheter ("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 coronary artery disease ("CAD"). In August 2019, we received the Breakthrough Device Designation from the FDA for our C2 catheters using our IVL System for the treatment of CAD. The second version of our Shockwave S4 IVL catheter ("S4 catheter") was cleared by the FDA in August 2019. We also have ongoing clinical programs across several products and indications, which, if successful, will allow us to expand commercialization of our products into new geographies and indications. Importantly, we are undertaking ongoing clinical trials of our C2 catheter intended to support a pre-market application ("PMA") in the United States and a Shonin submission in Japan for the treatment of CAD. In October 2018, we received staged 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. 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 first half of 2022.

The first two indications we are targeting with our IVL System are PAD, the narrowing or blockage of vessels that carry blood from the heart to the extremities, and CAD, the narrowing or blockage of the arteries that supply blood to the heart. In the future, we see significant opportunity in the potential treatment of aortic stenosis ("AS"), a condition where the heart's aortic valve becomes increasingly calcified with age, causing it to narrow and obstruct blood flow from the heart.

We have adapted the use of lithotripsy to the cardiovascular field with the aim of creating what we believe can become the safest, most effective means of addressing the growing challenge of cardiovascular calcification. Lithotripsy has been used to successfully treat kidney stones (deposits of hardened calcium) for over 30 years. By integrating lithotripsy into a device that resembles a standard balloon catheter, physicians can prepare, deliver and treat calcified lesions using a familiar form factor, without disruption to their standard procedural workflow. Our differentiated IVL System works by delivering shockwaves through the entire depth of the artery wall, modifying calcium in the medial layer of the artery, not just at the superficial most intimal layer. The shockwaves crack this calcium and enable the stenotic artery to expand at low pressures, thereby minimizing complications inherent to traditional balloon dilations, such as dissections or tears. Preparing the vessel with IVL facilitates optimal outcomes with other therapies, including stents and drug-eluting technologies. Using IVL also avoids complications associated with atherectomy devices such as dissection, perforation and embolism. When followed by an anti-proliferative therapy such as a drug-coated balloons ("DCB") or drug-eluting stents ("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.

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 more than 35 countries. 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 three months ended September 30, 2019 and 2018, we generated product revenue of $11.3 million and $3.6 million, respectively, and a loss from operations of $13.1 million and $10.1 million, respectively. For the three months ended September 30, 2019 and 2018, 45% and 43%, respectively, of our product revenue was generated from customers located outside of the United States.

For the nine months ended September 30, 2019 and 2018, we generated product revenue of $28.6 million and $7.2 million, respectively, and a loss from operations of $36.5 million and $30.1 million, respectively. For the nine months ended September 30, 2019 and 2018, 47% and 38%, respectively, of our product revenue was generated from customers located outside of the United States.

Initial Public Offering

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

Components of Our Results of Operations

Product revenue

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

We sell our products to hospitals, primarily through direct sales representatives, as well as through distributors in selected international markets. For products sold through direct sales representatives, control is transferred upon delivery to customers. For products sold to distributors internationally and certain customers that purchase stocking orders in the United States, control is transferred upon shipment or delivery to the customer's named location, based on the contractual shipping terms. Additionally, a 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 the 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 ("R&D") expenses consist of applicable personnel, consulting, materials and clinical trial expenses. R&D expenses include:

- certain personnel-related expenses, including salaries, benefits, bonus, travel and stock-based compensation;

- cost of clinical studies to support new products and product enhancements, including expenses for clinical research organizations ("CROs") and site payments;
- materials and supplies used for internal R&D and clinical activities;
- allocated overhead including facilities and information technology expenses; and
- cost of outside consultants who assist with technology development, regulatory affairs, clinical affairs and quality assurance.

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

Sales and marketing expenses

Sales and marketing expenses consist of personnel-related expenses, including salaries, benefits, sales commissions, travel and stock-based compensation. Other sales and marketing expenses consist of marketing and promotional activities, including trade shows and market research. We expect to continue to grow our sales force and increase marketing efforts as we continue commercializing products based on our IVL Technology. As a result, we expect sales and marketing expenses to increase in absolute dollars 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 consist of professional services fees, including legal, audit and tax fees, insurance costs, outside consultant fees and employee recruiting and training costs. Moreover, we expect to incur additional expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance and investor relations. As a result, we expect general and administrative expenses to increase in absolute dollars in future periods.

Results of Operations

Comparison of the Three Months Ended September 30, 2019 and 2018

The following table shows our results of operations for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,			
	2019	2018	Change $	Change %
	(in thousands, except percentages)			
Revenue:				
Product revenue	$ 11,333	$ 3,600	$ 7,733	215%
Operating expenses:				
Cost of product revenue	4,401	1,973	2,428	123%
Research and development	8,368	5,533	2,835	51%
Sales and marketing	8,192	4,801	3,391	71%
General and administrative	3,437	1,369	2,068	151%
Total operating expenses	24,398	13,676	10,722	78%
Loss from operations	(13,065)	(10,076)	(2,989)	30%
Interest expense	(251)	(158)	(93)	59%
Change in fair value of warrant liability	—	(104)	104	(100)%
Other income, net	385	166	219	132%
Net loss before taxes	(12,931)	(10,172)	(2,759)	27%
Income tax provision	26	6	20	333%
Net loss	$ (12,957)	$ (10,178)	$ (2,779)	27%

Product revenue

Product revenue increased by $7.7 million, or 215%, from $3.6 million during the three months ended September 30, 2018 to $11.3 million during the three months ended September 30, 2019. The increase was primarily due to an increase in the number of customers and an increase in purchase volume of our products both within the United States and internationally. We sold to a greater number of customers in the United States and to a greater number of distributors internationally for the three months ended September 30, 2019 as compared to the three months September 30, 2018.

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 $6.2 million within the United States and $5.1 million for all other countries in the three months ended September 30, 2019 compared to $2.1 million within the United States and $1.5 million for all other countries in the three months ended September 30, 2018.

Cost of product revenue and gross margin percentage

Cost of product revenue increased by $2.4 million, or 123%, from $2.0 million during the three months ended September 30, 2018 to $4.4 million during the three months ended September 30, 2019. The increase was primarily due to growth in sales volume. Gross margin percentage improved to 61.2% for the three months ended September 30, 2019, compared to 45.2% for the three months ended September 30, 2018. This change in gross margin percentage was primarily due to lower fixed costs per unit from increased sales volume of our IVL catheters and increased efficiencies from improvements to operations and production.

Research and development expenses

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

	Three Months Ended September 30,	
	2019	2018
	(in thousands)	
Compensation and personnel-related costs	$ 3,316	$ 2,574
Clinical-related costs	3,526	1,341
Material and supplies	580	597
Facilities and other allocated costs	494	540
Outside consultants	340	324
Other research and development costs	112	157
Total research and development expenses	$ 8,368	$ 5,533

R&D expenses increased by $2.8 million, or 51%, from $5.5 million during the three months ended September 30, 2018 to $8.4 million during the three months ended September 30, 2019. The change was primarily due to a $2.2 million increase in clinical-related costs and a $0.7 million increase in compensation and personnel-related costs to support clinical trials. Clinical-related costs during the three months ended September 30, 2019 were primarily related to the CAD III and CAD IV clinical trials.

Sales and marketing expenses

Sales and marketing expenses increased by $3.4 million, or 71%, from $4.8 million during the three months ended September 30, 2018 to $8.2 million during the three months ended September 30, 2019. The change was primarily due to a $2.7 million increase in compensation and personnel-related costs, which included a $1.1 million increase in commission expense, as a result of increased headcount and increased sales of our products. Marketing and promotional expenses increased by $0.4 million to support the commercialization of our products.

General and administrative expenses

General and administrative expenses increased by $2.1 million, or 151%, from $1.4 million during the three months ended September 30, 2018 to $3.4 million during the three months ended September 30, 2019. The change was primarily due to a $0.5 million increase in professional services and general corporate expenses incurred in connection with becoming a public company, a $0.6 million increase in legal fees, a $0.7 million increase in compensation and personnel-related costs, and a $0.2 million increase in costs associated with outside consultants.

Comparison of the Nine Months Ended September 30, 2019 and 2018

The following table shows our results of operations for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,		Change	Change
	2019	2018	$	%
	(in thousands, except percentages)			
Revenue:				
Product revenue	$ 28,615	$ 7,201	$ 21,414	297%
Operating expenses:				
Cost of product revenue	11,606	3,946	7,660	194%
Research and development	22,778	16,579	6,199	37%
Sales and marketing	21,023	12,611	8,412	67%
General and administrative	9,684	4,137	5,547	134%
Total operating expenses	65,091	37,273	27,818	75%
Loss from operations	(36,476)	(30,072)	(6,404)	21%
Interest expense	(746)	(216)	(530)	245%
Change in fair value of warrant liability	(609)	(53)	(556)	1,049%
Other income, net	1,518	489	1,029	210%
Net loss before taxes	(36,313)	(29,852)	(6,461)	22%
Income tax provision	51	27	24	89%
Net loss	$ (36,364)	$ (29,879)	$ (6,485)	22%

Product revenue

Product revenue increased by $21.4 million, or 297%, from $7.2 million during the nine months ended September 30, 2018 to $28.6 million during the nine months ended September 30, 2019. The change was primarily due to an increase in the number of customers and an increase in purchase volume of our products both within the United States and internationally. We sold to a greater number of customers in the United States and to a greater number of distributors internationally for the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018.

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 $15.1 million within the United States and $13.5 million for all other countries in the nine months ended September 30, 2019 compared to $4.5 million within the United States and $2.7 million for all other countries in the nine months ended September 30, 2018.

Cost of product revenue and gross margin percentage

Cost of product revenue increased by $7.7 million, or 194% from $3.9 million during the nine months ended September 30, 2018 to $11.6 million during the nine months ended September 30, 2019. The increase was primarily due to growth in sales volume. Gross margin percentage improved to 59.4% for the nine months ended September 30, 2019, compared to 45.2% for the nine months ended September 30, 2018. This change in gross margin percentage was primarily due to lower fixed costs per unit from increased sales volume of our IVL catheters and increased efficiencies from improvements to operations and production.

Research and development expenses

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

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Compensation and personnel-related costs	$ 9,202	$ 8,043
Clinical-related costs	8,515	3,875
Material and supplies	1,546	1,847
Facilities and other allocated costs	1,769	1,205
Outside consultants	1,130	1,019
Other research and development costs	616	590
Total research and development expenses	$ 22,778	$ 16,579

R&D expenses increased by $6.2 million, or 37%, from $16.6 million during the nine months ended September 30, 2018 to $22.8 million during the nine months ended September 30, 2019. The increase was primarily due to a $4.6 million increase in clinical-related costs and a $1.2 million increase in compensation and personnel-related costs to support clinical trials. Clinical-related costs during the nine months ended September 30, 2019 were primarily related to the CAD II, CAD III and CAD IV clinical trials. There was also a $0.6 million increase in facilities and other allocated costs due to increased rent and building expenditures. These increases were partially offset by a $0.3 million decrease in materials and supplies for R&D.

Sales and marketing expenses

Sales and marketing expenses increased by $8.4 million, or 67%, from $12.6 million during the nine months ended September 30, 2018 to $21.0 million during the nine months ended September 30, 2019. The increase was primarily due to a $6.9 million increase in compensation and personnel-related costs, which included a $1.3 million increase in commission expense, as a result of a higher headcount and increased sales of our products. Marketing and promotional expenses increased by $1.2 million to support the commercialization of our products.

General and administrative expenses

General and administrative expenses increased by $5.5 million, or 134%, from $4.1 million during the nine months ended September 30, 2018 to $9.7 million during the nine months ended September 30, 2019. The change was primarily due to a $1.8 million increase in professional services and general corporate expenses incurred in connection with our preparation to become a public company and our operations as a public company, a $1.6 million increase in compensation and personnel-related costs, a $1.3 million increase in legal fees, and a $0.8 million increase in costs associated with outside consultants.

Liquidity and Capital Resources

To date, our principal sources of liquidity have been the net proceeds we received through the sale of our common stock in our IPO, private sales of our equity securities, and payments received from customers using our products. On March 11, 2019, we completed our IPO, including the underwriters full exercise of their over-allotment option, selling 6,555,000 shares of our common stock at $17.00 per share. Upon completion of our IPO, we received net proceeds of $99.9 million, after deducting underwriting discounts and commissions and offering expenses. Concurrent with the IPO, we issued 588,235 shares of common stock in our Private Placement for net proceeds of $10.0 million.

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 (the “2018 Loan and Security Agreement”). The 2018 Loan and Security Agreement 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. 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 “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources”. We had $15.0 million outstanding under the term loan and no amounts outstanding under the revolving line of credit as of September 30, 2019.

We believe that our cash, cash equivalents and short-term investments as of September 30, 2019 will be sufficient to fund our operations for at least the next 12 months from the date of this filing. As of September 30, 2019, we had $114.1 million in cash, cash equivalents and short-term investments and an accumulated deficit of $163.2 million.

We have a number of ongoing clinical trials, and expect to continue to make substantial investments in these trials and in additional clinical trials that are designed to provide clinical evidence of the safety and efficacy of our products. We intend to continue to make significant investments in our sales and marketing organization by increasing the number of U.S. sales representatives and expanding our international marketing programs to help facilitate further adoption among existing hospital accounts and physicians as well as broaden awareness of our products to new hospitals. We also expect to continue to make investments in R&D, regulatory affairs and clinical studies to develop future generations of products based on our IVL Technology, support regulatory submissions and demonstrate the clinical efficacy of our products. Moreover, we expect to 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:

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales from our current and potential products;
- the degree of success we experience in commercializing our products;
- the emergence of competing or complementary technologies;
- the cost of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Cash Flows

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

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Cash used in operating activities	$ (35,536)	$ (31,651)
Cash (used in) provided by investing activities	(76,334)	677
Cash provided by financing activities	111,679	10,489
Net decrease in cash, cash equivalents and restricted cash	$ (191)	$ (20,485)

Operating activities

During the nine months ended September 30, 2019, cash used in operating activities was $35.5 million, attributable to a net loss of $36.4 million and a net change in our net operating assets and liabilities of $3.5 million, partially offset by non-cash charges of $4.4 million. Non-cash charges primarily consisted of $2.3 million in stock-based compensation, $0.9 million in depreciation and amortization, $0.7 million in amortization of right-of-use assets, $0.6 million in change in fair value of warrant liability, $0.3 million in amortization of debt issuance costs and $0.1 million in loss on write down of fixed assets, partially offset by $0.5 million in accretion of discount on available-for-sale securities. The change in our net operating assets and liabilities was primarily due to a $4.1 million increase in inventory and $2.7 million increase in accounts receivable due to an increase in sales, a $1.1 million increase in prepaid expenses and other current assets and a $0.7 million decrease in lease liabilities. These changes were partially offset by a $5.1 million increase in accrued and other current liabilities and accounts payable resulting primarily from expansion in our operating activities and accrued professional services fees.

During the nine months ended September 30, 2018, cash used in operating activities was $31.7 million, attributable to a net loss of $29.9 million and a net change in our net operating assets and liabilities of $3.3 million, partially offset by non-cash charges of $1.5 million. Non-cash charges primarily consisted of $0.9 million in stock-based compensation, $0.5 million in depreciation and $0.1 million in amortization of debt issuance costs. The change in our net operating assets and liabilities was primarily due to a $2.7 million increase in inventory for anticipated growth in our business and a $2.0 million increase in accounts receivable due to increase in sales. These changes were partially offset by a $1.5 million increase in accrued and other current liabilities and accounts payable resulting primarily from increases in our operating activities.

Investing activities

During the nine months ended September 30, 2019, cash used in investing activities was $76.3 million, attributable to the purchase of available-for-sale securities of $106.3 million and purchase of property and equipment of $2.3 million, partially offset by proceeds from maturities of available-for-sale investments of $32.3 million.

During the nine months ended September 30, 2018, cash provided by investing activities was $0.7 million, attributable to maturity of available-for-sale investments of $1.8 million, partially offset by purchase of property and equipment of $1.1 million.

Financing activities

During the nine months ended September 30, 2019, cash provided by financing activities was $111.7 million, attributable to net proceeds of $100.5 million from the IPO, net proceeds of $10.0 million from the Private Placement of our common stock and proceeds of $1.1 million from stock option exercises and $0.1 million from warrant exercises.

During the nine months ended September 30, 2018, cash provided by financing activities was $10.5 million, attributable to net proceeds of $10.0 million from term notes, $0.4 million from stock option exercises and $0.1 million from warrant exercises.

Contractual Obligations and Commitments

During the nine months ended September 30, 2019, there have been no material changes to our contractual obligations from those disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the Prospectus.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

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

During the nine months ended September 30, 2019, there were no material changes to our critical accounting policies or in the methodology used for estimates from those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the Prospectus.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest rate risk

Our cash, cash equivalents and short-term investments as of September 30, 2019 consisted of $114.1 million in bank deposits, money market funds and available-for-sale securities. 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 September 30, 2019, we had $15.4 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% (3.25% as of September 30, 2019).

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 nine months ended September 30, 2019 and 2018, approximately 28% and 24% 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 $0.8 million and $0.2 million in foreign currency cash and accounts receivable as of September 30, 2019 and December 31, 2018, respectively. As our operations in countries outside of the United States grow, our results of operations and cash flows may be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any material foreign currency hedging contracts, although we may do so in the future.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures.

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in internal control over financial reporting.

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control.

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Petitions for *inter partes* review ("IPR") of U.S. Pat. Nos. 9,642,673, 8,956,371 and 8,728,091 (the "IPR Patents"), which are three of our issued U.S. patents that relate to our current IVL Technology, were filed in December 2018 at the USPTO's Patent Trial and Appeal Board (the "PTAB") by Cardiovascular Systems, Inc., one of our competitors. The PTAB has decided to institute IPR proceedings for all three patents. Scheduled deadlines for each IPR start with our responses to the petitions due in November 2019, and end with an optional oral hearing on April 16, 2020. The PTAB is expected to issue a decision in each IPR by July 2020. The IPR proceedings could result in the loss or narrowing in scope of the IPR Patents, which could limit our ability to stop others from using or commercializing products and technology similar or identical to ours. For more information regarding the risks presented by such proceedings, please see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

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

Item 1A. Risk Factors.

Certain factors may have a material adverse effect on our business, financial condition, and results of operations. You should carefully consider the following risks, together with all of the other information contained in this Quarterly Report on Form 10-Q, including the sections titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q. Any of the following risks could have an adverse effect on our business, financial condition, operating results, or prospects and could cause the trading price of our common stock to decline, which would cause you to lose all or part of your investment. Our business, financial condition, operating results, or prospects could also be harmed by risks and uncertainties not currently known to us or that we currently do not believe are material.

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. For the nine months ended September 30, 2019 and 2018, we reported net losses of $36.4 million and $29.9 million, respectively. We reported net losses of $41.1 million and $30.6 million for the years ended December 31, 2018 and 2017, respectively. As a result of these losses, as of September 30, 2019, we had an accumulated deficit of approximately $163.2 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 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 M^5 catheter for treating PAD in the United States and Europe in 2018 and our C^2 catheter for treating CAD in Europe in 2018. We initiated a limited launch of our S^4 catheter in the first half of 2019 and expect to commence a full launch in the United States in the fourth quarter of 2019. Our C^2 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 TAVR feasibility clinical trials and obtain FDA pre-market approval for, and successfully commercialize, our C^2 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 IVL Technology. If we are unable to successfully market and sell products incorporating our IVL Technology, our business prospects will be significantly harmed and we may be unable to achieve revenue growth.

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

- the actual and perceived effectiveness and reliability of our products, especially relative to alternative products;
- the prevalence and severity of any adverse patient events involving our products;
- the results of clinical trials relating to the use of our products;
- our ability to sustain meaningful clinical benefits for our patients;
- our ability to obtain regulatory approval to market our planned or future products for use in treating PAD, CAD and AS in the United States;
- the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for conditions treated by our products;
- the degree to which treatments using our products are covered and receive adequate reimbursement from third-party payors, including governmental and private insurers;
- the degree to which physicians adopt our products;
- our ability to obtain, maintain, protect and enforce our intellectual property rights in and to our IVL Technology and our products that incorporate our IVL Technology;
- our ability to treat medial calcium and sustain a meaningful clinical benefit better than our competitors and alternative treatments or therapies;
- achieving and maintaining compliance with all regulatory requirements applicable to our products;
- the extent to which we are successful in educating physicians about PAD, CAD and AS in general, and the benefits of our products in treating such conditions;
- the strength of our marketing and distribution infrastructure;
- the effectiveness of our and our distributors' marketing and sales efforts in the United States and abroad, including our efforts to build out our sales team;
- the level of education and awareness among physicians and hospitals concerning our products;
- our reputation among physicians and hospitals;
- our ability to continue to develop, validate and maintain a commercially viable manufacturing process that is compliant with current Good Manufacturing Practices ("cGMP") and Quality Systems Regulations ("QSR"); and
- whether we are required by the FDA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for future or current indications.

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

We 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 M^5 catheters for the treatment of above-the-knee PAD in the United States and internationally and C^2 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 industry's relationship with physicians is under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General (the "OIG"), the U.S. Department of Justice (the "DOJ"), the state attorney generals and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry's relationships with physicians or an investigation into our compliance by the OIG, the DOJ, state attorney generals and other government agencies, could have a material adverse effect on our business, financial condition and results of operations. Additional information regarding the laws impacting our relationships with physicians and other healthcare professionals can be found below under "Risks Related to Government Regulation and Our Industry."

We 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 $11.3 million and $3.6 million for the three months ended September 30, 2019 and 2018, respectively and $28.6 million and $7.2 million for the nine months ended September 30, 2019 and 2018, respectively. Our sales were $12.3 million and $1.7 million for the years ended December 31, 2018 and 2017, respectively. We launched our M^5 catheters for the treatment of PAD in the United States, Europe and select other countries in 2018, we launched our C^2 catheters for the treatment of CAD in Europe in 2018, and we expect to launch our C^2 catheters for the treatment of CAD in the United States in the first half of 2021, subject to FDA approval. We initiated a limited launch of our S^4 catheter in the first half of 2019 and expect to commence a full launch in the United States in the fourth quarter of 2019. 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:

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

For example, in July 2018, we initiated and subsequently completed a voluntary recall of our S^4 catheters after seeing a higher instance of leaks in the balloon, which prevented the balloon from staying inflated at four atmospheres (“atm”) for the full course of lithotripsy application. Although there were no patient safety issues reported and no reports of adverse clinical events related to this issue, and the issue has been corrected, customer satisfaction problems early in a product’s launch can have lasting negative impact on our ability to sell such product. We have also proceeded with a limited launch of our S^4 catheter in the United States in the first half of 2019. However, we cannot guarantee that issues with our S^4 catheters will not resurface. Any future government or voluntary recalls of our S^4 catheter could divert managerial and financial resources, harm our reputation and adversely affect our business.

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

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

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

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

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete or plan to compete with manufacturers and distributors of cardiovascular medical devices. 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:

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

We believe that our proprietary IVL Technology, our focus on calcified cardiovascular disease and our organizational culture and strategy, will be important factors in our future success. We compete primarily on the basis that our products treat patients with calcified cardiovascular disease safely and effectively, with improved outcomes and procedural cost savings. Our continued success depends on our ability to:

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

In addition, competitors with greater financial resources than ours could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing products, which may cause our revenue to decline and would harm our business.

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

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

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the level of demand for our products and any approved products, which may vary significantly;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- the timing and cost of obtaining regulatory approvals or clearances for planned or future products or indications;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners;

- coverage and reimbursement policies with respect to our products, if approved, and potential future products that compete with our products;
- the timing and success or failure of preclinical studies or clinical trials for our products or any future products we develop or competing products;
- the timing of customer orders or medical procedures using our products and the number of available selling days in any quarterly period, which can be impacted by holidays, the mix of products sold and the geographic mix of where products are sold;
- seasonality, including the seasonal slowing of demand for our products we have experienced in the fourth quarter and summer months based on the elective nature of procedures performed using our products, and which we expect to become more pronounced in the future as our business grows;
- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our products, which may change from time to time;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers; and
- future accounting pronouncements or changes in our accounting policies.

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

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

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 M^5 and S^4 catheters for the treatment of calcified plaque in patients with PAD in the United States and international markets and our C^2 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. 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:

- 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;
- 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;
- trial results may not meet the level of statistical significance required by the FDA or other regulatory authorities;
- the FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans;
- the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;

- there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities;
- there may be delays in obtaining institutional review board approvals or governmental approvals to conduct clinical trials at prospective sites;
- the FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory;
- 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;
- we may have trouble in managing multiple clinical sites;
- we may have trouble finding patients to enroll in our trials;
- 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
- 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:

- the FDA or other regulators disagreeing as to the design, protocol or implementation of our clinical trials;
- the delay or refusal of regulators or institutional review boards ("IRBs") to authorize us to commence a clinical trial at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective clinical research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials to observe statistically significant treatment effects in the trial;
- having clinical sites deviate from the trial protocol or dropping out of a trial;
- 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;
- 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;
- reports from preclinical or clinical testing of other similar therapies that raise safety or efficacy concerns;
- 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;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- 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;
- delays relating to adding new clinical trial sites;

- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- the quality of the products falling below acceptable standards;
- the inability to manufacture sufficient quantities of our products to commence or complete clinical trials; and
- 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 FDA's current Good Clinical Practice ("GCP"), 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 "off-label" use. We cannot prevent a physician from using our products for off-label use, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, we are not allowed to actively promote or advertise our products for off-label uses. In addition, we cannot make comparative claims regarding the use of our products against any alternative treatments without conducting head-to-head comparative clinical studies, which would be expensive and time-consuming. If the FDA determines that our promotional, reimbursement or training materials for sales representatives or physicians constitute promotion of an off-label use, the FDA could request that we modify our training, promotional or reimbursement materials and/or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, disgorgement of profits, significant penalties, including civil fines and criminal penalties. Other federal, state or foreign governmental authorities also might take action if they consider our promotion, reimbursement or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Although we train our sales force not to promote our products for off-label uses, and our instructions for use in all markets specify that our products are not intended for use outside of those indications cleared or approved for use, the FDA or another regulatory agency could conclude that we have engaged in off-label promotion. For example, the government may take the position that off-label promotion resulted in inappropriate reimbursement for an off-label use in violation of the federal civil False Claims Act for which it might impose significant civil fines and even pursue criminal action. In those possible events, our reputation could be damaged and adoption of the products would be impaired.

We currently require limited training in the use of our products incorporating our IVL Technology 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.

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 equity securities and, to a lesser extent, product revenue. As of September 30, 2019, we had $114.1 million in cash, cash equivalents and short-term investments, and an accumulated deficit of $163.2 million. Based on our current planned operations, we expect our cash, cash equivalents and short-term investments will enable us to fund our operating expenses for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

We have a number of ongoing clinical trials, and expect to continue to make substantial investments in these trials and in additional clinical trials that are designed to provide clinical evidence of the safety and efficacy of our products. We 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:

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales from our current and potential products;
- the degree of success we experience in commercializing our products;
- the emergence of competing or complementary technologies;
- the cost of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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

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.

Our Loan and Security Agreement with Silicon Valley Bank (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. In April 2019, all of these common stock warrants were net exercised into 29,887 shares of common stock. 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources."

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.

The report of our independent registered public accounting firm for the year ended December 31, 2018 includes a "going concern" 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 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 "key man" insurance policies on the lives of these individuals or the lives of any of our other employees.

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

As of September 30, 2019, we had 260 full-time employees worldwide. We have significantly expanded the size of our organization over the past three years, particularly in the number of sales and marketing personnel, and expect to do so in the future. As our sales and marketing strategies develop and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

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

We 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 47% of our revenue for the nine months ended September 30, 2019. We intend to increase our sales outside the United States, and our C^2 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:

- differing regulatory requirements in foreign countries;
- differing reimbursement regimes in foreign countries, including price controls;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses, reduced revenue and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended (the “FCPA”), or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- product shortages resulting from any events affecting raw material or finished good supply or distribution or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

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

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

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

Our future growth may depend, in part, on our ability to develop and commercialize our planned and future products in foreign markets. We are not permitted to market or promote any of our planned or future products before we receive regulatory approval from

applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our planned or future products. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our planned or future products. If we obtain regulatory approval of our products and ultimately commercialize our planned or future products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of medical devices in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses, reduced revenue and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, typhoons, floods and fires.

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

We partner with distributors for our products in select geographies outside of the United States. Specifically, in as of September 30, 2019 we have sold to distributors located in Europe, Canada, Asia, South Africa, Middle East, Australia and New Zealand. For the nine months ended September 30, 2019, approximately 47% 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 "U.K. Bribery Act") 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:

- decreased demand for our products;
- injury to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to market and sell our products.

We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses and reduce product sales.

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

Litigation and other legal proceedings may adversely affect our business.

From time to time we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

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

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing and inventory management. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. We could be subject to an unintentional event that involves a third party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data or result in release of our confidential information. We address these data security concerns in more detail below. Technological interruptions would disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability use our products for treatments. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition and results of operations. Currently, we carry business interruption coverage to mitigate certain potential losses but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy limits. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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 ("Anti-Kickback Statute") and federal civil False Claims Act. There are similar laws in other countries. Our relationships and our distributors' 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:

- the Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. In addition, the government may assert that a claim, including items or services resulting from a violation of the Anti-Kickback Statute, constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The Anti-Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the Anti-Kickback Statute; however, those exceptions and safe harbors are drawn narrowly, and there may be limited or no exception or safe harbor for many common business activities, such as reimbursement support programs, educational and research grants or charitable donations. Practices that involve remuneration to those who prescribe, purchase or recommend medical devices, including discounts, providing items or services for free or engaging such individuals as consultants, advisors or speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor and would be subject to a facts and circumstances analysis to determine compliance with the Anti-Kickback Statute. Our practices, such as the loan, consignment, or purchase of certain components of our IVL System to customers, may not in all cases meet all of the criteria for statutory exception or regulatory safe harbor protection from anti-kickback liability. In October 2019, the federal government published two proposed regulations that would create new safe harbors for (among other things) certain value-based arrangements and patient engagement tools, and modify and clarify the scope of existing safe harbors for warranties and personal service agreements; even if it is finalized, the impact of the proposed regulation on our operations is not yet clear.

- federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which prohibits, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Actions under the federal civil False Claims Act may be brought by the government or as a *qui tam* action by a private individual in the name of the government. These individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial financial settlements with the federal government under the federal civil False Claims Act for a variety of alleged improper activities, including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non-reimbursable uses and interactions with prescribers and other customers, including those that may have affected their billing or coding practices and submission of claims to the federal government. Federal civil False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory monetary penalties for each false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and medical device companies often resolve allegations 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.
- 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;
- 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;
- the federal Physician Payments Sunshine Act, also known as Open Payments, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions to the Centers for Medicare & Medicaid Services ("CMS"), information related to payments or other "transfers of value" made to physicians and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state beneficiary inducement laws, which are state laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018 ("BBA") 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 HIPAA's healthcare fraud and privacy provisions.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors 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 customers' 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 management's attention from the operation of our business. Companies settling federal civil False Claims Act, Anti-Kickback Statute or civil monetary penalties law cases also may be required to enter into a Corporate Integrity Agreement with the OIG in order to avoid exclusion from participation (i.e., loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs on companies to ensure compliance. Defending against any such actions can be costly, time-consuming and may require significant personnel resources, and may have a material adverse effect on our business, financial condition and results of operations.

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

Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

The FDA and similar agencies regulate our products as medical devices. Complying with these regulations is costly, time-consuming, complex and uncertain. For instance, before a new medical device, or a new intended use for, an existing device can be marketed in the United States, a company must first submit and receive either 510(k) clearance or approval of a PMA from the FDA, unless an exemption applies.

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

- product design, development, manufacture (including suppliers) and testing;
- laboratory, preclinical and clinical studies;
- product safety and effectiveness;
- product labeling;
- product storage and shipping;
- record keeping;
- pre-market clearance or approval;
- marketing, advertising and promotion;
- product sales and distribution;
- product changes;
- product recalls; and
- post-market surveillance and reporting of deaths or serious injuries and certain malfunctions.

Our current products are subject to extensive regulation by the FDA and non-U.S. regulatory agencies. Further, all of our potential products and improvements of our current products will be subject to extensive regulation and will likely require permission from regulatory agencies and ethics boards to conduct clinical trials and clearance or approval from the FDA and non-U.S. regulatory agencies prior to commercial sale and distribution. Failure to comply with applicable U.S. requirements regarding, for example, promoting, manufacturing or labeling our products, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

The FDA can also refuse to clear or approve pending applications. Any enforcement action by the FDA and other comparable non-U.S. regulatory agencies could have a material adverse effect on our business, financial condition and results of operations.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement or refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

If any of these events were to occur, it would have a material and adverse effect on our business, financial condition and results of operations.

We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained 510(k) clearance to market our M[5] and S[4] catheters, our clearance can be revoked if safety or efficacy problems develop.

The FDA also regulates the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

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

Medical devices regulated by the FDA are subject to "general controls" which include: registration with the FDA; listing commercially distributed products with the FDA; complying with cGMPs under QSR; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting certain device field removals and corrections to the FDA; and obtaining pre-market notification 510(k) clearance for devices prior to marketing. Some devices known as "510(k)-exempt" devices can be marketed without prior marketing-clearance or approval from the FDA. In addition to the "general controls," some Class II medical devices are also subject to "special controls," including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510(k) clearance, most Class III devices are subject to PMA. Our C[2] 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 management's attention from their regular duties, any of which may have a material and adverse effect on our business, financial condition and results of operations, and may result in greater and continuing governmental scrutiny of our business in the future.

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 "substantial equivalence," a PMA requires that the applicant demonstrate reasonable assurance that the device is safe and effective by producing valid scientific evidence, including data from preclinical studies and human clinical trials. Therefore, to obtain regulatory clearance or approvals, we typically must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to their satisfaction that our products satisfy the criteria for approval. Preclinical testing and clinical trials must comply with the regulations of the FDA and other government authorities in the United States and similar agencies in other countries.

We may be required to obtain PMAs, PMA supplements or additional 510(k) pre-market clearances to market modifications to our existing products. The FDA requires device manufacturers to make and document a determination of whether a modification

requires approval or clearance; however, the FDA can review a manufacturer's decision. The FDA may not agree with our decisions not to seek approvals or clearances for particular device modifications. If the FDA requires us to obtain PMAs, PMA supplements or pre-market clearances for any modification to a previously cleared or approved device, we may be required to cease manufacturing and marketing of the modified device and perhaps also to recall such modified device until we obtain FDA clearance or approval. We may also be subject to significant regulatory fines or penalties.

The FDA may not approve our current or future PMA applications or supplements or clear our 510(k) applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business, financial condition and results of operations.

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

International regulatory approval processes may take more or less time than the FDA clearance or approval process. If we fail to comply with applicable FDA and comparable non-U.S. regulatory requirements, we may not receive regulatory clearances or approvals or may be subject to FDA or comparable non-U.S. enforcement actions. We may be unable to obtain future regulatory clearance or approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. A failure or delay in obtaining necessary regulatory clearances or approvals would materially adversely affect our business, financial condition and results of operations.

Although we have obtained regulatory clearance for our M5 and S4 catheters for the treatment of PAD in the United States, and our M5 and S4 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 and S4 catheters for the treatment of PAD have obtained regulatory clearance in the United States, and our M5 and S4 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) or PMA application. Accordingly, we continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory clearances or approvals that we have received for our products will be subject to limitations on the cleared or approved indicated uses for which the product may be marketed and promoted, will be subject to the conditions of approval, or will contain requirements for potentially costly post-marketing testing. We are required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing product safety issues could result in increased costs to assure compliance. The FDA and other agencies, including the DOJ, closely regulate and monitor the post-clearance or approval marketing and promotion of products to ensure that they are marketed and distributed only for the cleared or approved indications and in accordance with the provisions of the cleared or approved labeling. We have to comply with requirements concerning advertising and promotion for our products.

Promotional communications with respect to devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the products' cleared or approved labeling. As such, we may not promote our products for indications or uses for which they do not have clearance or approval. For certain changes, to a cleared or approved product, including certain changes to product labeling, the holder of a cleared 510(k) or approved PMA application may be required to submit a new application and obtain clearance or approval. We train our marketing and sales force against promoting our products for uses outside of the cleared or approved indications for use, known as "off-label uses." However, physicians may use our products for off-label purposes and are allowed to do so when in the physician's independent professional medical judgment he or she deems it appropriate. If the FDA determines that our promotional materials or training constitute promotion of an off-label or other improper use, or that our internal policies and procedures are inadequate to prevent such off-label uses, it could subject us to regulatory or enforcement actions as discussed below.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with our facility where the product is manufactured or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

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

In addition, violations of the Federal Food, Drug and Cosmetic Act ("FD&C Act"), relating to the promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition and results of operations.

Even though we have received breakthrough device designation for our C^2 catheter for lithotripsy-enabled, low pressure dilatation of calcified, stenotic de novo coronary arteries prior to stenting, such designation may not expedite the development or review of the C^2 catheter and does not provide assurance ultimately of PMA submission or approval by FDA.

The Breakthrough Devices Program is a voluntary program intended to expedite the review, development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions for which no approved or cleared treatment exists or that offer significant advantages over existing approved or cleared alternatives. All submissions for devices designated as Breakthrough Devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as needed.

Although breakthrough designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. Although we obtained breakthrough device designation for the C^2 catheter for the CAD indication, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. For example, the time required to identify and resolve issues relating to manufacturing and controls, the acquisition of a sufficient supply of our product for clinical trial purposes or the need to conduct additional nonclinical or clinical studies may delay approval by the FDA, even if the product qualifies for breakthrough designation or access to any other expedited program. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product.

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 four atm for the full course of lithotripsy application. While there were no patient safety issues reported and no reports of adverse clinical events related to this issue and the issue has been corrected, we believe it was prudent to suspend utilization of the device and recall the product while we determined the cause of the leak.

In addition, we are subject to medical device reporting regulations that require us to report to the FDA or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction recurred. Failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to the FDA's satisfaction, can subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

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

Our manufacturing processes and those of our third-party suppliers are required to comply with the FDA's QSR, which covers the design controls, document controls, purchasing controls, identification and traceability, production and process controls, acceptance activities, nonconforming product requirements, corrective and preventive action requirements, labeling and packaging controls, handling, storage, distribution and installation requirements, complaint handling, records requirements, servicing requirements and statistical techniques potentially applicable to the production of our medical devices. We and our suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process where we market products overseas. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facilities and records for periodic announced or unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we experience an unsuccessful Quality System inspection, our operations could be disrupted and our manufacturing could be interrupted. Failure to take adequate corrective action in response to an adverse Quality System inspection could result in, among other things, a shut-down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our product and cause our revenue to decline.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Health Services ("CDHS"). We anticipate that we and certain of our third-party component suppliers will be subject to FDA and CDHS inspections.

We completed the move of our production of our IVL catheters from our prior Fremont, California facility to our facility in Santa Clara, California in the second half of 2019. We produce all of our IVL catheters in-house at our facility in Santa Clara, California, which, together with our research and development, controlled environment room and office space, currently totals 35,000 square feet. Our Santa Clara facility has been inspected by the FDA and by the British Standards Institution ("BSI"). We can provide no assurance that 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 customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits. Taking corrective action may be expensive, time-consuming and a distraction for management, and if we experience a shutdown or delay at our manufacturing facilities, we may be unable to produce our products, which would harm our business.

Current regulations depend heavily on administrative interpretation. If the FDA does not believe that we are in compliance with applicable FDA regulations, the agency could take legal or regulatory enforcement actions against us and/or our products. We are also

subject to periodic inspections by the FDA and other governmental regulatory agencies, as well as certain third-party regulatory groups. Future interpretations made by the FDA or other regulatory bodies made during the course of these inspections may vary from current interpretations and may adversely affect our business and prospects. The FDA's and other comparable non-U.S. regulatory agencies' statutes, regulations or policies may change, and additional government regulation or statutes may be enacted, which could increase post-approval regulatory requirements, or delay, suspend or prevent marketing of any cleared or approved products or necessitate the recall of distributed products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

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

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

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

Under FDA medical device reporting regulations ("MDR regulations"), 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 ("ACA"), is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges and the expansion of the Medicaid program. 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. Legislation enacted in 2017, informally known as the, the Tax Cuts and Jobs Act of 2017 ("TCJA"), includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 (the "2018 Continuing Resolution"), 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 "donut hole." In December 2018, CMS published a new final rule further permitting 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 "individual mandate" 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:

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

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. While some of these measures may require additional authorization to become effective, 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 manufacturer's decision. Any modification to an FDA-cleared device that could significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a PMA. For Class III products, changes that affect safety and effectiveness will require the submission and approval of a PMA supplement. We may not be able to obtain additional 510(k) clearances or PMAs for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our products in the past and expect to make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for these modifications, we may be required to recall and to stop selling or marketing such products as modified, which could harm our operating results and require us to redesign such products. In these circumstances, we may be subject to significant enforcement actions.

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 suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our on our business, financial condition and results of operations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive, and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our business, financial condition and results of operation.

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

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

This risk is enhanced in certain jurisdictions and, as we expand our operations domestically and internationally, we may be subject to additional laws in other jurisdictions. Any failure, or perceived failure, by us to comply with privacy and data protection laws, rules and regulations could result in proceedings or actions against us by governmental entities or others. These proceedings or actions may subject us to significant penalties and negative publicity, require us to change our business practices, increase our costs and severely disrupt our business. For example, in the United States, California recently adopted the CCPA, which will come into effect beginning in January 2020 and will, among other things, require new disclosures to California consumers and afford such consumers new abilities to opt out of certain sales of personal information, in addition to severely limiting our ability to use their information. It remains unclear how various provisions of the CCPA will be interpreted and enforced. The effects of the CCPA are potentially significant, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply. In addition, the GDPR, which became effective in May 2018, applies extraterritorially and imposes several stringent requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of personal data and pseudonymized (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR provides that European Union ("EU") member states may make their own laws and regulations limiting the (i) processing of personal data, including special categories of data (e.g., racial or ethnic origin, political opinions, religious or philosophical beliefs) and (ii) profiling and automated individual decision-making of individuals, which could limit our ability to use and share personal data or other data and could cause our costs to increase, harming our business and financial condition. Non-compliance with GDPR is subject to significant penalties, including fines of up to €20 million or 4% of total worldwide revenue. The interpretations of the GDPR by local data protection authorities in EU member states, along with the complexity of the new data protection regime itself, will leave the interpretation and enforcement of the law unclear in the near term, with potential inconsistencies across the EU member states. The implementation and enforcement of the

GDPR may subject us to enforcement risk and requirements to change certain of our data collection, processing and other policies and practices. We could incur significant costs investigating and defending such claims and, if we are found liable, significant damages. If any of these events were to occur, our business and financial results could be adversely affected. Other jurisdictions outside the EU are similarly introducing or enhancing laws and regulations relating to privacy and data security, which enhances risks relating to compliance with such laws.

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

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

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

In the EU, on May 25, 2017 the new Medical Devices Regulation ("2017/745" or "MDR") 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-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office (the "USPTO"), or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review ("IPR"), or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology or products. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. For example, petitions for IPR of U.S. Pat. Nos. 9,642,673, 8,956,371 and 8,728,091 (the "IPR Patents"), which are three of our issued U.S. patents that relate to our current IVL Technology, were filed in December 2018 at the USPTO's Patent Trial and Appeal Board (the "PTAB") by Cardiovascular Systems, Inc., one of our competitors. The PTAB has decided to institute IPR proceedings for all three IPR Patents. Scheduled deadlines for each IPR start with our responses to the petitions due in November 2019, and end with an optional oral hearing on April 16, 2020. The PTAB is expected to issue a decision in each IPR by July 2020. The IPR proceedings could result in the loss or narrowing in scope of the IPR Patents, which could limit our ability to stop others from using or commercializing products and technology similar or identical to ours. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in the abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the “America Invents Act”), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to file any patent application related to our products or invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, IPR and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U.S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our products, we also rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position. We seek to protect such proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors, advisors, consultants and other third parties and invention assignment agreements with our employees. We also have agreements with some of our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses containing invention assignment, to grant us ownership of technologies that are developed through a relationship with employees or third parties.

We cannot guarantee that we have entered into such agreements with each party that has or may have had access to our trade secrets or proprietary information. Additionally, despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor or other third party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know-how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel from academic to industry scientific positions.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known, or be independently discovered by, competitors. To the extent that our employees, consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims challenging the ownership or inventorship of our patents and other intellectual property and, if unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, or to cease the development, manufacture and commercialization of one or more of our products.

We may be subject to claims that current or former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products. Litigation may be necessary to defend against these and other claims challenging inventorship of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. If we were to lose exclusive ownership of such intellectual property, other owners may be able to license their rights to other third parties, including our competitors. We also may be required to obtain and maintain licenses from third parties, including parties involved in any such disputes. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our products. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the sale and marketing of our products.

The medical device industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, we could become subject to significant intellectual property-related litigation and proceedings relating to our or third-party intellectual property and proprietary rights.

Our commercial success depends in part on our and any potential future collaborators' ability to develop, manufacture, market and sell any products that we may develop and use our proprietary technologies without infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. It is uncertain whether the issuance of any third-party patent would require us or any potential collaborators to alter our development or commercial strategies, obtain licenses or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, *inter partes* or post-grant review, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

Third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes upon these patents. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates. Moreover, we may face claims from non-practicing entities ("NPEs"), which have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Third parties, including NPEs, have claimed, and may in the future claim, that our products infringe or violate their patents or other intellectual property rights.

In the event that any third party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed by our products. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe third-party patents, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, such third parties may be able to block our ability to commercialize the applicable products or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay significant license fees and/or royalties, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same technology. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, we may be unable to commercialize our products, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit or outcome, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products and/or have to pay substantial damages for use of the asserted intellectual property, including treble damages and attorneys' fees were we found to willfully infringe such intellectual property. We also might have to redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure.

Engaging in litigation to defend against third-party infringement claims is very expensive, particularly for a company of our size, and time-consuming. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, or we may be required to defend against claims of infringement. In addition, our patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may not be successful in obtaining necessary rights to any products we may develop through acquisitions and in-licenses.

Many medical device companies and academic institutions are competing with us and filing patent applications potentially relevant to our business. We may find it necessary or prudent to obtain licenses from such third-party intellectual property holders. In addition, with respect to any patents we may in the future co-own with third parties, we may require licenses to such co-owners' interest to such patents. However, we may be unable to secure such licenses or otherwise acquire or in-license any intellectual property rights from third parties that we identify as necessary for planned or future products. The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant products, which could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Our employees, consultants and scientific advisors may be currently or previously employed or engaged at universities or other medical device or healthcare companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may in the future become subject to claims that we or these individuals have, inadvertently or otherwise, used or disclosed intellectual property, including trade secrets or other proprietary information, of their current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition and results of operations.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners and customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names or other intellectual property may be ineffective, could result in substantial costs and diversion of resources and could adversely affect our business, financial condition and results of operations.

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

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

Intellectual property rights do not necessarily address all potential threats.

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

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

- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to 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:

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

Any of these factors could cause delay or suspension of clinical trials, regulatory submissions, required approvals, commercialization or marketing of our products or cause us to incur higher costs. Furthermore, if our contract manufacturers fail to deliver the required commercial quantities of finished products on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenue. Any difficulties in locating and hiring third-party manufacturers, or in the ability of third-party manufacturers to supply quantities of our products at the times and in the quantities we need, could have a material adverse effect on our business. It may take a significant amount of time 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 supplier's, failure to comply with applicable regulations could cause sanctions to be imposed on us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals or clearances, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, which could harm our business. We cannot assure you that if we need to engage new suppliers to satisfy our business requirements, we can locate new suppliers in compliance with regulatory requirements at a reasonable cost and in an acceptable timeframe. Our failure to do so could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

Risks Related to Ownership of Our Common Stock

The market price of our common stock has been and may continue to be highly volatile, and you may not be able to resell your shares at or above the public offering price.

The trading price of our common stock has been and may continue to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control. Since our IPO which occurred in March 2019 through September 30, 2019, the price of our common stock has ranged from $29.40 per share to $66.02 per share. The market price for our common stock may be influenced by many factors, including:

- the sales levels for our products;
- the failure by our customers to obtain coverage and adequate reimbursements or reimbursement levels that would be sufficient to support product sales to our customers;
- unanticipated serious safety concerns related to the use of our products;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- announcements of technological or medical innovations for the treatment of vascular disease;
- our ability to effectively manage our growth;
- the size and growth of our target markets;
- actual or anticipated quarterly variations in our or our competitors' results of operations;
- failure to meet estimates or recommendations by securities analysts who cover our stock;
- failure to meet our own financial estimates;
- accusations that we have violated a law or regulation;
- recalls of our products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain, maintain, protect and enforce patent protection and other intellectual property rights for our technologies and products;
- significant litigation, including stockholder litigation or litigation related to intellectual property;
- our cash position;
- any delay in any regulatory filings for our planned or future products and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such products;
- adverse regulatory decisions, including failure to receive regulatory approval or clearance of our planned and future products or maintain regulatory approval or clearance for our existing products;
- changes in laws or regulations applicable to our products;
- adverse developments concerning our suppliers or distributors;
- our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices;
- our inability to establish and maintain collaborations if needed;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- trading volume of our common stock;
- additions or departures of key scientific or management personnel;
- changes in accounting principles;
- ineffectiveness of our internal controls;

- actual or anticipated changes in healthcare policy and reimbursement levels;
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general and the market for medical device companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially adversely affect our business, financial condition and results of operations.

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

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

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

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Any return to stockholders will therefore be limited to the appreciation in the value of their stock, if any.

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

As of December 31, 2018, we had net operating loss ("NOL") 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 "Code"), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership by 5% stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. We have not determined if we have experienced Section 382 ownership changes in the past and if a portion of our NOLs is subject to an annual limitation under Section 382. In addition, we may experience ownership changes in the future as a result of subsequent changes in our stock ownership, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical NOLs is materially limited, it could harm our future operating results by effectively increasing our future tax obligations. In addition, under the TCJA, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely but generally may not be carried back and the deductibility of such NOLs is limited to 80% of taxable income.

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

The TCJA enacted many significant changes to the U.S. tax laws, 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.

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

As of September 30, 2019, our executive officers, directors and 5% stockholders beneficially owned approximately 16.8% of the outstanding shares of capital stock. In addition, as of September 30, 2019, our executive officers and directors held options to purchase an aggregate of 2,017,549 shares of our common stock at a weighted-average exercise price of $4.85 per share. These stockholders will have the ability to influence us through this ownership position. The interests of this group of stockholders may not coincide with the interests of other stockholders.

Sales of substantial amounts of our common stock in the public markets, or the perception that such sales could occur, could reduce the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could adversely affect the market price of our common stock. As of September 30, 2019, we had 28,255,893 shares of common stock outstanding. Of these shares, the 6,555,000 shares of common stock sold in our IPO are freely tradable.

In addition, as of September 30, 2019 there were 3,658,436 shares of common stock subject to outstanding options, and 226,550 shares of common stock to be issued upon the vesting of outstanding restricted stock units ("RSUs"). We have registered all of the shares of common stock issuable upon the exercise of outstanding options, upon the vesting of outstanding restricted stock and upon exercise or settlement of any other equity incentives we may grant in the future, for public resale under the Securities Act. Accordingly, these shares may be freely sold in the public market upon issuance as permitted by any applicable vesting requirements. Furthermore, holders of approximately 6,998,197 shares of our common stock have certain rights with respect to the registration of such shares under the Securities Act.

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 "JOBS Act"). 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 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 completed our IPO, 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 our IPO, (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 are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), as well as rules subsequently adopted by the SEC and the Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring that we evaluate and determine the effectiveness of our internal control over financial reporting, 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 "emerging growth company," 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 "Dodd-Frank Act"), was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Emerging growth companies are permitted to implement many of these requirements over a longer period and up until March 6, 2024, which is five years from the pricing of our IPO. 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 "emerging growth company," 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.

We are at risk of securities class action litigation.

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

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

Our stock price and trading volume is heavily influenced by the way analysts and investors interpret our financial information and other disclosures. If securities or industry analysts do not publish research or reports about our business, delay publishing reports about our business or publish negative reports about our business, regardless of accuracy, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. A limited number of analysts are currently covering our company. If the number of analysts that cover us declines, demand for our common stock could decrease and our common stock price and trading volume may decline.

Even if our common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over-reliance by analysts or investors on any particular metric to forecast our future results may result in forecasts that differ significantly from our own.

Regardless of accuracy, unfavorable interpretations of our financial information and other public disclosures could have a negative impact on our stock price. If our financial performance fails to meet analyst estimates, for any of the reasons discussed above or otherwise, or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our stock price would likely decline.

Our restated certificate of incorporation, our amended and restated bylaws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of Delaware law (where we are incorporated), our restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders;
- requiring supermajority stockholder voting to effect certain amendments to our restated certificate of incorporation and amended and restated bylaws;
- eliminating the ability of stockholders to call and bring business before special meetings of stockholders;
- prohibiting stockholder action by written consent;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings;
- dividing our board of directors into three classes so that only one third of our directors will be up for election in any given year; and
- providing that our directors may be removed by our stockholders only for cause.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which may have an anti-takeover effect with respect to transactions not approved in advance by our board of directors, including discouraging takeover attempts that could have resulted in a premium over the market price for shares of our common stock.

These provisions apply even if a takeover offer may be considered beneficial by some stockholders and could delay or prevent an acquisition that our board of directors determines is not in our and our stockholders' best interests and could also affect the price that some investors are willing to pay for our common stock.

Our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business and financial condition. This exclusive forum provision will not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Unregistered Sales of Equity Securities

None.

Use of Proceeds from Public Offering of Common Stock

The registration statement on Form S-1 (File No. 333-229590) and the registration statement on Form S-1 (File No. 333-230110) filed pursuant to Rule 462(b) relating thereto, each relating to the IPO of shares of our common stock, became effective on March 6, 2019. The registration statements registered the offer and sale of 6,555,000 shares of our common stock (including 855,000 shares of our common stock subject to the underwriters' over-allotment option). On March 11, 2019, we completed the sale of all 6,555,000 of the shares of our common stock registered thereunder at an IPO price of $17.00 per share for an aggregate offering price of approximately $111.4 million. The underwriters of the offering were Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated. Following the sale of the shares in connection with the closing of the IPO, the offering terminated.

We received net proceeds of approximately $99.9 million after deducting underwriting discount and commissions of $7.1 million and offering costs of $4.4 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates.

We maintain the funds received from our IPO in a savings account, pending their use. We intend to use the net proceeds from our IPO 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 the IPO 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. There has been no material change in the planned use of proceeds from our IPO from that described in the prospectus dated March 6, 2019 filed with the SEC pursuant to Rule 424(b)(4).

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Furnish the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

Exhibit Number	Description	Form	File No.	Exhibit(s)	Filing Date
10.1*†	Separation Pay Agreement with Douglas Godshall				
10.2*†	Form of Separation Pay Agreement				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.

† Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ShockWave Medical, Inc.

Date: November 8, 2019 By: /s/ Douglas Godshall

Douglas Godshall
President and Chief Executive Officer

Date: November 8, 2019 By: /s/ Dan Puckett

Dan Puckett
Chief Financial Officer

Exhibit 10.1

SEPARATION PAY AGREEMENT

This Separation Pay Agreement (the "**Agreement**") is made and entered into as of August 19, 2019, by and between Doug Godshall (the "**Executive**") and Shockwave Medical, Inc., a Delaware corporation (the "**Company**").

WHEREAS, the Company desires to address and handle certain aspects of the employment the Executive on the terms and conditions set forth herein; and

WHEREAS, the Executive desires to have such aspects of his employment addressed and handled by the Company on such terms and conditions.

NOW, THEREFORE, in consideration of the mutual covenants, promises, and obligations set forth herein, the parties agree as follows:

Term. This Agreement shall be effective as of the date hereof (the "**Effective Date**") until such time as the Executive's employment is terminated pursuant to Section 2.6 below (such period, the "**Employment Term**").

Termination of Employment. The Employment Term and the Executive's employment hereunder may be terminated by either the Company or the Executive at any time and for any reason; provided that, unless otherwise provided herein, either party shall be required to give the other party at least thirty (30) days advance written notice of any termination of the Executive's employment. Upon termination of the Executive's employment during the Employment Term, the Executive shall be entitled to the compensation and benefits described in this Section 2 and shall have no further rights to any compensation or any other benefits from the Company or any of its affiliates.

Termination for Cause or Resignation without Good Reason.

The Executive's employment hereunder may be terminated by the Company for Cause or by the Executive without Good Reason. If the Executive's employment is terminated, by the Company for Cause or by the Executive without Good Reason, the Executive shall be entitled to receive:

any accrued but unpaid salary and accrued but unused vacation which shall be paid on the Termination Date in accordance with the Company's customary payroll procedures;

any earned but unpaid incentive under the Company's annual cash incentive plan (the "**Annual Incentive**") with respect to any completed calendar year immediately preceding the Termination Date, which shall be paid on the otherwise applicable payment date; provided that, if the Executive's employment is terminated by the Company for Cause, then any such accrued but unpaid Annual Incentive shall be forfeited;

reimbursement for unreimbursed business expenses properly incurred by the Executive, which shall be subject to and paid in accordance with the Company's expense reimbursement policy; and

such employee benefits (including equity compensation), if any, to which the Executive may be entitled under the Company's employee benefit plans as of the Termination Date; provided that, in no event shall the Executive be entitled to any payments in the nature of severance or termination payments except as specifically provided herein.

Items 2.1(a)(i) through 2.1(a)(iv) are referred to herein collectively as the "**Accrued Amounts**".

For purposes of this Agreement, "**Cause**" shall mean:

the Executive's willful failure to perform his duties (other than any such failure resulting from incapacity due to physical or mental illness);

the Executive's engagement in dishonesty, illegal conduct, or gross misconduct, which, in each case, poses a substantial risk of material injury to the Company or its affiliates;

the Executive's embezzlement, misappropriation, or fraud, whether or not related to the Executive's employment with the Company;

the Executive's conviction of or plea of guilty or nolo contendere to a crime that constitutes a felony (or state law equivalent) or a crime that constitutes a misdemeanor involving moral turpitude;

the Executive's material breach of any material obligation under this Agreement or any other written agreement between the Executive and the Company; or

any material failure by the Executive to comply with the Company's written policies or rules, as they may be in effect from time to time during the Employment Term, if such failure poses a substantial risk of material reputational or financial harm to the Company.

For purposes of this provision, no act or failure to act on the part of the Executive shall be considered "willful" unless it is done, or omitted to be done, by the Executive in bad faith or without reasonable belief that the Executive's action or omission was in the best interests of the Company. Any act, or failure to act, based upon authority given pursuant to a resolution duly adopted by the Board or upon the advice of counsel for the Company shall be conclusively presumed to be done, or omitted to be done, by the Executive in good faith and in the best interests of the Company.

Termination of the Executive's employment shall not be deemed to be for Cause unless and until the Company delivers to the Executive a copy of a resolution duly adopted by the affirmative vote of not less than a majority of the Board, finding that the Executive has engaged in the conduct described in any of (i)-(vi) above. Except for a failure, breach, or refusal which, by its nature, cannot reasonably be expected to be cured, the Executive shall have ten (10) business days from the delivery of written notice by the Company within which to cure any acts

constituting Cause; provided however, that, if the Company reasonably expects irreparable injury from a delay of ten (10) business days, the Company may give the Executive notice of such shorter period within which to cure as is reasonable under the circumstances, which may include the termination of the Executive's employment without notice and with immediate effect. The Company may place the Executive on paid leave for up to sixty (60) days while it is determining whether there is a basis to terminate the Executive's employment for Cause. Any such action by the Company will not constitute Good Reason.

For purposes of this Agreement, "**Good Reason**" shall mean the occurrence of any of the following, in each case during the Employment Term without the Executive's written consent:

a material reduction in the Executive's annual rate of base salary other than a general reduction that affects all similarly situated executives in substantially the same proportions;

a material reduction in the Executive's target incentive opportunity under the Annual Incentive;

a relocation of the Executive's principal place of employment by more than 30 miles;

any material breach by the Company of any material provision of this Agreement;

the Company's failure to obtain an agreement from any successor to the Company to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no succession had taken place, except where such assumption occurs by operation of law;

the Company's failure to nominate the Executive for election to the Board and to use its best efforts to have him elected and re-elected, as applicable;

a material, adverse change in the Executive's title, authority, duties, or responsibilities (other than temporarily while the Executive is physically or mentally incapacitated or as required by applicable law); or

a material adverse change in the reporting structure applicable to the Executive.

The Executive cannot terminate his employment for Good Reason unless he has provided written notice to the Company of the existence of the circumstances providing grounds for termination for Good Reason within ninety (90) days of the initial existence of such grounds and the Company has had at least 30 days from the date on which such notice is provided to cure such circumstances. If the Executive does not terminate his employment for Good Reason within one hundred twenty (120) days after the first occurrence of the applicable grounds, then the Executive will be deemed to have waived his right to terminate for Good Reason with respect to such grounds.

Termination without Cause or Resignation for Good Reason. The Employment Term and the Executive's employment hereunder may be terminated by the Executive for Good Reason or by the Company without Cause. In the event of such termination, the Executive shall be entitled to receive the Accrued Amounts and subject to the Executive's execution of a release of claims in favor of the Company, its affiliates and their respective officers and directors in a form provided by the Company (the "**Release**") and such Release becoming effective within sixty (60) days following the Termination Date (such 60-day period, the "**Release Execution Period**"), the Executive shall be entitled to receive the following:

equal installment payments payable in accordance with the Company's normal payroll practices, but no less frequently than monthly, which are in the aggregate equal to 1.5 times the sum of the Executive's annual rate of base salary for the year in which the Termination Date occurs, which shall begin within 60 days following the Termination Date; provided that, if the Release Execution Period begins in one taxable year and ends in another taxable year, payments shall not begin until the beginning of the second taxable year; provided further that, the first installment payment shall include all amounts that would otherwise have been paid to the Executive during the period beginning on the Termination Date and ending on the first payment date if no delay had been imposed;

a payment equal to the product of (i) the Annual Incentive, if any, that the Executive would have earned for the calendar year in which the Termination Date (as determined in accordance with Section 2.6) occurs based on achievement of the applicable performance goals for such year and (ii) a fraction, the numerator of which is the number of days the Executive was employed by the Company during the year of termination and the denominator of which is the number of days in such year (the "**Pro-Rata Bonus**"). This amount shall be paid on the date that annual bonuses are paid to similarly situated executives, but in no event later than two-and-a-half (2 1/2) months following the end of the calendar year in which the Termination Date occurs;

If the Executive timely and properly elects health continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("**COBRA**"), the Company shall reimburse the Executive for the difference between the monthly COBRA premium paid by the Executive for himself and his dependents and the monthly premium amount paid by similarly situated active executives. Such reimbursement shall be paid to the Executive on the 15th day of the month immediately following the month in which the Executive timely remits the premium payment. The Executive shall be eligible to receive such reimbursement until the earliest of: (i) the eighteen-month anniversary of the Termination Date; (ii) the date the Executive is no longer eligible to receive COBRA continuation coverage; and (iii) the date on which the Executive becomes eligible to receive substantially similar coverage from another employer or other source. Notwithstanding the foregoing, if the Company's making payments under this Section 2.2(c) would violate the nondiscrimination rules applicable to non-grandfathered plans under the Affordable Care Act (the "**ACA**"), or result in the imposition of penalties under the ACA and the related regulations and guidance promulgated thereunder), the parties agree to reform this Section 2.2(c) in a manner as is necessary to comply with the ACA.

The treatment of each outstanding equity award, if any, shall be determined in accordance with the terms of the applicable plan and award agreement.

Death or Disability.

The Executive's employment hereunder shall terminate automatically upon the Executive's death during the Employment Term, and the Company may terminate the Executive's employment on account of the Executive's Disability.

If the Executive's employment is terminated during the Employment Term on account of the Executive's death or Disability, the Executive (or the Executive's estate and/or beneficiaries, as the case may be) shall be entitled to receive the Accrued Amounts**.** Notwithstanding any other provision contained herein, all payments made in connection with the Executive's Disability shall be provided in a manner which is consistent with federal and state law.

For purposes of this Agreement, "**Disability**" shall mean the Executive's inability, due to physical or mental incapacity, to perform the essential functions of his job, with or without reasonable accommodation, for one hundred eighty (180) days out of any three hundred sixty-five (365) day period or one hundred twenty (120) consecutive days, or the Executive's becoming entitled to receive long-term disability benefits under the Company's long-term disability plan.

Change in Control Termination.

Notwithstanding any other provision contained herein, if the Executive's employment hereunder is terminated by the Executive for Good Reason or by the Company without Cause (other than on account of the Executive's death or Disability), in each case within three (3) months prior to or within twelve (12) months following a Change in Control, the Executive shall be entitled to receive the Accrued Amounts and, subject to the Executive's execution of a Release which becomes effective within sixty (60) days following the Termination Date, the Executive shall be entitled to receive the following:

equal installment payments payable in accordance with the Company's normal payroll practices, but no less frequently than monthly, which are in the aggregate equal to 2.0 times the sum of the Executive's annual rate of base salary for the year in which the Termination Date occurs, which shall begin within sixty (60) days following the Termination Date; provided that, if the Release Execution Period begins in one taxable year and ends in another taxable year, payments shall not begin until the beginning of the second taxable year; provided further that, the first installment payment shall include all amounts that would otherwise have been paid to the Executive during the period beginning on the Termination Date and ending on the first payment date if no delay had been imposed;

a payment equal to the product of (i) the Annual Incentive, if any, that the Executive would have earned for the calendar year in which the Termination Date (as determined in accordance with Section 2.6) occurs based on achievement of the applicable performance goals for such year and (ii) a fraction, the numerator of which is the number of days the Executive was employed by the Company during the year of termination and the denominator of which is the number of days in such year (the "**Pro-Rata Bonus**"). This amount shall be paid on the date that annual bonuses are paid to similarly situated executives, but in no event later than two-and-a-half (2 1/2) months following the end of the calendar year in which the Termination Date occurs;

If the Executive timely and properly elects health continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("**COBRA**"), the

Company shall reimburse the Executive for the difference between the monthly COBRA premium paid by the Executive for himself and his dependents and the monthly premium amount paid by similarly situated active executives. Such reimbursement shall be paid to the Executive on the 15th day of the month immediately following the month in which the Executive timely remits the premium payment. The Executive shall be eligible to receive such reimbursement until the earliest of: (i) the eighteen-month anniversary of the Termination Date; (ii) the date the Executive is no longer eligible to receive COBRA continuation coverage; and (iii) the date on which the Executive becomes eligible to receive substantially similar coverage from another employer or other source. Notwithstanding the foregoing, if the Company's making payments under this Section 2.4(a)(iii) would violate the nondiscrimination rules applicable to non-grandfathered plans under the Affordable Care Act (the "**ACA**"), or result in the imposition of penalties under the ACA and the related regulations and guidance promulgated thereunder), the parties agree to reform this Section 2.4(a)(iii) in a manner as is necessary to comply with the ACA.

The treatment of each outstanding equity award, if any, shall be determined in accordance with the terms of the applicable plan and award agreement.

For purposes of this Agreement, "**Change in Control**" shall mean the occurrence of any of the following after the Effective Date:

one person (or more than one person acting as a group) acquires ownership of stock of the Company that, together with the stock held by such person or group, constitutes more than 50% of the total fair market value or total voting power of the stock of such corporation; provided that, a Change in Control shall not occur if any person (or more than one person acting as a group) owns more than 50% of the total fair market value or total voting power of the Company's stock and acquires additional stock;

one person (or more than one person acting as a group) acquires (or has acquired during the twelve-month period ending on the date of the most recent acquisition) ownership of the Company's stock possessing 30% or more of the total voting power of the stock of such corporation;

a majority of the members of the Board are replaced during any twelve-month period by directors whose appointment or election is not endorsed by a majority of the Board before the date of appointment or election; or

the sale of all or substantially all of the Company's assets.

Notwithstanding the foregoing, a Change in Control shall not occur unless such transaction constitutes a change in the ownership of the Company, a change in effective control of the Company, or a change in the ownership of a substantial portion of the Company's assets under Section 409A of the U.S. Internal Revenue Code ("Code").

Notice of Termination. Any termination of the Executive's employment hereunder by the Company or by the Executive during the Employment Term (other than termination pursuant to Section 2.3(a) on account of the Executive's death) shall be communicated by written notice of

termination ("**Notice of Termination**") to the other party hereto in accordance with Section 13. The Notice of Termination shall specify:

The termination provision of this Agreement relied upon;

To the extent applicable, the facts and circumstances claimed to provide a basis for termination of the Executive's employment under the provision so indicated; and

The applicable Termination Date.

Termination Date. The Executive's "**Termination Date**" shall be:

If the Executive's employment hereunder terminates on account of the Executive's death, the date of the Executive's death;

If the Executive's employment hereunder is terminated on account of the Executive's Disability, the date that it is determined that the Executive has a Disability;

If the Company terminates the Executive's employment hereunder for Cause, the date the Notice of Termination is delivered to the Executive;

If the Company terminates the Executive's employment hereunder without Cause, the date specified in the Notice of Termination, which shall be no less than 30 days following the date on which the Notice of Termination is delivered;

If the Executive terminates his employment hereunder with or without Good Reason, the date specified in the Executive's Notice of Termination, which shall be no less than thirty (30) days following the date on which the Notice of Termination is delivered; provided that, the Company may waive all or any part of the 30-day notice period for no consideration by giving written notice to the Executive and for all purposes of this Agreement, the Executive's Termination Date shall be the date determined by the Company; and

Notwithstanding anything contained herein, the Termination Date shall not occur until the date on which the Executive incurs a "separation from service" within the meaning of Section 409A.

Mitigation. In no event shall the Executive be obligated to seek other employment or take any other action by way of mitigation of the amounts payable to the Executive under any of the provisions of this Agreement and except as provided in Section 2.2(c) or Section 2.4(a)(iii), any amounts payable pursuant to this Section 2 shall not be reduced by compensation the Executive earns on account of employment with another employer.

Resignation of All Other Positions. Upon termination of the Executive's employment hereunder for any reason, the Executive agrees to resign, effective on the Termination Date from all positions that the Executive holds as an officer or member of the Board (or a committee thereof) of the Company or any of its affiliates.

Section 280G.

If any of the payments or benefits received or to be received by the Executive (including, without limitation, any payment or benefits received in connection with a Change

in Control or the Executive's termination of employment, whether pursuant to the terms of this Agreement or any other plan, arrangement, or agreement, or otherwise) (all such payments collectively referred to herein as the **"280G Payments"**) constitute "parachute payments" within the meaning of Section 280G of the Code and would, but for this Section 2.9, be subject to the excise tax imposed under Section 4999 of the Code (the **"Excise Tax"**), then such 280G Payments shall be reduced in a manner determined by the Company (by the minimum possible amounts) that is consistent with the requirements of Section 409A until no amount payable to the Executive will be subject to the Excise Tax. If two economically equivalent amounts are subject to reduction but are payable at different times, the amounts shall be reduced (but not below zero) on a pro rata basis.

All calculations and determinations under this Section 2.9 shall be made by an independent accounting firm or independent tax counsel appointed by the Company (the **"Tax Counsel"**) whose determinations shall be conclusive and binding on the Company and the Executive for all purposes. For purposes of making the calculations and determinations required by this Section 2.9, the Tax Counsel may rely on reasonable, good faith assumptions and approximations concerning the application of Section 280G and Section 4999 of the Code. The Company and the Executive shall furnish the Tax Counsel with such information and documents as the Tax Counsel may reasonably request in order to make its determinations under this Section 2.9. The Company shall bear all costs the Tax Counsel may reasonably incur in connection with its services.

Governing Law; Jurisdiction and Venue. This Agreement, for all purposes, shall be construed in accordance with the laws of California without regard to conflicts of law principles. Subject to Section 4 below, any action or proceeding by either of the parties to enforce this Agreement shall be brought only in a state or federal court located in the state of California, in the counties of Santa Clara or San Francisco. The parties hereby irrevocably submit to the non-exclusive jurisdiction of such courts and waive the defense of inconvenient forum to the maintenance of any such action or proceeding in such venue.

Arbitration. Any dispute, controversy, or claim arising out of or related to the Executive's employment with the Company or termination of employment, this Agreement, or any alleged breach of this Agreement (in each case other than any claims the parties may not, as a matter of law, agree to arbitrate) shall be submitted to and decided by binding arbitration in the state of California, in the county of Santa Clara, under the arbitration rules set forth in California Code of Civil Procedure Sections 1280 through 1294.2, including Section 1281.8 (the "Act"), and pursuant to California law. Arbitration shall be administered before Judicial Arbitration & Mediation Services, Inc. ("**JAMS**"), pursuant to the JAMS Employment Arbitration Rules & Procedures (the "**JAMS Rules**"). A copy of the JAMS Rules is available online at https://www.jamsadr.com/rules-employment-arbitration/english. If the JAMS Rules are inconsistent with the terms of this Agreement, the terms of this Agreement shall govern. The Company will pay the arbitrator's fees and arbitration expenses and any other costs unique to the arbitration hearing. Discovery in any arbitration proceeding shall be conducted according to the JAMS Rules.

Any arbitral award determination shall be final and binding on the parties and may be entered as a judgment in a court of competent jurisdiction. This agreement to arbitrate is freely negotiated between the Executive and the Company and is mutually entered into between the parties. By entering into this Agreement, the parties are waiving all rights to have their disputes heard or decided by a jury or in a court trial.

_____ By initialing here, the Executive acknowledges the Executive has read this Section 4 and agrees with the arbitration provision.

Entire Agreement. Unless specifically provided herein, this Agreement contains all of the understandings and representations between the Executive and the Company pertaining to the subject matter hereof and supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to such subject matter. The parties mutually agree that the Agreement can be specifically enforced in court and can be cited as evidence in legal proceedings alleging breach of the Agreement.

Modification and Waiver. No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in writing and signed by the Executive and by the General Counsel of the Company. No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power, or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power, or privilege.

Severability. Should any provision of this Agreement be held by a court of competent jurisdiction to be enforceable only if modified, or if any portion of this Agreement shall be held as unenforceable and thus stricken, such holding shall not affect the validity of the remainder of this Agreement, the balance of which shall continue to be binding upon the parties with any such modification to become a part hereof and treated as though originally set forth in this Agreement.

Captions. Captions and headings of the sections and paragraphs of this Agreement are intended solely for convenience and no provision of this Agreement is to be construed by reference to the caption or heading of any section or paragraph.

Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

Section 409A.

General Compliance. Each payment or benefit provided under this Agreement is intended to comply with Section 409A or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this Agreement, payments provided under this Agreement may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes of Section 409A, each installment payment provided under this Agreement shall be treated as a separate payment. Any payments to be made under this Agreement upon a termination of employment shall only be made upon a “separation from service” under Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A, and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest, or other expenses that may be incurred by the Executive on account of non-compliance with Section 409A.

Specified Employees. Notwithstanding any other provision of this Agreement, if any payment or benefit provided to the Executive in connection with his termination of employment is determined to constitute “nonqualified deferred compensation” within the meaning of Section 409A and the Executive is determined to be a “specified employee” as defined in Section 409A(a)(2)(b)(i),

then such payment or benefit shall not be paid until the first payroll date to occur following the six-month anniversary of the Termination Date or, if earlier, on the Executive's death (the "**Specified Employee Payment Date**"). The aggregate of any payments that would otherwise have been paid before the Specified Employee Payment Date shall be paid to the Executive in a lump sum on the Specified Employee Payment Date and thereafter, any remaining payments shall be paid without delay in accordance with their original schedule.

Successors and Assigns. This Agreement is personal to the Executive and shall not be assigned by the Executive. Any purported assignment by the Executive shall be null and void from the initial date of the purported assignment. The Company may assign this Agreement to any successor or assign (whether direct or indirect, by purchase, merger, consolidation, or otherwise) to all or substantially all of the business or assets of the Company. This Agreement shall inure to the benefit of the Company and permitted successors and assigns.

Notice. Notices and all other communications provided for in this Agreement shall be in writing and shall be delivered personally or sent by registered or certified mail, return receipt requested, or by overnight carrier to the parties at the addresses set forth below (or such other addresses as specified by the parties by like notice):

If to the Company:

Shockwave Medical, Inc.
5403 Betsy Ross Drive
Santa Clara, California 95054
Attention: General Counsel

If to the Executive: to the address on file for the Executive in the records of the Company.

Withholding. The Company shall have the right to withhold from any amount payable hereunder any Federal, state, and local taxes in order for the Company to satisfy any withholding tax obligation it may have under any applicable law or regulation.

Survival. Upon the expiration or other termination of this Agreement, the respective rights and obligations of the parties hereto shall survive such expiration or other termination to the extent necessary to carry out the intentions of the parties under this Agreement.

[SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

SHOCKWAVE MEDICAL, INC.

By: /s/ Hajime Tada

Name: Hajime Tada

Title: General Counsel

DOUG GODSHALL (EXECUTIVE)

Signature: /s/ Doug Godshall

Print Name: Doug Godshall

Exhibit 10.2

SEPARATION PAY AGREEMENT

This Separation Pay Agreement (the "**Agreement**") is made and entered into as of _____ __, 20__, by and between [NAME] (the "**Executive**") and ShockWave Medical, Inc., a Delaware corporation (the "**Company**").

WHEREAS, the Company desires to address and handle certain aspects of the employment the Executive on the terms and conditions set forth herein; and

WHEREAS, the Executive desires to have such aspects of [his/her] employment addressed and handled by the Company on such terms and conditions.

NOW, THEREFORE, in consideration of the mutual covenants, promises, and obligations set forth herein, the parties agree as follows:

Term. This Agreement shall be effective as of the date hereof (the "**Effective Date**") until such time as the Executive's employment is terminated pursuant to Section 2.6 below (such period, the "**Employment Term**").

Termination of Employment. The Employment Term and the Executive's employment hereunder may be terminated by either the Company or the Executive at any time and for any reason; provided that, unless otherwise provided herein, either party shall be required to give the other party at least thirty (30) days advance written notice of any termination of the Executive's employment. Upon termination of the Executive's employment during the Employment Term, the Executive shall be entitled to the compensation and benefits described in this Section 2 and shall have no further rights to any compensation or any other benefits from the Company or any of its affiliates.

Termination for Cause or Resignation.

The Executive's employment hereunder may be terminated by the Company for Cause or by the Executive for any reason. If the Executive's employment is terminated, by the Company for Cause or by the Executive for any reason, the Executive shall be entitled to receive:

any accrued but unpaid salary and accrued but unused vacation which shall be paid on the Termination Date in accordance with the Company's customary payroll procedures;

any earned but unpaid incentive under the Company's annual cash incentive plan (the "**Annual Incentive**") with respect to any completed calendar year immediately preceding the Termination Date, which shall be paid on the otherwise applicable payment date; provided that, if the Executive's employment is terminated by the Company for Cause, then any such accrued but unpaid Annual Incentive shall be forfeited;

reimbursement for unreimbursed business expenses properly incurred by the Executive, which shall be subject to and paid in accordance with the Company's expense reimbursement policy; and

such employee benefits (including equity compensation), if any, to which the Executive may be entitled under the Company's employee benefit plans as of the Termination Date; provided that, in no event shall the Executive be entitled to any payments in the nature of severance or termination payments except as specifically provided herein.

Items 2.1(a)(i) through 2.1(a)(iv) are referred to herein collectively as the "**Accrued Amounts**".

For purposes of this Agreement, "**Cause**" shall mean:

the Executive's willful failure to perform [his/her] duties (other than any such failure resulting from incapacity due to physical or mental illness);

the Executive's engagement in dishonesty, illegal conduct, or gross misconduct, which, in each case, poses a substantial risk of material injury to the Company or its affiliates;

the Executive's embezzlement, misappropriation, or fraud, whether or not related to the Executive's employment with the Company;

the Executive's conviction of or plea of guilty or nolo contendere to a crime that constitutes a felony (or state law equivalent) or a crime that constitutes a misdemeanor involving moral turpitude;

the Executive's material breach of any material obligation under this Agreement or any other written agreement between the Executive and the Company; or

any material failure by the Executive to comply with the Company's written policies or rules, as they may be in effect from time to time during the Employment Term, if such failure poses a substantial risk of material reputational or financial harm to the Company.

For purposes of this provision, no act or failure to act on the part of the Executive shall be considered "willful" unless it is done, or omitted to be done, by the Executive in bad faith or without reasonable belief that the Executive's action or omission was in the best interests of the Company. Any act, or failure to act, based upon authority given pursuant to a resolution duly adopted by the Board or upon the advice of counsel for the Company shall be conclusively presumed to be done, or omitted to be done, by the Executive in good faith and in the best interests of the Company.

Termination of the Executive's employment shall not be deemed to be for Cause unless and until the Company delivers to the Executive a copy of a resolution duly adopted by the affirmative vote of not less than a majority of the Board, finding that the Executive has engaged in the conduct described in any of (i)-(vi) above. Except for a failure, breach, or refusal which, by its nature, cannot reasonably be expected to be cured, the Executive shall have ten (10) business days from the delivery of written notice by the Company within which to cure any acts

constituting Cause; provided however, that, if the Company reasonably expects irreparable injury from a delay of ten (10) business days, the Company may give the Executive notice of such shorter period within which to cure as is reasonable under the circumstances, which may include the termination of the Executive's employment without notice and with immediate effect. The Company may place the Executive on paid leave for up to sixty (60) days while it is determining whether there is a basis to terminate the Executive's employment for Cause. Any such action by the Company will not constitute Good Reason.

Termination without Cause. The Employment Term and the Executive's employment hereunder may be terminated by the Company without Cause. In the event of such termination, the Executive shall be entitled to receive the Accrued Amounts and, subject to the Executive's execution of a release of claims in favor of the Company, its affiliates and their respective officers and directors in a form provided by the Company (the "**Release**") and such Release becoming effective within sixty (60) days following the Termination Date (such 60-day period, the "**Release Execution Period**"), the Executive shall be entitled to receive the following:

equal installment payments payable in accordance with the Company's normal payroll practices, but no less frequently than monthly, which are in the aggregate equal to 0.75 times the sum of the Executive's annual rate of base salary for the year in which the Termination Date occurs, which shall begin within sixty (60) days following the Termination Date; provided that, if the Release Execution Period begins in one taxable year and ends in another taxable year, payments shall not begin until the beginning of the second taxable year; provided further that, the first installment payment shall include all amounts that would otherwise have been paid to the Executive during the period beginning on the Termination Date and ending on the first payment date if no delay had been imposed;

a payment equal to the product of (i) the Annual Incentive, if any, that the Executive would have earned for the calendar year in which the Termination Date (as determined in accordance with Section 2.6) occurs based on achievement of the applicable performance goals for such year and (ii) a fraction, the numerator of which is the number of days the Executive was employed by the Company during the year of termination and the denominator of which is the number of days in such year (the "**Pro-Rata Bonus**"). This amount shall be paid on the date that annual bonuses are paid to similarly situated executives, but in no event later than two-and-a-half (2 1/2) months following the end of the calendar year in which the Termination Date occurs;

If the Executive timely and properly elects health continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("**COBRA**"), the Company shall reimburse the Executive for the difference between the monthly COBRA premium paid by the Executive for the Executive and the Executive's dependents and the monthly premium amount paid by similarly situated active executives. Such reimbursement shall be paid to the Executive on the 15th day of the month immediately following the month in which the Executive timely remits the premium payment. The Executive shall be eligible to receive such reimbursement until the earliest of: (i) the nine-month anniversary of the Termination Date; (ii) the date the Executive is no longer eligible to receive COBRA continuation coverage; and (iii) the date on which the Executive becomes eligible to receive substantially similar coverage from another employer or other source. Notwithstanding the foregoing, if the Company's making payments under this Section 2.2(c) would violate the nondiscrimination rules applicable to non-grandfathered plans under the Affordable Care Act (the "**ACA**"), or result in

the imposition of penalties under the ACA and the related regulations and guidance promulgated thereunder), the parties agree to reform this Section 2.2(c) in a manner as is necessary to comply with the ACA.

The treatment of each outstanding equity award, if any, shall be determined in accordance with the terms of the applicable plan and award agreement.

Death or Disability.

The Executive's employment hereunder shall terminate automatically upon the Executive's death during the Employment Term, and the Company may terminate the Executive's employment on account of the Executive's Disability.

If the Executive's employment is terminated during the Employment Term on account of the Executive's death or Disability, the Executive (or the Executive's estate and/or beneficiaries, as the case may be) shall be entitled to receive the Accrued Amounts**.** Notwithstanding any other provision contained herein, all payments made in connection with the Executive's Disability shall be provided in a manner which is consistent with federal and state law.

For purposes of this Agreement, "**Disability**" shall mean the Executive's inability, due to physical or mental incapacity, to perform the essential functions of [his/her] job, with or without reasonable accommodation, for one hundred eighty (180) days out of any three hundred sixty-five (365) day period or one hundred twenty (120) consecutive days, or the Executive's becoming entitled to receive long-term disability benefits under the Company's long-term disability plan.

Change in Control Termination.

Notwithstanding any other provision contained herein, if the Executive's employment hereunder is terminated by the Executive for Good Reason or by the Company without Cause (other than on account of the Executive's death or Disability), in each case within three (3) months prior to or within twelve (12) months following a Change in Control, the Executive shall be entitled to receive the Accrued Amounts and, subject to the Executive's execution of a Release which becomes effective within sixty (60) days following the Termination Date, the Executive shall be entitled to receive the following:

equal installment payments payable in accordance with the Company's normal payroll practices, but no less frequently than monthly, which are in the aggregate equal to 1.5 times the sum of the Executive's annual rate of base salary for the year in which the Termination Date occurs, which shall begin within sixty (60) days following the Termination Date; provided that, if the Release Execution Period begins in one taxable year and ends in another taxable year, payments shall not begin until the beginning of the second taxable year; provided further that, the first installment payment shall include all amounts that would otherwise have been paid to the Executive during the period beginning on the Termination Date and ending on the first payment date if no delay had been imposed;

a payment equal to the product of (i) the Annual Incentive, if any, that the Executive would have earned for the calendar year in which the Termination Date (as determined in accordance with Section 2.6) occurs based on achievement of the

applicable performance goals for such year and (ii) a fraction, the numerator of which is the number of days the Executive was employed by the Company during the year of termination and the denominator of which is the number of days in such year (the "**Pro-Rata Bonus**"). This amount shall be paid on the date that annual bonuses are paid to similarly situated executives, but in no event later than two-and-a-half (2 1/2) months following the end of the calendar year in which the Termination Date occurs.

If the Executive timely and properly elects health continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("**COBRA**"), the Company shall reimburse the Executive for the difference between the monthly COBRA premium paid by the Executive for himself and [his/her] dependents and the monthly premium amount paid by similarly situated active executives. Such reimbursement shall be paid to the Executive on the 15th day of the month immediately following the month in which the Executive timely remits the premium payment. The Executive shall be eligible to receive such reimbursement until the earliest of: (i) the eighteen-month anniversary of the Termination Date; (ii) the date the Executive is no longer eligible to receive COBRA continuation coverage; and (iii) the date on which the Executive becomes eligible to receive substantially similar coverage from another employer or other source. Notwithstanding the foregoing, if the Company's making payments under this Section 2.4(a) would violate the nondiscrimination rules applicable to non-grandfathered plans under the Affordable Care Act (the "**ACA**"), or result in the imposition of penalties under the ACA and the related regulations and guidance promulgated thereunder), the parties agree to reform this Section 2.4(a) in a manner as is necessary to comply with the ACA.

Notwithstanding the terms of any equity incentive plan or award agreements, as of the Termination Date, all unvested equity awards granted to the Executive that are then outstanding and unvested shall become fully vested and exercisable immediately thereon, and all stock options granted to the Executive that are then outstanding shall remain exercisable for a period of one year following the Termination Date, or, if shorter for a given stock option, for the remainder of that stock option's full term. For avoidance of doubt, this provision shall serve only to expand, and not to reduce the Executive's rights with respect to any equity award.

For purposes of this Agreement, "**Change in Control**" shall mean the occurrence of any of the following after the Effective Date:

one person (or more than one person acting as a group) acquires ownership of stock of the Company that, together with the stock held by such person or group, constitutes more than 50% of the total fair market value or total voting power of the stock of such corporation; provided that, a Change in Control shall not occur if any person (or more than one person acting as a group) owns more than 50% of the total fair market value or total voting power of the Company's stock and acquires additional stock;

one person (or more than one person acting as a group) acquires (or has acquired during the twelve-month period ending on the date of the most recent acquisition) ownership of the Company's stock possessing 30% or more of the total voting power of the stock of such corporation;

a majority of the members of the Board are replaced during any twelve-month period by directors whose appointment or election is not endorsed by a majority of the Board before the date of appointment or election; or

the sale of all or substantially all of the Company's assets.

Notwithstanding the foregoing, a Change in Control shall not occur unless such transaction constitutes a change in the ownership of the Company, a change in effective control of the Company, or a change in the ownership of a substantial portion of the Company's assets under Section 409A.

For purposes of this Agreement, "**Good Reason**" shall mean the occurrence of any of the following, in each case during the Employment Term without the Executive's written consent:

a material reduction in the Executive's annual rate of base salary other than a general reduction that affects all similarly situated executives in substantially the same proportions;

a material reduction in the Executive's target incentive opportunity under the Annual Incentive;

a relocation of the Executive's principal place of employment by more than thirty (30) miles;

any material breach by the Company of any material provision of this Agreement;

the Company's failure to obtain an agreement from any successor to the Company to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no succession had taken place, except where such assumption occurs by operation of law;

a material, adverse change in the Executive's title, authority, duties, or responsibilities (other than temporarily while the Executive is physically or mentally incapacitated or as required by applicable law); or

a material adverse change in the reporting structure applicable to the Executive.

The Executive cannot terminate [his/her] employment for Good Reason unless the Executive provided written notice to the Company of the existence of the circumstances providing grounds for termination for Good Reason within ninety (90) days of the initial existence of such grounds and the Company has had at least thirty (30) days from the date on which such notice is provided to cure such circumstances. If the Executive does not terminate [his/her] employment for Good Reason within one hundred twenty (120) days after the first occurrence of the applicable grounds, then the Executive will be deemed to have waived [his/her] right to terminate for Good Reason with respect to such grounds.

Notice of Termination. Any termination of the Executive's employment hereunder by the Company or by the Executive during the Employment Term (other than termination pursuant to Section 2.3(a) on account of the Executive's death) shall be communicated by written notice of termination ("**Notice of Termination**") to the other party hereto in accordance with Section 13. The Notice of Termination shall specify:

The termination provision of this Agreement relied upon;

To the extent applicable, the facts and circumstances claimed to provide a basis for termination of the Executive's employment under the provision so indicated; and

The applicable Termination Date.

Termination Date. The Executive's "**Termination Date**" shall be:

If the Executive's employment hereunder terminates on account of the Executive's death, the date of the Executive's death;

If the Executive's employment hereunder is terminated on account of the Executive's Disability, the date that it is determined that the Executive has a Disability;

If the Company terminates the Executive's employment hereunder for Cause, the date the Notice of Termination is delivered to the Executive;

If the Company terminates the Executive's employment hereunder without Cause, the date specified in the Notice of Termination, which shall be no less than thirty (30) days following the date on which the Notice of Termination is delivered;

If the Executive terminates [his/her] employment hereunder with or without Good Reason, the date specified in the Executive's Notice of Termination, which shall be no less than thirty (30) days following the date on which the Notice of Termination is delivered; provided that, the Company may waive all or any part of the 30-day notice period for no consideration by giving written notice to the Executive and for all purposes of this Agreement, the Executive's Termination Date shall be the date determined by the Company; and

Notwithstanding anything contained herein, the Termination Date shall not occur until the date on which the Executive incurs a "separation from service" within the meaning of Section 409A.

Mitigation. In no event shall the Executive be obligated to seek other employment or take any other action by way of mitigation of the amounts payable to the Executive under any of the provisions of this Agreement and except as provided in Section 2.2(c) or Section 2.4(a)(iii), any amounts payable pursuant to this Section 2 shall not be reduced by compensation the Executive earns on account of employment with another employer.

Resignation of All Other Positions. Upon termination of the Executive's employment hereunder for any reason, the Executive agrees to resign, effective on the Termination Date from all positions that the Executive holds as an officer or member of the Board (or a committee thereof) of the Company or any of its affiliates.

Section 280G.

If any of the payments or benefits received or to be received by the Executive (including, without limitation, any payment or benefits received in connection with a Change in Control or the Executive's termination of employment, whether pursuant to the terms of this Agreement or any other plan, arrangement, or agreement, or otherwise) (all such payments collectively referred to herein as the **"280G Payments"**) constitute "parachute payments" within the meaning of Section 280G of the Code and would, but for this Section 2.9, be subject to the excise tax imposed under Section 4999 of the Code (the **"Excise Tax"**), then such 280G Payments shall be reduced in a manner determined by the Company (by the minimum possible amounts) that is consistent with the requirements of Section 409A until no amount payable to the Executive will be subject to the Excise Tax. If two economically equivalent amounts are subject to reduction but are payable at different times, the amounts shall be reduced (but not below zero) on a pro rata basis.

All calculations and determinations under this Section 2.9 shall be made by an independent accounting firm or independent tax counsel appointed by the Company (the **"Tax Counsel"**) whose determinations shall be conclusive and binding on the Company and the Executive for all purposes. For purposes of making the calculations and determinations required by this Section 2.9, the Tax Counsel may rely on reasonable, good faith assumptions and approximations concerning the application of Section 280G and Section 4999 of the Code. The Company and the Executive shall furnish the Tax Counsel with such information and documents as the Tax Counsel may reasonably request in order to make its determinations under this Section 2.9. The Company shall bear all costs the Tax Counsel may reasonably incur in connection with its services.

Governing Law: Jurisdiction and Venue. This Agreement, for all purposes, shall be construed in accordance with the laws of California without regard to conflicts of law principles. Subject to Section 5 below, any action or proceeding by either of the parties to enforce this Agreement shall be brought only in a state or federal court located in the state of California, in the counties of Santa Clara or San Francisco. The parties hereby irrevocably submit to the non-exclusive jurisdiction of such courts and waive the defense of inconvenient forum to the maintenance of any such action or proceeding in such venue.

Arbitration. Any dispute, controversy, or claim arising out of or related to the Executive's employment with the Company or termination of employment, this Agreement, or any alleged breach of this Agreement (in each case other than any claims the parties may not, as a matter of law, agree to arbitrate) shall be submitted to and decided by binding arbitration in the state of California, in the county of Santa Clara, under the arbitration rules set forth in California Code of Civil Procedure Sections 1280 through 1294.2, including Section 1281.8 (the "Act"), and pursuant to California law. Arbitration shall be administered before Judicial Arbitration & Mediation Services, Inc. (**"JAMS"**), pursuant to the JAMS Employment Arbitration Rules & Procedures (the **"JAMS Rules"**). A copy of the JAMS Rules is available online at https://www.jamsadr.com/rules-employment-arbitration/english. If the JAMS Rules are inconsistent with the terms of this Agreement, the terms of this Agreement shall govern. The Company will pay the arbitrator's fees and arbitration expenses and any other costs unique to the arbitration hearing. Discovery in any arbitration proceeding shall be conducted according to the JAMS Rules.

Any arbitral award determination shall be final and binding on the parties and may be entered as a judgment in a court of competent jurisdiction. This agreement to arbitrate is freely negotiated between the Executive and the Company and is mutually entered into between the parties. By entering into this Agreement, the parties are waiving all rights to have their disputes heard or decided by a jury or in a court trial.

_____ By initialing here, the Executive acknowledges the Executive has read this Section 4 and agrees with the arbitration provision.

Entire Agreement. Unless specifically provided herein, this Agreement contains all of the understandings and representations between the Executive and the Company pertaining to the subject matter hereof and supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to such subject matter. The parties mutually agree that the Agreement can be specifically enforced in court and can be cited as evidence in legal proceedings alleging breach of the Agreement.

Modification and Waiver. No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in writing and signed by the Executive and by General Counsel of the Company. No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power, or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power, or privilege.

Severability. Should any provision of this Agreement be held by a court of competent jurisdiction to be enforceable only if modified, or if any portion of this Agreement shall be held as unenforceable and thus stricken, such holding shall not affect the validity of the remainder of this Agreement, the balance of which shall continue to be binding upon the parties with any such modification to become a part hereof and treated as though originally set forth in this Agreement.

Captions. Captions and headings of the sections and paragraphs of this Agreement are intended solely for convenience and no provision of this Agreement is to be construed by reference to the caption or heading of any section or paragraph.

Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

Section 409A.

General Compliance. Each payment or benefit provided under this Agreement is intended to comply with Section 409A or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this Agreement, payments provided under this Agreement may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes of Section 409A, each installment payment provided under this Agreement shall be treated as a separate payment. Any payments to be made under this Agreement upon a termination of employment shall only be made upon a “separation from service” under Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A, and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest, or other expenses that may be incurred by the Executive on account of non-compliance with Section 409A.

Specified Employees. Notwithstanding any other provision of this Agreement, if any payment or benefit provided to the Executive in connection with [his/her] termination of employment is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and the Executive is determined to be a "specified employee" as defined in Section 409A(a)(2)(b)(i), then such payment or benefit shall not be paid until the first payroll date to occur following the six-month anniversary of the Termination Date or, if earlier, on the Executive's death (the "**Specified Employee Payment Date**"). The aggregate of any payments that would otherwise have been paid before the Specified Employee Payment Date shall be paid to the Executive in a lump sum on the Specified Employee Payment Date and thereafter, any remaining payments shall be paid without delay in accordance with their original schedule.

Successors and Assigns. This Agreement is personal to the Executive and shall not be assigned by the Executive. Any purported assignment by the Executive shall be null and void from the initial date of the purported assignment. The Company may assign this Agreement to any successor or assign (whether direct or indirect, by purchase, merger, consolidation, or otherwise) to all or substantially all of the business or assets of the Company. This Agreement shall inure to the benefit of the Company and permitted successors and assigns.

Notice. Notices and all other communications provided for in this Agreement shall be in writing and shall be delivered personally or sent by registered or certified mail, return receipt requested, or by overnight carrier to the parties at the addresses set forth below (or such other addresses as specified by the parties by like notice):

If to the Company:

ShockWave Medical, Inc.
5403 Betsy Ross Drive
Santa Clara, California 95054
Attention: General Counsel

If to the Executive: to the address on file for the Executive in the records of the Company.

Withholding. The Company shall have the right to withhold from any amount payable hereunder any Federal, state, and local taxes in order for the Company to satisfy any withholding tax obligation it may have under any applicable law or regulation.

Survival. Upon the expiration or other termination of this Agreement, the respective rights and obligations of the parties hereto shall survive such expiration or other termination to the extent necessary to carry out the intentions of the parties under this Agreement.

[SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

SHOCKWAVE MEDICAL, INC.

By_____

Name: _____

Title: _____

[NAME] (EXECUTIVE)

Signature: _____

Print Name: _____

Exhibit 31.1

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

I, Douglas Godshall, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ShockWave Medical, Inc.;

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

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

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

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

   (b) *Reserved*;

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

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

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

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

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

Date: November 8, 2019

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

Exhibit 31.2

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

I, Dan Puckett, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ShockWave Medical, Inc.;

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

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

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

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

   (b) *Reserved*;

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

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

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

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

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

Date: November 8, 2019

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

Exhibit 32.1

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

In connection with the Quarterly Report of ShockWave Medical, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 8, 2019

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

Exhibit 32.2

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

In connection with the Quarterly Report of ShockWave Medical, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 8, 2019

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