

**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 **March 31, 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
(State or other jurisdiction of
incorporation or organization)

5403 Betsy Ross Drive
Santa Clara, California
(Address of principal executive offices)

27-0494101
(I.R.S. Employer
Identification No.)

95054
(Zip Code)

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

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

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

As of May 1, 2019, the registrant had 28,012,387 shares of common stock, \$0.001 par value per share, outstanding.

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Item 1. Financial Statements.

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

	<u>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
		(1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 138,064	\$ 39,643
Accounts receivable, net	3,939	2,850
Inventory	7,014	5,131
Prepaid expenses and other current assets	2,508	1,112
Total current assets	<u>151,525</u>	<u>48,736</u>
Operating lease right-of-use assets	2,645	—
Property and equipment, net	2,803	2,619
Other assets	566	2,066
TOTAL ASSETS	<u>\$ 157,539</u>	<u>\$ 53,421</u>
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	\$ 3,967	\$ 1,487
Term notes, current portion	3,333	1,667
Accrued liabilities	6,439	6,217
Lease liability, current portion	877	—
Total current liabilities	<u>14,616</u>	<u>9,371</u>
Lease liability, noncurrent portion	1,916	—
Term notes, noncurrent portion	11,821	13,383
Convertible preferred stock warrant liability	—	313
Other liabilities	—	136
TOTAL LIABILITIES	<u>28,353</u>	<u>23,203</u>
Commitments and contingencies (Note 6)		
Convertible preferred stock	—	152,806
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock	—	—
Common stock	28	2
Additional paid-in capital	268,822	4,275
Accumulated other comprehensive loss	—	—
Accumulated deficit	<u>(139,664)</u>	<u>(126,865)</u>
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	<u>129,186</u>	<u>(122,588)</u>
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	<u>\$ 157,539</u>	<u>\$ 53,421</u>

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	
	March 31,	
	2019	2018
Revenue:		
Product revenue	\$ 7,269	\$ 1,322
Operating expenses:		
Cost of product revenue	3,072	794
Research and development	7,484	5,516
Sales and marketing	5,871	3,438
General and administrative	3,001	1,376
Total operating expenses	19,428	11,124
Loss from operations	(12,159)	(9,802)
Interest expense	(245)	(18)
Change in fair value of warrant liability	(609)	41
Other income, net	221	185
Net loss before taxes	(12,792)	(9,594)
Income tax provision	7	—
Net loss	\$ (12,799)	\$ (9,594)
Unrealized gain on available-for-sale securities	—	1
Total comprehensive loss	\$ (12,799)	\$ (9,593)
Net loss per share, basic and diluted	\$ (1.37)	\$ (5.63)
Shares used in computing net loss per share, basic and diluted	9,364,755	1,705,144

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 Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance — December 31, 2018	18,670,328	\$ 152,806	1,824,852	\$ 2	\$ 4,275	\$ —	\$ (126,865)	\$ (122,588)
Exercise of common stock warrants for cash	—	—	50,331	—	110	—	—	110
Issuance of common stock upon net exercise of warrants	—	—	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

	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)

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)

	Three Months Ended March 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (12,799)	\$ (9,594)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	255	129
Stock-based compensation	412	273
Amortization of right-of-use assets	249	—
Loss on write down of fixed assets	19	—
Change in fair value of warrant liability	609	(41)
Amortization of debt issuance costs	104	—
Changes in operating assets and liabilities:		
Accounts receivable	(1,089)	(503)
Inventory	(1,883)	(1,168)
Prepaid expenses and other current assets	(1,396)	11
Other assets	(19)	(143)
Accounts payable	369	346
Accrued and other current liabilities	991	(678)
Lease liabilities	(237)	—
Other liabilities	—	(9)
Net cash used in operating activities	<u>(14,415)</u>	<u>(11,377)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from maturities of available-for-sale securities	—	1,807
Purchase of property and equipment	(420)	(315)
Net cash (used in) provided by investing activities	<u>(420)</u>	<u>1,492</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon initial public offering, net of issuance costs paid	102,977	—
Proceeds from issuance of common stock in private placement	10,000	—
Proceeds from stock option exercises	169	315
Proceeds from warrant exercises	110	101
Net cash provided by financing activities	<u>113,256</u>	<u>416</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	98,421	(9,469)
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	<u>\$ 138,514</u>	<u>\$ 42,454</u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	\$ 132	\$ 18
Income tax paid	\$ 4	\$ —
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	\$ —	\$ 211
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	\$ —
Deferred offering costs included in accounts payable and accrued liabilities	\$ 2,215	\$ —
Right-of-use asset obtained in exchange for lease liability	\$ 73	\$ —
Property and equipment purchases included in accounts payable	\$ 93	\$ 74
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.

Notes to 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 \$100.1 million from the IPO, after deducting underwriters’ discounts and commissions of \$7.1 million and offering costs of \$4.2 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 for the period presented, which fractional shares will be 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 March 31, 2019, the Company had an accumulated deficit of \$139.7 million. Management expects to continue to incur additional substantial losses in the foreseeable future.

As of March 31, 2019, the Company had cash and cash equivalents of \$138.1 million, which are available to fund future operations. The Company believes that its cash and cash equivalents as of March 31, 2019, together with available borrowings under a revolving line of credit, 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.

Notes to Condensed Consolidated Financial Statements

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 balance sheet as of March 31, 2019, the condensed consolidated statements of operations and comprehensive loss, the condensed consolidated statements of convertible preferred stock and stockholders’ equity (deficit) and the statements of cash flows for the three months ended March 31, 2019 and 2018 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 as of March 31, 2019 and its results of operations and cash flows for the three months ended March 31, 2019 and 2018. The financial data and the other financial information contained in these notes to the condensed consolidated financial statements related to the three month periods are also unaudited. The results of operations for the three months ended March 31, 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 March 31, 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:

	March 31, 2019	December 31, 2018
	(in thousands)	
Cash and cash equivalents	\$ 138,064	\$ 39,643
Restricted cash	450	450
Total cash, cash equivalents, and restricted cash	<u>\$ 138,514</u>	<u>\$ 40,093</u>

Fair Value of Financial Instruments

The Company’s cash and cash equivalents, restricted cash, 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.

Notes to Condensed Consolidated Financial Statements

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 months ended March 31, 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, all 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).

Notes to Condensed Consolidated Financial Statements

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:

	March 31, 2019			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Money market funds	\$ 111,801	\$ —	\$ —	\$ 111,801
Total assets	<u>\$ 111,801</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 111,801</u>
	December 31, 2018			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Money market funds	\$ 21,680	\$ —	\$ —	\$ 21,680
Total assets	<u>\$ 21,680</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 21,680</u>
Liabilities:				
Convertible preferred stock warrant liability	\$ —	\$ —	\$ 313	\$ 313
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 313</u>	<u>\$ 313</u>

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

Notes to Condensed Consolidated Financial Statements

The change in the fair value of the warrant liability for the three months ended March 31, 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 March 31, 2019	<u>\$ —</u>

The change in the fair value of the warrant liability for the three months ended March 31, 2018 is summarized below (in thousands):

Balance at December 31, 2017	\$ 577
Exercise of warrants	(211)
Expiration of warrants, included in change in fair value of warrant liability	(87)
Change in fair value of warrant liability	46
Balance at March 31, 2018	<u>\$ 325</u>

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 was determined using the Black-Scholes option pricing model and the following assumptions:

	Three Months Ended March 31,	
	2019	2018
Expected term (in years)	5.28	6.21
Expected volatility	43.9%	42.8%
Risk-free interest rate	2.49%	2.62%
Expected dividend yield	0%	0%

4. Cash Equivalents

The following is a summary of the Company's cash equivalents:

	March 31, 2019			Fair Value
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	
(in thousands)				
Money market funds	\$ 111,801	\$ —	\$ —	\$ 111,801
Total	<u>\$ 111,801</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 111,801</u>
Reported as:				
Cash equivalents				\$ 111,801
Total				<u>\$ 111,801</u>

Notes to Condensed Consolidated Financial Statements

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

5. Balance Sheet Components

Inventory

Inventory consists of the following:

	March 31, 2019	December 31, 2018
	(in thousands)	
Raw material	\$ 1,915	\$ 1,084
Work in progress	1,103	634
Finished goods	2,643	2,313
Consigned inventory	1,353	1,100
Total inventory	\$ 7,014	\$ 5,131

Accrued Liabilities

Accrued liabilities consist of the following:

	March 31, 2019	December 31, 2018
	(in thousands)	
Accrued employee compensation	\$ 2,965	\$ 3,135
Accrued research and development costs	1,736	1,115
Accrued professional services	713	1,391
Other	1,025	576
Total accrued liabilities	\$ 6,439	\$ 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 Company is using the facility for office, manufacturing and research and development purposes. In connection with the lease, the Company recognized an operating lease right-of-use asset of \$0.1 million as of March 31, 2019 and an aggregate lease liability of \$0.1 million on its condensed consolidated balance sheet. The remaining lease term is six months.

Notes to Condensed Consolidated Financial Statements

In May 2018, the Company entered into a new lease agreement for office and laboratory space which consist of approximately 35,000 square feet located in Santa Clara, California. The lease term commenced in September 2018 and ends in August 2022. In connection with the lease, the Company maintains a letter of credit for the benefit of the landlord in the amount of \$0.5 million, which is secured by restricted cash recorded as other assets on the condensed consolidated balance sheets. In connection with the lease, the Company recognized an operating lease right-of-use asset of \$2.4 million as of March 31, 2019 and an aggregate lease liability of \$2.6 million on its condensed consolidated balance sheet. The remaining lease term is three years and four months.

The Company also leases several vehicles for use by employees. In connection with the vehicle leases, the Company recognized an operating lease right-of-use asset of \$0.1 million as of March 31, 2019 and an aggregate lease liability of \$0.1 million on its condensed consolidated balance sheet. The weighted average remaining lease term is 14 months.

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

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. Rent expense for the three months ended March 31, 2019 and 2018 was \$0.3 million and \$0.1 million, respectively.

The following is a maturity analysis of the annual undiscounted cash flows reconciled to the carrying value of the operating lease liabilities as of March 31, 2019:

	<u>(in thousands)</u>
Remainder of 2019	\$ 812
2020	861
2021	855
2022	581
Total minimum lease payments	<u>\$ 3,109</u>
Less: imputed interest	<u>(316)</u>
Total	<u>\$ 2,793</u>

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 will be settled in cash. As of March 31, 2019, the Company has not paid this liability.

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 March 31, 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.

Common Stock Warrants

As part of the IPO, 91,446 related party common stock warrants were net exercised based on the IPO price of \$17.00 per share into 79,632 shares of common stock.

Notes to Condensed Consolidated Financial Statements

In February 2018, in connection with the execution of the 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.

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

	Warrants Outstanding March 31, 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	34,440	\$ 4.026	February 2028
Common stock warrant issued in connection with conversion of preferred stock warrants upon initial public offering	54,903	—	\$ 3.096	June 2024
Total common stock warrants	<u>89,343</u>	<u>176,218</u>		

8. Stock-Based Compensation

Total stock-based compensation was as follows:

	Three Months March 31,	
	2019	2018
	(in thousands)	
Cost of product revenue	\$ 27	\$ 15
Research and development	72	49
Sales and marketing	108	43
General and administrative	205	166
Total stock-based compensation	<u>\$ 412</u>	<u>\$ 273</u>

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 three months ended March 31, 2019 and 2018 were as follows:

	Three Months Ended March 31,	
	2019	2018
Expected term (in years)	6.08	6.08
Expected volatility	42.4%-42.9%	45.9%
Risk-free interest rate	2.5%-2.6%	1.9%
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.

Notes to Condensed Consolidated Financial Statements

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 awards under the 2019 Plan. 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 March 31, 2019, there were 1,694,114 shares available for issuance under the 2019 Plan.

Activity under the 2009 Plan and 2019 Plan is set forth below:

	Shares Available for Grant	Number of Shares	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance, December 31, 2018	392,299	3,636,358	\$ 3.54	7.79	\$ 11,267
Awards authorized	2,000,430	—			
2009 Plan shares expired	(293,953)	—			
Options granted	(425,983)	425,983	14.08		
Options exercised	—	(80,515)	2.12		
Options cancelled	21,321	(21,321)	3.12		
Balance, March 31, 2019	<u>1,694,114</u>	<u>3,960,505</u>	\$ 4.67	7.87	\$ 114,058
Vested and exercisable, March 31, 2019		<u>1,716,874</u>	\$ 2.78	6.59	\$ 52,691
Vested and expected to vest, March 31, 2019		<u>3,960,505</u>	\$ 4.67	7.87	\$ 114,058

Employees 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 is expected to begin on September 1, 2019 and 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.

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 period presented due to their anti-dilutive effect:

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Convertible preferred stock on an as-converted basis	—	17,562,214
Common stock options issued and outstanding	3,960,505	3,121,530
Early exercised options subject to future vesting	5,328	41,240
Convertible preferred stock warrants	—	94,345
Common stock warrants	89,343	176,218
Total	<u>4,055,176</u>	<u>20,995,547</u>

Notes to Condensed Consolidated Financial Statements

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 March 31,	
	2019	2018
	(in thousands)	
United States	\$ 3,636	\$ 897
Germany	643	254
Rest of Europe	2,736	129
All other countries	254	42
Product revenue	<u>\$ 7,269</u>	<u>\$ 1,322</u>

As of March 31, 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 and the Prospectus. 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”). We have ongoing clinical programs across several products and indications which, if successful, will allow us to expand commercialization of our products into new geographies and indications. Importantly, we are undertaking ongoing clinical trials of our C2 catheter intended to support a pre-market application (“PMA”) within the United States and a Shonin submission in Japan for the treatment of CAD. We anticipate having final data from these ongoing clinical trials intended to support a U.S. launch of our C2 catheter in the first half of 2021.

The first two indications we are targeting with our IVL System are PAD, the narrowing or blockage of vessels that carry blood from the heart to the extremities, and CAD, the narrowing or blockage of the arteries that supply blood to the heart. In the future, we see significant opportunity in the potential treatment of 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, including in Australia, the Baltics, Canada, Czech Republic, France, Italy, the Netherlands, New Zealand, the Nordic region, Poland, Spain and the United Kingdom. We are actively expanding our international field presence through new distributors, additional sales and clinical personnel and are adding new U.S. sales territories.

For the three months ended March 31, 2019 and 2018, we generated product revenue of \$7.3 million and \$1.3 million, respectively, and a \$12.2 million and \$9.8 million loss from operations for the three months ended March 31, 2019 and 2018, respectively. For the three months ended March 31, 2019 and 2018, 50% and 32%, 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 \$100.1 million in net proceeds after deducting underwriters' discounts and commissions of \$7.1 million and offering costs of \$4.2 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 include marketing and promotional activities, including trade shows and market research, and cost of outside consultants. We expect to continue to grow our sales force and increase marketing efforts as we continue commercializing products based on our IVL Technology. As a result, we expect sales and marketing expenses to increase in absolute dollars in future periods.

General and administrative expenses

General and administrative expenses consist of personnel-related expenses, including salaries, benefits, bonus, travel and stock-based compensation. Other general and administrative expenses include professional services fees, including legal, audit and tax fees, insurance costs, cost of outside consultants and employee recruiting and training costs. Moreover, we expect to incur additional expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance and investor relations. As a result, we expect general and administrative expenses to increase in absolute dollars in future periods.

Results of Operations

Comparison of the Three Months Ended March 31, 2019 and 2018

The following table shows our results of operations for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,		Change \$	Change %
	2019	2018		
Revenue:				
Product revenue	\$ 7,269	\$ 1,322	\$ 5,947	450%
Operating expenses:				
Cost of product revenue	3,072	794	2,278	287%
Research and development	7,484	5,516	1,968	36%
Sales and marketing	5,871	3,438	2,433	71%
General and administrative	3,001	1,376	1,625	118%
Total operating expenses	19,428	11,124	8,304	75%
Loss from operations	(12,159)	(9,802)	(2,357)	24%
Interest expense	(245)	(18)	(227)	*
Change in fair value of warrant liability	(609)	41	(650)	*
Other income, net	221	185	36	19%
Net loss before taxes	(12,792)	(9,594)	(3,198)	33%
Income tax provision	7	—	7	*
Net loss	<u>\$ (12,799)</u>	<u>\$ (9,594)</u>	<u>\$ (3,205)</u>	33%

* Not meaningful

Product revenue

Product revenue increased by \$5.9 million, or 450%, from \$1.3 million during the three months ended March 31, 2018 to \$7.3 million during the three months ended March 31, 2019. The increase was primarily due to an increase in the number of customers and an increase in purchase volume of our products per customer both within the United States and internationally.

Product revenue consisted primarily of the sale of our IVL catheters. Product revenue, classified by the major geographic areas in which our products are shipped, was \$3.7 million within the United States and \$3.6 million for all other countries in the three months ended March 31, 2019 and \$0.9 million within the United States and \$0.4 million for all other countries in the three months ended March 31, 2018.

Cost of product revenue and gross margin percentage

Cost of product revenue increased by \$2.3 million, or 287% from \$0.8 million during the three months ended March 31, 2018 to \$3.1 million during the three months ended March 31, 2019. The increase was primarily due to growth in sales volume. Gross margin percentage was 39.9% for the three months ended March 31, 2018. Gross margin percentage improved to 57.7% for the three months ended March 31, 2019. This change in gross margin percentage was primarily due to increased sales volume of our IVL catheters and improved manufacturing efficiencies.

Research and development expenses

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

	Three Months Ended March 31,	
	2019	2018
Compensation and related personnel costs	\$ 2,713	\$ 2,814
Clinical-related costs	2,732	1,217
Material and supplies	485	695
Facilities and other allocated costs	698	240
Outside consultants	530	313
Other research and development costs	326	237
Total research and development expenses	<u>\$ 7,484</u>	<u>\$ 5,516</u>

R&D expenses increased by \$2.0 million, or 36%, from \$5.5 million during the three months ended March 31, 2018 to \$7.5 million during the three months ended March 31, 2019. The increase was primarily due to a \$1.5 million increase in clinical-related costs and a \$0.2 million increase in costs associated with outside consultants to support clinical trials. Clinical-related costs during the three months ended March 31, 2019 were primarily related to the PAD III, CAD II and CAD III clinical trials. There was also a \$0.5 million increase in facilities and other allocated costs due to higher rent and building expenditures. These increases were partially offset by a \$0.2 million decrease in materials and supplies for R&D.

Sales and marketing expenses

Sales and marketing expenses increased by \$2.4 million, or 71%, from \$3.4 million during the three months ended March 31, 2018 to \$5.9 million during the three months ended March 31, 2019. The increase was primarily due to a \$2.0 million increase in compensation and related personnel costs, which included a \$0.7 million increase in commission expense, as a result of increased headcount and increased business development related activities to expand the domestic and international customer base. Marketing and promotional expenses increased by \$0.4 million to support the commercialization of our products.

General and administrative expenses

General and administrative expenses increased by \$1.6 million, or 118%, from \$1.4 million during the three months ended March 31, 2018 to \$3.0 million during the three months ended March 31, 2019. The increase was primarily due to a \$1.0 million increase in professional services and general corporate expenses incurred in connection with our preparation to become a public company, a \$0.3 million increase in compensation and related personnel costs, and a \$0.3 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 equity securities, and payments received from customers using our product. 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 \$100.1 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—Debt obligations” included in the Prospectus. We had \$15.0 million outstanding under the term loan and no amounts outstanding under the revolving line of credit as of March 31, 2019.

We believe that our cash and cash equivalents as of March 31, 2019 will be sufficient to fund our operations for at least the next 12 months from the date of this filing. As of March 31, 2019, we had \$138.1 million in cash and cash equivalents and an accumulated deficit of \$139.7 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:

	Three Months Ended	
	March 31,	
	2019	2018
	(in thousands)	
Cash used in operating activities	\$ (14,415)	\$ (11,377)
Cash (used in) provided by investing activities	(420)	1,492
Cash provided by financing activities	113,256	416
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 98,421</u>	<u>\$ (9,469)</u>

Operating activities

During the three months ended March 31, 2019, cash used in operating activities was \$14.4 million, attributable to a net loss of \$12.8 million and a net change in our net operating assets and liabilities of \$3.3 million, partially offset by non-cash charges of \$1.6 million. Non-cash charges primarily consisted of \$0.4 million in stock-based compensation, \$0.3 million in depreciation and amortization, \$0.2 million in amortization of right-of-use assets and \$0.7 million in amortization of debt issuance costs and change in fair value of warrant liability. The change in our net operating assets and liabilities was primarily due to a \$1.9 million increase in inventory and \$1.1 million increase in accounts receivable due to an increase in sales, a \$1.4 million increase in prepaid and other current assets and a \$0.2 million decrease in lease liabilities. These changes were partially offset by a \$1.4 million increase in accrued and other current liabilities and accounts payable resulting primarily from increases in our operating activities and accrued professional services fees.

During the three months ended March 31, 2018, cash used in operating activities was \$11.4 million, attributable to a net loss of \$9.6 million and a net change in our net operating assets and liabilities of \$2.1 million, partially offset by non-cash charges of \$0.4 million. Non-cash charges primarily consisted of \$0.3 million in stock-based compensation and \$0.1 million in depreciation. The change in our net operating assets and liabilities was primarily due to a \$1.2 million increase in inventory for anticipated growth in our business, a \$0.5 million increase in accounts receivable due to increase in sales, an increase of \$0.1 million in other assets and a decrease of \$0.7 million in accrued and other current liabilities. These changes were partially offset by a \$0.3 million increase in accounts payable resulting primarily from increases in our operating activities.

Investing activities

During the three months ended March 31, 2019, cash used in investing activities was \$0.4 million, attributable to the purchase of property and equipment.

During the three months ended March 31, 2018, cash used in investing activities was \$1.5 million, attributable to purchase of property and equipment of \$0.3 million, partially offset by maturity of available-for-sale investments of \$1.8 million.

Financing activities

During the three months ended March 31, 2019, cash provided by financing activities was \$113.3 million, attributable to proceeds of \$103.0 million from the IPO, net of issuance costs paid, net proceeds of \$10.0 million from the Private Placement and proceeds from stock option exercises and warrant exercises of \$0.3 million.

During the three months ended March 31, 2018, cash provided by financing activities was \$0.4 million, attributable to net proceeds of \$0.3 million from stock option exercises and warrant exercises of \$0.1 million.

Contractual Obligations and Commitments

During the three months ended March 31, 2019, there have been no material changes outside the ordinary course of business 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 three months ended March 31, 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 and cash equivalents as of March 31, 2019 consisted of \$138.1 million in bank deposits and money market funds. Such interest-earning instruments carry a degree of interest rate risk. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents.

As of March 31, 2019, we had \$15.0 million in variable rate debt outstanding. The 2018 Loan and Security Agreement matures in December 2021, with interest-only monthly payments until September 2019. The term loan accrues interest at a floating per annum rate equal to the greater of the Wall Street Journal prime rate minus 1.75% and 2.75% (3.75% as of March 31, 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 three months ended March 31, 2019 and 2018, approximately 37% and 29% 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 \$0.4 million in foreign currency cash and accounts receivable as of March 31, 2019. 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 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. We submitted our preliminary responses to these petitions in April 2019, and the PTAB is expected to decide whether or not to institute the *inter partes* reviews by July 2019. If the PTAB decides to institute an *inter partes* review with respect to one or more of the IPR Patents, it could result in the loss or narrowing in scope of such patents, which could limit our ability to stop others from using or commercializing products and technology similar or identical to ours. For more information regarding the risks presented by such proceedings, please see the section titled “Risk Factors—Risks Related to Our Intellectual Property” included in the Prospectus.

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.

As of the date of this Quarterly Report on Form 10-Q, there have been no material changes from the risk factors disclosed in our Prospectus dated March 6, 2019 as filed by us with the SEC pursuant to Rule 424(b)(4) under the Securities Act, relating to our registration statement on Form S-1 (File No. 333-229590). Any of these factors could result in a significant or material adverse effect on our result of operations or financial conditions. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations. We may disclose changes to such factors or disclose additional factors from time to time in our future filings with the SEC.

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

(a) Sales of Unregistered Securities

Between January 1, 2019 and March 6, 2019 (the date of the filing of our registration statement on Form S-8, No. 333-230113):

We granted to our directors, officers, employees and consultants options to purchase an aggregate of 425,983 shares of common stock under our equity compensation plans, at exercise prices ranging from \$6.59 to \$17.00 per share.

We issued and sold to our directors, officers, employees and consultants an aggregate of 78,005 shares of common stock upon the exercise of options under our equity compensation plans at exercise prices ranging from \$0.49 to \$6.71 per share, for an aggregate amount of \$0.2 million.

We issued 50,331 shares of our common stock upon the exercise of a warrant at \$2.196 per share, for cash consideration of approximately \$0.1 million.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act (or Regulation D promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions.

(b) 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 initial public offering 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 \$100.1 million after deducting underwriting discount and commissions of \$7.1 million and offering costs of \$4.2 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
3.1	Restated Certificate of Incorporation of ShockWave Medical, Inc.	8-K	001-38829	3.3	March 12, 2019
3.2	Amended and Restated Bylaws of ShockWave Medical, Inc.	8-K	001-38829	3.4	March 12, 2019
4.1	Form of Common Stock Certificate	S-1	333-229590	4.1	February 8, 2019
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.

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: May 9, 2019

By: _____
Douglas Godshall
President and Chief Executive Officer

Date: May 9, 2019

By: _____
Dan Puckett
Chief Financial Officer

**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 March 31, 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: May 9, 2019

By: _____ /s/ Douglas Godshall

Douglas Godshall
President and Chief Executive Officer

**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 March 31, 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: May 9, 2019

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