

**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 June 30, 2020

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-38829

**Shockwave Medical, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**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**

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

<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)

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

As of August 6, 2020, the registrant had 34,002,860 shares of common stock, \$0.001 par value per share, outstanding.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify these statements by forward-looking words such as “may,” “might,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential” or “continue,” the negative of these terms and other comparable terminology. These forward-looking statements, which are subject to risks, uncertainties and assumptions about us, may include projections of our future financial performance, our anticipated growth strategies and anticipated trends in our business. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to statements about:

- the impact of the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including on sales, expenses, supply chain, manufacturing, research and development activities, clinical trials and employees;
- our ability to design, develop, manufacture and market innovative products to treat patients with challenging medical conditions, particularly in peripheral artery disease, coronary artery disease and aortic stenosis;
- our expected future growth, including growth in international sales;
- the size and growth potential of the markets for our products, and our ability to serve those markets;
- the rate and degree of market acceptance of our products;
- coverage and reimbursement for procedures performed using our products;
- the performance of third parties in connection with the development of our products, including third-party suppliers;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines;
- our plans to research, develop and commercialize our products and any other approved or cleared product;
- our ability to scale our organizational culture of cooperative product development and commercial execution;
- the development, regulatory approval, efficacy and commercialization of competing products;
- the loss of key scientific or management personnel;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our ability to develop and maintain our corporate infrastructure, including our internal controls;
- our financial performance and capital requirements; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others.

These statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements, including those factors discussed in the section entitled “*Risk Factors*” of our Annual Report on Form 10-K for the year ended December 31, 2019, as updated in the section entitled “*Risk Factors*” of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 and in this Quarterly Report on Form 10-Q. Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. We undertake no obligation to update any of these forward-looking statements for any reason, even if new information becomes available in the future, except as may be required by law.

## Item 1. Financial Statements.

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

	June 30, 2020	December 31, 2019
		(1)
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 218,296	\$ 139,045
Short-term investments	13,109	56,304
Accounts receivable, net	6,365	7,377
Inventory	23,427	12,074
Prepaid expenses and other current assets	3,117	1,897
Total current assets	264,314	216,697
Operating lease right-of-use assets	8,130	8,825
Property and equipment, net	13,287	4,910
Other assets	1,622	1,506
<b>TOTAL ASSETS</b>	<b>\$ 287,353</b>	<b>\$ 231,938</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 2,562	\$ 2,790
Term notes, current portion	—	6,667
Accrued liabilities	14,381	13,777
Lease liability, current portion	798	774
Total current liabilities	17,741	24,008
Lease liability, noncurrent portion	7,903	8,125
Term notes, noncurrent portion	16,286	7,152
<b>TOTAL LIABILITIES</b>	<b>41,930</b>	<b>39,285</b>
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock	—	—
Common stock	34	31
Additional paid-in capital	460,235	370,561
Accumulated other comprehensive income	21	35
Accumulated deficit	(214,867)	(177,974)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>245,423</b>	<b>192,653</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 287,353</b>	<b>\$ 231,938</b>

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

(1) The consolidated balance sheet as of December 31, 2019 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
<b>Revenue:</b>				
Product revenue	\$ 10,286	\$ 10,012	\$ 25,483	\$ 17,282
<b>Cost of revenue:</b>				
Cost of product revenue	3,592	4,133	9,243	7,205
Gross profit	<u>6,694</u>	<u>5,879</u>	<u>16,240</u>	<u>10,077</u>
<b>Operating expenses:</b>				
Research and development	8,101	6,926	19,991	14,410
Sales and marketing	11,206	6,961	21,617	12,831
General and administrative	5,398	3,245	11,622	6,247
Total operating expenses	<u>24,705</u>	<u>17,132</u>	<u>53,230</u>	<u>33,488</u>
Loss from operations	(18,011)	(11,253)	(36,990)	(23,411)
Interest expense	(306)	(250)	(583)	(495)
Change in fair value of warrant liability	-	-	—	(609)
Other income, net	220	913	724	1,133
Net loss before taxes	(18,097)	(10,590)	(36,849)	(23,382)
Income tax provision	21	18	44	25
Net loss	<u>\$ (18,118)</u>	<u>\$ (10,608)</u>	<u>\$ (36,893)</u>	<u>\$ (23,407)</u>
Unrealized gain/(loss) on available-for-sale securities	(82)	75	(14)	75
Total comprehensive loss	<u>\$ (18,200)</u>	<u>\$ (10,533)</u>	<u>\$ (36,907)</u>	<u>\$ (23,332)</u>
Net loss per share, basic and diluted	<u>\$ (0.56)</u>	<u>\$ (0.38)</u>	<u>\$ (1.16)</u>	<u>\$ (1.25)</u>
Shares used in computing net loss per share, basic and diluted	<u>32,156,476</u>	<u>28,002,887</u>	<u>31,900,259</u>	<u>18,735,307</u>

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

**SHOCKWAVE MEDICAL, INC.**  
**Condensed Consolidated Statements of Stockholders' Equity**  
*(Unaudited)*  
(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance — December 31, 2019	—	\$ —	31,446,787	\$ 31	\$ 370,561	\$ 35	\$ (177,974)	\$ 192,653
Exercise of stock options	—	—	356,128	1	1,112	—	—	1,113
Issuance of common stock under employee stock purchase plan	—	—	24,691	—	842	—	—	842
Unrealized gain on available-for-sale securities	—	—	—	—	—	68	—	68
Stock-based compensation	—	—	—	—	1,871	—	—	1,871
Net loss	—	—	—	—	—	—	(18,775)	(18,775)
Balance — March 31, 2020	—	—	31,827,606	32	374,386	103	(196,749)	177,772
Exercise of stock options	—	—	137,178	—	480	—	—	480
Issuance of common stock in connection with public offering, net of issuance costs of \$6.1 million	—	—	1,955,000	2	83,380	—	—	83,382
Issuance of common stock in connection with vesting of restricted stock units	—	—	41,229	—	—	—	—	—
Restricted stock units withheld in net settlement for tax	—	—	(15,456)	—	(616)	—	—	(616)
Unrealized loss on available-for-sale securities	—	—	—	—	—	(82)	—	(82)
Stock-based compensation	—	—	—	—	2,605	—	—	2,605
Net loss	—	—	—	—	—	—	(18,118)	(18,118)
Balance — June 30, 2020	—	\$ —	33,945,557	\$ 34	\$ 460,235	\$ 21	\$ (214,867)	\$ 245,423

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

**SHOCKWAVE MEDICAL, INC.**  
**Condensed Consolidated Statements of Stockholders' Equity**  
*(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
Settlement of 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
Offering cost related to the initial public offering	—	—	—	—	(215)	—	—	(215)
Stock-based compensation	—	—	—	—	818	—	—	818
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

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)**

	Six Months Ended June 30,	
	2020	2019
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (36,893)	\$ (23,407)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	877	516
Stock-based compensation	4,262	1,230
Amortization of right-of-use assets	734	496
Accretion of discount on available-for-sale securities	201	(354)
Loss on write down of fixed assets	—	88
Change in fair value of warrant liability	—	609
Amortization of debt issuance costs	313	212
Changes in operating assets and liabilities:		
Accounts receivable	1,012	(2,392)
Inventory	(10,965)	(3,160)
Prepaid expenses and other current assets	(1,220)	(841)
Other assets	(116)	5
Accounts payable	(282)	713
Accrued and other current liabilities	(41)	1,848
Lease liabilities	(237)	(496)
Net cash used in operating activities	<u>(42,355)</u>	<u>(24,933)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of available-for-sale securities	(16,020)	(82,784)
Proceeds from maturities of available-for-sale securities	59,000	—
Purchase of property and equipment	(8,952)	(1,191)
Net cash provided by (used in) investing activities	<u>34,028</u>	<u>(83,975)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock upon initial public offering, net of issuance costs paid	—	100,762
Proceeds from issuance of common stock in private placement	—	10,000
Payments of offering costs	(179)	—
Proceed from issuance of common stock from public offering, net of issuance cost paid	83,784	—
Payments of taxes withheld on net settled vesting of restricted stock units	(616)	—
Principal payments of term loan	(1,111)	—
Net proceeds from term loan	3,265	—
Proceeds from stock option exercises	1,593	317
Proceeds from issuance of common stock under employee stock purchase plan	842	—
Proceeds from warrant exercises	—	110
Net cash provided by financing activities	<u>87,578</u>	<u>111,189</u>
Net increase in cash, cash equivalents and restricted cash	79,251	2,281
Cash, cash equivalents and restricted cash at beginning of period	140,495	40,093
Cash, cash equivalents and restricted cash equivalents at end of period	<u>\$ 219,746</u>	<u>\$ 42,374</u>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>		
Interest paid	\$ 256	\$ 276
Income tax paid	\$ 10	\$ 8
<b>NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>		
Common stock issued on conversion of convertible preferred stock	\$ —	\$ 152,806
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
Offering costs included in accounts payable and accrued liabilities	\$ 402	\$ 215
Right-of-use asset obtained in exchange for lease liability	\$ 39	\$ 73
Property and equipment purchases included in accounts payable and accrued liabilities	\$ 501	\$ 93
Transfer of fixed assets to inventory	\$ 174	\$ —

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.

***Need for Additional Capital***

The Company has incurred significant losses and has negative cash flows from operations. As of June 30, 2020, the Company had an accumulated deficit of \$214.9 million. Management expects to continue to incur additional substantial losses for the foreseeable future.

As of June 30, 2020, the Company had cash, cash equivalents and short-term investments of \$231.4 million, which are available to fund future operations. The Company believes that its cash, cash equivalents and short-term investments as of June 30, 2020, 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, the timing and cost of establishing additional sales and marketing capabilities and the scope, duration and continuing impact of the COVID-19 pandemic.

***Risk and Uncertainties***

The Company is subject to risks and uncertainties as a result of the ongoing effects of the COVID-19 pandemic. There are many uncertainties regarding the current COVID-19 pandemic, and the Company is continuing to closely monitor the impact of the pandemic on all aspects of its business, including how it is impacting and how it may continue to impact its customers, patients that would benefit from procedures utilizing the Company’s products, employees, suppliers, vendors, business partners and distribution channels. The capital markets and economies worldwide continue to be negatively impacted by the COVID-19 pandemic, including U.S. and global economic recessions. As such the Company’s future results of operations and liquidity may continue to be adversely impacted by a variety of factors related to the COVID-19 pandemic, including those discussed or referred to in the section entitled “*Risk Factors*” of this Quarterly Report on Form 10-Q.

As of the date of issuance of these condensed consolidated financial statements, the extent to which the COVID-19 pandemic may materially impact the Company’s financial condition, liquidity, or results of operations is uncertain. Given the ongoing uncertainty of the scope and duration of the COVID-19 pandemic, the Company is currently unable to accurately estimate the scale and duration of the impact on its business, including procedure volumes, clinical activities and product development, and by extension the Company’s financial results.

**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 unaudited interim 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 six months ended June 30, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2019 included herein was derived from the audited financial statements as of that date. The unaudited condensed consolidated

## Notes to Condensed Consolidated Financial Statements

financial statements should be read in conjunction with the Company's audited consolidated financial statements and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 12, 2020.

**Reclassifications**

Certain amounts in the prior period condensed consolidated financial statements have been reclassified to conform to the current period presentation.

**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 June 30, 2020 and December 31, 2019 relates to a letter of credit established for the Company's office lease 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:

	June 30, 2020	December 31, 2019
	(in thousands)	
Cash and cash equivalents	\$ 218,296	\$ 139,045
Restricted cash	1,450	1,450
Total cash, cash equivalents, and restricted cash	<u>\$ 219,746</u>	<u>\$ 140,495</u>

**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, except for credit-related impairment losses. The Company periodically evaluates whether declines in fair values of its marketable securities below their book value are other-than-temporary and if they are related to deterioration in credit risk. 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. The Company also 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. Effective January 1, 2020, any unrealized losses on available-for-sale debt securities that are attributed to credit risk are recorded to earnings through an allowance for credit losses. 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.

**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.

**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 products sold to customers that utilize stocking orders, control is transferred upon shipment or delivery to the customer's named location, based on the contractual shipping terms. For consignment inventory, control is transferred at the time the IVL catheters are consumed in a procedure.

In the United States 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.

**Recently Adopted Accounting Pronouncements**

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

In addition, Topic 326 also provides new guidance related to the measurement of expected credit losses on the Company's allowance for bad debt for accounts receivable, which is estimated upon assessment of various factors including historical collection experience, current and future economic market conditions and a review of the current aging status and financial condition of the Company's customers. During the six months ended June 30, 2020, the Company recorded an additional allowance for bad debt in response to an assessment of the evolving credit environment under the COVID-19 pandemic. The Company will continue to update its estimate of credit losses from accounts receivable in future periods in response to the uncertainties caused by the COVID-19 pandemic.

## Notes to Condensed Consolidated Financial Statements

## 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:

	June 30, 2020			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
<b>Assets:</b>				
U.S. Treasury securities	\$ 10,063	\$ —	\$ —	\$ 10,063
Money market funds	135,214	—	—	135,214
Corporate bonds	—	3,046	—	3,046
Total assets	<u>\$ 145,277</u>	<u>\$ 3,046</u>	<u>\$ —</u>	<u>\$ 148,323</u>

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

The Company's convertible preferred stock warrants were converted into common stock warrants upon the closing of an initial public offering of the Company's common stock ("IPO") in March 2019. 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 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:

	March 31, 2019
Expected term (in years)	5.3
Expected volatility	43.9%
Risk-free interest rate	2.5%
Expected dividend yield	0%

## Notes to Condensed Consolidated Financial Statements

## 4. Cash Equivalents and Short-Term Investments

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

	June 30, 2020			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury securities	\$ 10,043	\$ 20	\$ —	\$ 10,063
Money market funds	135,214	—	—	135,214
Corporate bonds	3,045	1	—	3,046
Total	<u>\$ 148,302</u>	<u>\$ 21</u>	<u>\$ —</u>	<u>\$ 148,323</u>
Reported as:				
Cash equivalents				\$ 135,214
Short-term investments				13,109
Total				<u>\$ 148,323</u>

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

The Company recognized no material gains or losses on its cash equivalents and short-term investments in the periods presented. As of June 30, 2020, the remaining contractual maturities for available-for-sale securities were less than one year.

## 5. Balance Sheet Components

*Inventory*

Inventory consists of the following:

	June 30, 2020	December 31, 2019
	(in thousands)	
Raw material	\$ 4,138	\$ 2,501
Work in progress	2,682	1,364
Finished goods	14,850	6,642
Consigned inventory	1,757	1,567
Total inventory	<u>\$ 23,427</u>	<u>\$ 12,074</u>

## Notes to Condensed Consolidated Financial Statements

**Accrued Liabilities**

Accrued liabilities consist of the following:

	June 30, 2020	December 31, 2019
	(in thousands)	
Accrued employee compensation	\$ 7,300	\$ 8,139
Accrued asset purchases	633	—
Accrued research and development costs	3,734	3,090
Accrued professional services	1,152	804
Other	1,562	1,744
Total accrued liabilities	<u>\$ 14,381</u>	<u>\$ 13,777</u>

**6. Term Notes****Loan and Security Agreement**

In February 2018, the Company entered into a Loan and Security Agreement with Silicon Valley Bank (the “Loan and Security Agreement”). The terms of the Loan and Security Agreement included a term loan of \$15.0 million and a revolving line of credit of \$2.0 million. The term loan was available in two tranches, of which the first tranche of \$10.0 million was funded in June 2018 and the second tranche of \$5.0 million was funded in December 2018.

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

In connection with the execution of the Loan and Security Agreement, the Company issued warrants to Silicon Valley Bank to purchase 34,440 shares of the Company’s common stock. Upon issuance, the fair value of the warrants of \$0.1 million was recorded as a debt issuance cost. The debt issuance cost was being amortized to interest expense, net over the expected repayment period of the loan.

In February 2020, the Company entered into a First Amendment to its Loan and Security Agreement (the “Amended Credit Facility”) to, among other things, refinance its existing term loan, which is accounted for as a modification of the Loan and Security Agreement. Under the Amended Credit Facility, the existing revolving line of credit of \$2.0 million was terminated and the termination fee of less than \$0.1 million was waived. The Amended Credit Facility provides the Company with a supplemental term loan in the amount of \$16.5 million. After repayment of the outstanding amount of the term loan, the Company received net proceeds of \$3.3 million, which reflects an additional \$4.3 million in principal as of the date of the modification less the final balloon payment fee of \$1.0 million. The principal amount outstanding under the supplemental term loan accrues interest at a floating per annum rate equal to the greater of the Prime Rate minus 1.25% and 3.5% (3.5% as of June 30, 2020).

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

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

## Notes to Condensed Consolidated Financial Statements

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

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

	June 30, 2020	December 31, 2019
	(in thousands)	
Principal amount of term note	\$ 16,500	\$ 13,334
Net (discount) premium associated with accretion of final payment, issuance of common stock warrants, and other debt issuance costs	(214)	485
Term note, current and noncurrent	16,286	13,819
Less term note, current portion	—	(6,667)
Term note, noncurrent portion	<u>\$ 16,286</u>	<u>\$ 7,152</u>

Future minimum payments of principal and estimated payments of interest on the Company's outstanding variable rate borrowings as of June 30, 2020 are as follows:

<u>Year ending December 31:</u>	(in thousands)
2020 (remainder)	\$ 294
2021	3,861
2022	6,961
2023	8,294
Total future payments	19,410
Less amounts representing interest	(1,342)
Less final payment	(1,568)
Total principal amount of term note payments	<u>\$ 16,500</u>

## 7. Stock-Based Compensation

Total stock-based compensation was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
Cost of product revenue	\$ 39	\$ 48	\$ 141	\$ 75
Research and development	650	204	\$ 1,138	276
Sales and marketing	837	201	\$ 1,396	309
General and administrative	924	365	\$ 1,587	570
Total stock-based compensation	<u>\$ 2,450</u>	<u>\$ 818</u>	<u>\$ 4,262</u>	<u>\$ 1,230</u>

## Notes to Condensed Consolidated Financial Statements

**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 six months ended June 30, 2020 and 2019 were as follows:

	Six Months Ended June 30,	
	2020	2019
Expected term (in years)	—	6.08
Expected volatility	—	42.4% - 42.9%
Risk-free interest rate	—	2.5% - 2.6%
Expected dividend yield	—	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 Equity Incentive Plan (the "2019 Plan"), which became effective in connection with the IPO. As a result, effective as of March 6, 2019, the Company may not grant any additional awards under the 2009 Plan. The 2009 Plan will continue to govern outstanding equity awards granted thereunder. The Company initially reserved 2,000,430 shares of common stock for the issuance of a variety of awards under the 2019 Plan, including stock options, stock appreciation rights, awards of restricted stock and awards of restricted stock units. In addition, the number of shares of common stock reserved for issuance under the 2019 Plan will automatically increase on the first day of January for a period of up to ten years, 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 June 30, 2020, there were 2,671,201 shares available for issuance under the 2019 Plan.

**Stock Options**

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

	Shares Available for Grant	Number of Shares	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance, December 31, 2019	1,704,244	3,315,001	\$ 5.08	7.28	\$ 128,774
Awards authorized	943,345	—			
Options exercised	—	(493,306)	3.23		
Options forfeited	23,612	(23,612)	3.95		
Balance, June 30, 2020	<u>2,671,201</u>	<u>2,798,083</u>	\$ 5.42	7.17	\$ 117,380
Vested and exercisable, June 30, 2020		<u>1,693,886</u>	\$ 4.18	6.75	\$ 73,156
Vested and expected to vest, June 30, 2020		<u>2,798,083</u>	\$ 5.42	7.17	\$ 117,380

**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 annual vesting, 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.



## Notes to Condensed Consolidated Financial Statements

RSU activity under the 2019 Plan is set forth below:

	Number of Shares	Weighted- Average Grant Date Fair Value Per Share
Balance, December 31, 2019	280,904	\$ 38.12
RSUs granted	517,515	42.40
RSUs vested	(41,229)	36.25
RSUs forfeited	(13,750)	40.40
Balance, June 30, 2020	<u>743,440</u>	<u>\$ 41.16</u>

#### Employee Stock Purchase Plan

In February 2019, the Company adopted the 2019 Employee Stock Purchase Plan (“ESPP”), which became effective as of March 6, 2019. The Company initially reserved 300,650 shares of common stock for purchase under the ESPP. Each offering period during which participating employees may purchase stock under the ESPP begins on each September 1 and March 1 and ends on the following February 28 or 29 and August 30, respectively. The first offering period began on September 1, 2019 and ended 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 Compensation Committee of the Company’s Board of Directors, in its sole discretion.

The fair value of the ESPP shares is estimated using the Black-Scholes option pricing model. The Company recorded \$207,000 and \$398,000 of stock-based compensation expense related to the ESPP for the three and six months ended June 30, 2020, respectively. At June 30, 2020, a total of 590,407 shares were available for issuance under the ESPP.

#### 8. 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:

	June 30,	
	2020	2019
Common stock options issued and outstanding	2,798,083	3,896,360
Restricted stock units	743,440	173,750
Total	<u>3,541,523</u>	<u>4,070,110</u>

## Notes to Condensed Consolidated Financial Statements

## 9. 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
United States	\$ 5,537	\$ 5,172	\$ 13,306	\$ 8,808
Germany	825	873	1,736	1,516
Rest of Europe	3,107	3,309	8,215	6,045
All other countries	817	658	2,226	913
Product revenue	<u>\$ 10,286</u>	<u>\$ 10,012</u>	<u>\$ 25,483</u>	<u>\$ 17,282</u>

As of June 30, 2020 and 2019, the Company's long-lived assets were 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 contained in our Annual Report on Form 10-K for the year ended December 31, 2019. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many important factors, including those set forth under “Special Note Regarding Forward-Looking Statements”, in the “Risk Factors” section of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, and in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2019, our actual results could differ materially from the results described in, or implied, by those forward-looking statements.*

### 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 select locations outside of the United States, 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 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. We began enrollment in the DISRUPT CAD III global study in 2019 and completed enrollment in April 2020. 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, a condition where the heart’s aortic valve becomes increasingly calcified with age, causing it to narrow and obstruct blood flow from the heart.

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

We market our products to hospitals whose interventional cardiologists, vascular surgeons and interventional radiologists treat patients with PAD and CAD. We have dedicated meaningful resources to establish a direct sales capability in the United States, Germany, Austria and Switzerland, which we have complemented with distributors in 47 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 June 30, 2020 and 2019, we generated product revenue of \$10.3 million and \$10.0 million, respectively, and a loss from operations of \$18.0 million and \$11.3 million, respectively. For the three months ended June 30, 2020 and 2019, 46% and 48%, respectively, of our product revenue was generated from customers located outside of the United States.

For the six months ended June 30, 2020 and 2019, we generated product revenue of \$25.5 million and \$17.3 million, respectively, and a loss from operations of \$37.0 million and \$23.4 million, respectively. For the six months ended June 30, 2020 and 2019, 48% and 49%, respectively, of our product revenue was generated from customers located outside of the United States.

### ***Impact of the COVID-19 pandemic***

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

Beginning in March 2020, the COVID-19 pandemic began impacting our operations and financial results. For example, on March 19, 2020, the Executive Department of the State of California issued Executive Order N-33-20, ordering all individuals in the State of California to stay at home or at their place of residence except as needed to maintain continuity of operations of federal critical infrastructure sectors. Our primary operations are located in Santa Clara, California. We have taken a variety of steps to address the impact of the COVID-19 pandemic, while attempting to minimize business disruption. Essential staff in manufacturing and limited support functions have continued to work from our Santa Clara office following appropriate hygiene and social distancing protocols. To reduce the risk to our employees and their families from potential exposure to COVID-19, all other staff in our Santa Clara office have been required to work from home. We have restricted non-essential travel to protect the health and safety of our employees and customers.

Moreover, beginning in March 2020, access to hospitals and other customer sites was restricted to essential personnel, which has negatively impacted our ability to promote the use of our products with physicians. In addition, hospitals and other therapeutic centers suspended many elective procedures, resulting in a significantly reduced volume of procedures using our products. The COVID-19 pandemic reduced our IVL catheter sales for the second quarter of 2020 as compared to our sales during the first quarter of 2020.

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

The ultimate extent of the impact of the COVID-19 pandemic on us remains highly uncertain and will depend on future developments and factors that continue to evolve, most of which are outside of our control, and could exist for an extended period of time even after the pandemic might end.

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

## **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 select international markets. For products sold through direct sales representatives, control is transferred upon delivery to customers. For products sold to distributors internationally and products sold to customers that utilize stocking orders, control is transferred upon shipment or delivery to the customer's named location, based on the contractual shipping terms. 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.

The COVID-19 pandemic reduced sales of our IVL catheters during the second quarter of 2020 as compared to our sales in the first quarter of 2020, although we did see an increase in daily sales volume towards the end of the second quarter of 2020. We are continuing to monitor the potential impact of COVID-19 in certain U.S. and international markets, and the potential positive impact of the decline of COVID-19 in other U.S. and international markets, on our product sales and on elective procedures using our products, during the third quarter of 2020.

### ***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. In addition, if the increase in elective procedures using our products and the corresponding increase in sales that we experienced towards the end of the second quarter of 2020, continues in the third quarter of 2020, we would expect to realize an increase in our gross margin percentage due to fixed costs being allocated over higher sales volume; however, the impact of the COVID-19 pandemic on our sales and procedures using our products in the third quarter of 2020 remains uncertain.

### ***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 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 approvals. The increase in engineering and clinical expenditures may be partially offset in the near term by delayed clinical projects and streamlined product development due to COVID-19 cost reduction efforts.

### ***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 over the long term. We expect certain costs will increase in the third quarter of 2020 as compared to the second quarter of 2020, such as travel and related expenses as sales personnel are able to visit customer hospitals. However, we are continuing to monitor the impact of COVID-19 on our sales and on elective procedures utilizing our products, and such impact in the third quarter of 2020 remains uncertain.

### ***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. These increases may be partially offset in the near term by measures taken to control discretionary items due to the COVID-19 pandemic.

## Results of Operations

### Comparison of the Three Months Ended June 30, 2020 and 2019

The following table shows our results of operations for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		Change \$	Change %
	2020	2019		
(in thousands, except percentages)				
<b>Revenue:</b>				
Product revenue	\$ 10,286	\$ 10,012	\$ 274	3%
<b>Cost of revenue:</b>				
Cost of product revenue	3,592	4,133	(541)	(13)%
Gross profit	6,694	5,879	815	14%
<b>Operating expenses:</b>				
Research and development	8,101	6,926	1,175	17%
Sales and marketing	11,206	6,961	4,245	61%
General and administrative	5,398	3,245	2,153	66%
Total operating expenses	24,705	17,132	7,573	44%
Loss from operations	(18,011)	(11,253)	(6,758)	60%
Interest expense	(306)	(250)	(56)	22%
Other income, net	220	913	(693)	(76)%
Net loss before taxes	(18,097)	(10,590)	(7,507)	71%
Income tax provision	21	18	3	17%
Net loss	\$ (18,118)	\$ (10,608)	\$ (7,510)	71%

### Product revenue

Product revenue increased by \$0.3 million, or 3%, from \$10.0 million during the three months ended June 30, 2019 to \$10.3 million during the three months ended June 30, 2020. The increase in revenue was less than expected due to the reduction in elective procedures performed utilizing our products and the corresponding decrease in sales due to the COVID-19 pandemic during the second quarter of 2020.

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 \$5.5 million within the United States and \$4.8 million for all other countries in the three months ended June 30, 2020 compared to \$5.2 million within the United States and \$4.8 million for all other countries in the three months ended June 30, 2019.

### Cost of product revenue, gross profit and gross margin percentage

Cost of product revenue decreased by \$0.5 million, or 13%, from \$4.1 million during the three months ended June 30, 2019 to \$3.6 million during the three months ended June 30, 2020. Gross margin percentage improved to 65.1% for the three months ended June 30, 2020, compared to 58.7% for the three months ended June 30, 2019. This change in gross margin percentage was primarily due to lower fixed costs per unit from increased in production volume of our IVL catheters and increased manufacturing efficiencies.

### **Research and development expenses**

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

	<b>Three Months Ended June 30,</b>	
	<b>2020</b>	<b>2019</b>
	<b>(in thousands)</b>	
Compensation and personnel-related costs	\$ 4,344	\$ 3,173
Clinical-related costs	2,010	2,257
Material and supplies	445	481
Facilities and other allocated costs	743	577
Outside consultants	425	260
Other research and development costs	134	178
Total research and development expenses	<u>\$ 8,101</u>	<u>\$ 6,926</u>

R&D expenses increased by \$1.2 million, or 17%, from \$6.9 million during the three months ended June 30, 2019 to \$8.1 million during the three months ended June 30, 2020. The change was primarily due to a \$1.2 million increase in compensation and personnel-related costs due to increase in headcount to support clinical trials and a \$0.2 million increase in facilities and other allocated costs due to increased rent and building expenditures. This was partially offset by a \$0.2 million decrease in clinical-related costs during the three months ended June 30, 2020.

### **Sales and marketing expenses**

Sales and marketing expenses increased by \$4.2 million, or 61%, from \$7.0 million during the three months ended June 30, 2019 to \$11.2 million during the three months ended June 30, 2020. The change was primarily due to a \$4.1 million increase in compensation and personnel-related costs, which included a \$1.1 million increase in commission expense, as a result of increased headcount. There was also a \$0.2 million increase in facilities and other allocated costs due to increased rent and building expenditures and a \$0.1 million increase in outside professional cost. This was partially offset by a \$0.3 million decrease in travel related expense due to the COVID-19 pandemic.

### **General and administrative expenses**

General and administrative expenses increased by \$2.2 million, or 66%, from \$3.2 million during the three months ended June 30, 2019 to \$5.4 million during the three months ended June 30, 2020. The change was primarily due to a \$1.3 million increase in compensation and personnel-related costs, a \$0.4 million increase in professional services and consulting cost, a \$0.3 million increase in legal fees, a \$0.1 million increase in business insurance and a \$0.1 million increase in other allocated costs due to increased rent and building expenditures.

### Comparison of the Six Months Ended June 30, 2020 and 2019

The following table shows our results of operations for the six months ended June 30, 2020 and 2019:

	<b>Six Months Ended June 30,</b>		<b>Change \$</b>	<b>Change %</b>
	<b>2020</b>	<b>2019</b>		
<b>(in thousands, except percentages)</b>				
<b>Revenue:</b>				
Product revenue	\$ 25,483	\$ 17,282	\$ 8,201	47%
<b>Cost of revenue:</b>				
Cost of product revenue	9,243	7,205	2,038	28%
Gross profit	16,240	10,077	6,163	61%
<b>Operating expenses:</b>				
Research and development	19,991	14,410	5,581	39%
Sales and marketing	21,617	12,831	8,786	68%
General and administrative	11,622	6,247	5,375	86%
Total operating expenses	53,230	33,488	19,742	59%
Loss from operations	(36,990)	(23,411)	(13,579)	58%
Interest expense	(583)	(495)	(88)	18%
Change in fair value of warrant liability	-	(609)	609	(100)%
Other income, net	724	1,133	(409)	(36)%
Net loss before taxes	(36,849)	(23,382)	(13,467)	58%
Income tax provision	44	25	19	76%
Net loss	\$ (36,893)	\$ (23,407)	\$ (13,486)	58%

#### **Product revenue**

Product revenue increased by \$8.2 million, or 47%, from \$17.3 million during the six months ended June 30, 2019 to \$25.5 million during the six months ended June 30, 2020. 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 six months ended June 30, 2020 as compared to the six months ended June 30, 2019.

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 \$13.3 million within the United States and \$12.2 million for all other countries in the six months ended June 30, 2020 compared to \$8.8 million within the United States and \$8.5 million for all other countries in the six months ended June 30, 2019.

#### **Cost of product revenue and gross margin percentage**

Cost of product revenue increased by \$2.0 million, or 28% from \$7.2 million during the six months ended June 30, 2019 to \$9.2 million during the six months ended June 30, 2020. The increase was primarily due to growth in sales volume. Gross margin percentage improved to 63.7% for the six months ended June 30, 2020, compared to 58.3% for the six months ended June 30, 2019. This change in gross margin percentage was primarily due to lower fixed costs per unit from increased sales volume of our IVL catheters and efficiencies from improvements to operations and production.



### Research and development expenses

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

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Compensation and personnel-related costs	\$ 8,319	\$ 5,886
Clinical-related costs	6,598	4,989
Material and supplies	1,297	967
Facilities and other allocated costs	1,440	1,275
Outside consultants	924	790
Other research and development costs	1,413	503
Total research and development expenses	<u>\$ 19,991</u>	<u>\$ 14,410</u>

R&D expenses increased by \$5.6 million, or 39%, from \$14.4 million during the six months ended June 30, 2019 to \$20.0 million during the six months ended June 30, 2020. The change was primarily due to a \$2.4 million increase in compensation and personnel-related costs due to an increase in headcount to support clinical trials and a \$1.6 million increase in clinical related costs. Clinical-related costs during the six months ended June 30, 2020, were primarily related to the CAD III, CAD IV and PAD III clinical trials. There was also a \$1.1 million increase in software license expense related to R&D, a \$0.3 million increase in material and supplies, and a \$0.2 million increase in other allocated costs due to increased rent and building expenditures.

### Sales and marketing expenses

Sales and marketing expenses increased by \$8.8 million, or 68%, from \$12.8 million during the six months ended June 30, 2019 to \$21.6 million during the six months ended June 30, 2020. The change was primarily due to a \$7.2 million increase in compensation and personnel-related costs, which included a \$1.8 million increase in commission expense, as a result of increased headcount and increased sales of our products. There was also a \$0.5 million increase in facilities and other allocated costs due to increased rent and building expenditures, a \$0.4 million increase in outside professional cost, a \$0.3 million increase in general corporate expense, a \$0.1 million increase marketing and promotional expenses to support the commercialization of our products, a \$0.2 million increase in travel related expense and a \$0.1 million increase in recruitment and training expense.

### General and administrative expenses

General and administrative expenses increased by \$5.4 million, or 86%, from \$6.2 million during the six months ended June 30, 2019 to \$11.6 million during the six months ended June 30, 2020. The change was primarily due to a \$2.3 million increase in compensation and personnel-related costs, a \$1.4 million increase in legal fees, a \$0.8 million increase general corporate expense (includes tax and license fees, supplies, software, and bad debt expense), a \$0.4 million increase in professional services and consulting cost, a \$0.3 million increase in other allocated costs due to increased rent and building expenditures, and a \$0.2 million increase in recruitment and training expense.

### Liquidity and Capital Resources

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

On February 11, 2020, we entered into the Amended Credit Facility to the Loan and Security Agreement to refinance our existing term loan, which is accounted for as a modification. The Amended Credit Facility provided us with a supplemental term loan in the amount of \$16.5 million. We received net proceeds of \$3.3 million, which reflects an additional \$4.3 million in principal as of the date of the modification less the final balloon payment fee of \$1.0 million.

We believe that our cash, cash equivalents and short-term investments as of June 30, 2020 will be sufficient to fund our operations for at least the next 12 months from the date of this filing. As of June 30, 2020, we had \$231.4 million in cash, cash equivalents, and short-term investments and an accumulated deficit of \$214.9 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. Although we have limited our hiring in response to the COVID-19 pandemic, as it is prudent to do so, we intend to continue to make significant investments in our sales and marketing organization by increasing the number of U.S. sales representatives. We also intend to continue expanding our international marketing programs to help facilitate further adoption among existing hospital accounts and physicians as well as broaden awareness of our products to new hospitals. We also expect to continue to make investments in R&D, regulatory affairs and clinical studies to develop future generations of products based on our IVL Technology, support regulatory submissions and demonstrate the clinical efficacy of our products. Moreover, we expect to continue to incur expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance, investor relations and other expenses. Because of these and other factors, we expect to continue to incur substantial net losses and negative cash flows from operations for the foreseeable future.

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

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

In addition, as a result of the COVID-19 pandemic, we expect to continue to experience reduced cash flow from operations as a result of decreased revenues, extended payment terms on sales and increased cost of product revenue as a percentage of product revenue. Moreover, we are focused on ensuring that we have adequate supplies on hand given the potential disruption of the COVID-19 pandemic to our suppliers and their supply chain and, accordingly, we expect to continue to increase inventory during the third quarter of 2020 and beyond.

## Cash Flows

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

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2020</b>	<b>2019</b>
	<b>(in thousands)</b>	
Cash used in operating activities	\$ (42,355)	\$ (24,933)
Cash provided by (used in) investing activities	34,028	(83,975)
Cash provided by financing activities	87,578	111,189
Net increase in cash, cash equivalents and restricted cash	<u>\$ 79,251</u>	<u>\$ 2,281</u>

### **Operating activities**

During the six months ended June 30, 2020, cash used in operating activities was \$42.4 million, attributable to a net loss of \$36.9 million and a net change in our net operating assets and liabilities of \$11.8 million, partially offset by non-cash charges of \$6.4 million. Non-cash charges primarily consisted of \$4.3 million in stock-based compensation, \$0.9 million in depreciation and amortization, \$0.7 million in amortization of right-of-use assets, \$0.3 million in amortization of debt issuance costs, and \$0.2 million in accretion of discount on available-for-sale securities. The change in our net operating assets and liabilities was primarily due to a \$11.0 million increase in inventory and \$1.2 million increase in prepaid expenses and other current assets, a \$1.0 million decrease in accounts receivable, a \$0.3 million decrease in accounts payable and a \$0.2 million decrease in lease liability.

During the six months ended June 30, 2019, cash used in operating activities was \$24.9 million, attributable to a net loss of \$23.4 million and a net change in our net operating assets and liabilities of \$4.3 million, partially offset by non-cash charges of \$2.8 million. Non-cash charges primarily consisted of \$1.2 million in stock-based compensation, \$0.5 million in depreciation and amortization, \$0.6 million in change in fair value of warrant liability, \$0.5 million in amortization of right-of-use assets and \$0.2 million in amortization of debt issuance costs, partially offset by \$0.4 million in accretion of discount on available-for-sale securities. The change in our net operating assets and liabilities was primarily due to a \$3.2 million increase in inventory and \$2.4 million increase in accounts receivable due to an increase in sales, a \$0.8 million increase in prepaid and other current assets and a \$0.5 million decrease in lease liabilities. These changes were partially offset by a \$2.6 million increase in accrued and other current liabilities and accounts payable resulting primarily from expansion in our operating activities and accrued professional services fees.

### **Investing activities**

During the six months ended June 30, 2020, cash provided by investing activities was \$34.0 million, attributable to proceeds from maturities of available-for-sale investments of \$59.0 million, partially offset by purchase of available-for-sale investments of \$16.0 million and purchase of property and equipment of \$9.0 million.

During the six months ended June 30, 2019, cash used in investing activities was \$84.0 million, attributable to the purchase of available-for-sale securities of \$82.8 million and purchase of property and equipment of \$1.2 million.

### **Financing activities**

During the six months ended June 30, 2020, cash provided by financing activities was \$87.6 million, attributable to net proceeds of \$83.8 million from the public offering of our common stock, a \$3.3 million from borrowings under new credit facility entered on February 11, 2020, proceeds of \$1.6 million from stock option exercises and proceeds of \$0.8 million from issuance of shares under our employee stock purchase plan, partially offset by principal payment on our term loan of \$1.1 million and a 0.6 million payment of taxes withheld on net settled vesting of restricted stock units.

During the six months ended June 30, 2019, cash provided by financing activities was \$111.2 million, attributable to net proceeds of \$100.8 million from the IPO, net proceeds of \$10.0 million from the private placement of our common stock and proceeds of \$0.4 million from stock option exercises and warrant exercises.

### **Contractual Obligations and Commitments**

During the three months ended June 30, 2020, there have been no material changes to our contractual obligations as compared to those disclosed in “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” included in our Annual Report on Form 10-K for the year ended December 31, 2019.

### **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.

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, we disclosed our critical accounting policies and the assumptions and estimates associated with the greatest potential impact on our consolidated financial statements in the section titled “*Management’s Discussion and Analysis of Financial Condition and Results of Operations.*” During the three and six months ended June 30, 2020, as a result of the COVID-19 pandemic, we believe that the assumptions and estimates associated with credit losses of accounts receivable and net realizable value of inventory associated with product shelf life and potential expiration may also have a material impact to our consolidated financial statements in future periods.

#### ***Accounts receivable – allowance for bad debt***

We are exposed to credit losses through our receivables from customers. Our expected loss allowance methodology for receivables is developed using our historical collection experience, current and future economic market conditions and a review of the current aging status and financial condition of our customers. Specific allowance amounts are established to record the appropriate allowance for customers that have an identified risk of default. General allowance amounts are established based upon our assessment of expected credit losses for our receivables by aging category. Balances are written off when they are ultimately determined to be uncollectible. We considered the current and expected future economic and market conditions surrounding the COVID-19 pandemic, however, no additional reserve was required for the three months ended June 30, 2020. We will continue to monitor the impact of COVID-19 pandemic and we may need to make further adjustments to this estimate in future periods.

#### ***Inventories – expiration risk***

Inventories are valued at the lower of cost, computed on a first-in, first-out basis, or net realizable value. We produce our IVL catheters at our facilities in Santa Clara, California. At the time of manufacture, our IVL catheters generally have a two-year shelf life prior to expiration. We maintain finished goods inventory at our facilities in Santa Clara, with our sales representatives, with our third-party logistics provider in the Netherlands, and on consignment at hospital locations. Each reporting period, we update provisions for excess and obsolete inventory based on our estimates of forecast demand and, where applicable, product expiration. As of June 30, 2020, the substantial majority of our finished goods inventory had expiration dates in second half of 2021 or later. We considered the current and expected future economic and market conditions surrounding the COVID-19 pandemic, however, no additional reserve was required for the three months ended June 30, 2020. We will continue to monitor the impact of COVID-19 pandemic and we may need to make further adjustments to this estimate in future periods.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

#### ***Interest rate risk***

Our cash, cash equivalents and short-term investments as of June 30, 2020 consisted of \$231.4 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 June 30, 2020, we had \$16.5 million in variable rate debt outstanding. In February 2020, we refinanced our existing term loan by means of a supplemental term loan in the amount of \$16.5 million. The supplemental term loan requires monthly repayments of principal starting as early as June 2021, subject to a contingent deferral if we meet certain milestones, discussed further in Note 6 to Item 1- Financial Statements, above. The supplemental term loan matures on December 1, 2023 and accrues interest at a floating per annum rate equal to the greater of the Prime Rate minus 1.25% and 3.5%. The interest rate on the term loan was 3.5% as of June 30, 2020.

#### ***Foreign currency exchange risk***

As we expand internationally, our results of operations and cash flows may become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our revenue is denominated primarily in U.S. dollars and Euros. For the six months ended June 30, 2020 and 2019, approximately 26% and 44% 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 \$0.3 million and \$1.2 million in foreign currency cash and accounts receivable as of June 30, 2020 and December 31, 2019, respectively. As our operations in countries outside of the United States grow,

our results of operations and cash flows may be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any material foreign currency hedging contracts, although we may do so in the future.

#### **Item 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 (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.

**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 instituted IPR proceedings for all three patents. The PTAB held oral hearings on April 15-16, 2020. On July 8, 2020, the PTAB ruled that one claim in U.S. Pat. No. 8,956,371 (the “’371 patent”) is valid, and ruled that all other claims in the ‘371 patent are invalid and that all claims of U.S. Pat. No. 8,728,091 (the “’091 patent”) are invalid. On July 20, 2020, the PTAB ruled that all claims of U.S. Pat. No. 9,642,673 are invalid. We do not agree with the PTAB’s rulings against the claims in the IPR Patents, and we intend to appeal those rulings to the U.S. Court of Appeals for the Federal Circuit. All claims of the IPR Patents remain valid and enforceable until such appeals have been exhausted. Upon the conclusion of such appeals, if we are unsuccessful in whole or in part, the IPR proceedings could result in the loss or narrowing in scope of the IPR Patents, which could limit our ability to stop others from using or commercializing products and technology similar or identical to ours. For more information regarding the risks presented by such proceedings, please see the section of our Annual Report on Form 10-K for the year ended December 31, 2019, 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.**

There have been no material changes from the risk factors disclosed in Part I, Item IA – *Risk Factors* contained in our Annual Report on Form 10-K for the year ended December 31, 2019 (the “2019 Annual Report”) and in Part II, Item 1A – *Risk Factors* contained in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 (the “Q120 Quarterly Report”). The risk factors described in those sections, as well as other information set forth in this Quarterly Report on Form 10-Q, could materially adversely affect our business, financial condition, results of operations and prospects, and should be carefully considered. The risks and uncertainties that we face, however, are not limited to those described in the 2019 Annual Report and the Q120 Quarterly Report. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business and the trading price of our securities, particularly in light of the fast-changing nature of the COVID-19 pandemic, containment measures and the related impacts to economic and operating conditions.

**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 our IPO, 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 a 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 \$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.

The registration statements on Form S-1 (File No. 333-234640) and the registration statement on Form S-1 (File No. 333-234711) filed pursuant to Rule 462(b) relating thereto, each relating to the follow-on public offering of shares of our common stock, became effective on November 15, 2019. The registration statement registered the offer and sale of 2,854,048 shares of our common stock, including 372,267 shares sold pursuant to the underwriters’ exercise of their option to purchase additional shares, at a public offering price of \$36.25 per share. On November 15, 2019, we completed the sale of all 2,854,048 shares of our common stock

registered thereunder at a public offering price of \$36.25 per share for an aggregate offering price of approximately \$103.5 million. We received net proceeds of approximately \$96.7 million from the follow-on offering after deducting underwriting discounts and commissions of \$6.2 million and offering costs of \$0.6 million. The underwriters of the offering were BofA Securities, Inc. and Morgan Stanley & Co. Following the sale of the shares in connection with the closing of the follow-on offering, the offering terminated.

On June 16, 2020 we filed a registration statement on Form S-3ASR (File No. 333-239202) (the “Shelf Registration Statement”) and a related prospectus with the Securities and Exchange Commission. Pursuant to the Shelf Registration Statement we may offer, from time to time, debt securities, common stock, preferred stock, depositary shares, warrants, purchase contracts or units. On June 16, 2020, we filed a prospectus and prospectus supplement with the Securities and Exchange Commission. The prospectus and prospectus supplement registered the offer and sale of up to 1,955,000 shares of our common stock, including the full exercise of the underwriters’ option to purchase an additional 255,000 shares of common stock, pursuant to the Shelf Registration Statement, at a public offering price of \$45.75 per share. On June 16, 2020, we completed the sale of all 1,955,000 shares of our common stock registered under the Shelf Registration Statement, at a public offering price of \$45.75 per share, for an aggregate offering price of approximately \$89.4 million. We received net proceeds of \$83.4 million from the offering after deducting underwriters’ discounts and commissions of \$5.4 million and offering costs of \$0.6 million. The underwriters of the offering were BofA Securities, Inc. and Morgan Stanley & Co. Following the sale of the shares in connection with the closing of the offering, the offering terminated.

We maintain the funds received from the offerings referred to above in an interest bearing account, pending their use. We are using and intend to continue using the net proceeds from our the offerings 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 offerings 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 actual or planned use of the proceeds from the offerings described above from that described in the prospectuses, respectively, dated March 6, 2019 and November 14, 2019, filed with the SEC pursuant to Rule 424(b)(4) and, the prospectus and prospectus supplement, each dated June 16, 2020, filed with the SEC pursuant to Rule 424(b)(5).

**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).

<u>Exhibit Number</u>	<u>Description</u>	<u>Form</u>	<u>File No.</u>	<u>Exhibit(s)</u>	<u>Filing Date</u>
31.1*	<a href="#"><u>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.</u></a>				
31.2*	<a href="#"><u>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.</u></a>				
32.1*	<a href="#"><u>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.</u></a>				
32.2*	<a href="#"><u>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.</u></a>				
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: August 12, 2020

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

Date: August 12, 2020

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

**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: August 12, 2020

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

**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: August 12, 2020

By: /s/ Dan Puckett  
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 June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 12, 2020

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 June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 12, 2020

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