UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	**27-0494101**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5403 Betsy Ross Drive **Santa Clara, California**	**95054**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

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

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

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

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

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

As of November 3, 2020, the registrant had 34,259,784 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 Reports on Form 10-Q for the quarters ended March 31, 2020 and June 30, 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)

	September 30, 2020	December 31, 2019 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 215,256	$ 139,045
Short-term investments	—	56,304
Accounts receivable, net	10,711	7,377
Inventory	28,868	12,074
Prepaid expenses and other current assets	3,033	1,897
Total current assets	257,868	216,697
Operating lease right-of-use assets	7,841	8,825
Property and equipment, net	13,282	4,910
Other assets	1,667	1,506
TOTAL ASSETS	$ 280,658	$ 231,938
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,972	$ 2,790
Term notes, current portion	1,650	6,667
Accrued liabilities	16,662	13,777
Lease liability, current portion	841	774
Total current liabilities	21,125	24,008
Lease liability, noncurrent portion	7,685	8,125
Term notes, noncurrent portion	14,801	7,152
TOTAL LIABILITIES	43,611	39,285
STOCKHOLDERS' EQUITY:		
Preferred stock	—	—
Common stock	34	31
Additional paid-in capital	464,812	370,561
Accumulated other comprehensive income	—	35
Accumulated deficit	(227,799)	(177,974)
TOTAL STOCKHOLDERS' EQUITY	237,047	192,653
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 280,658	$ 231,938

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 September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Revenue:				
Product revenue	$ 19,590	$ 11,333	$ 45,073	$ 28,615
Cost of revenue:				
Cost of product revenue	5,277	4,401	14,520	11,606
Gross profit	14,313	6,932	30,553	17,009
Operating expenses:				
Research and development	7,891	8,368	27,882	22,778
Sales and marketing	13,619	8,192	35,236	21,023
General and administrative	5,610	3,437	17,232	9,684
Total operating expenses	27,120	19,997	80,350	53,485
Loss from operations	(12,807)	(13,065)	(49,797)	(36,476)
Interest expense	(314)	(251)	(897)	(746)
Change in fair value of warrant liability	—	—	—	(609)
Other income, net	218	385	942	1,518
Net loss before taxes	(12,903)	(12,931)	(49,752)	(36,313)
Income tax provision	29	26	73	51
Net loss	$ (12,932)	$ (12,957)	$ (49,825)	$ (36,364)
Other comprehensive income (loss):				
Unrealized gain/(loss) on available-for-sale securities	—	(18)	(14)	57
Adjustment for net gain realized and included in other income, net	(21)	—	(21)	—
Total other comprehensive income (loss)	(21)	(18)	(35)	57
Total comprehensive loss	$ (12,953)	$ (12,975)	$ (49,860)	$ (36,307)
Net loss per share, basic and diluted	$ (0.38)	$ (0.46)	$ (1.53)	$ (1.66)
Shares used in computing net loss per share, basic and diluted	34,078,726	28,085,821	32,631,715	21,886,396

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
Exercise of stock options	—	—	254,523	—	993	—	—	993
Issuance of common stock under employee stock purchase plan	—	—	27,921	—	953	—	—	953
Offering cost related to the public offering	—	—	—	—	(14)	—	—	(14)
Issuance of common stock in connection with vesting of restricted stock units	—	—	12,775	—	—	—	—	—
Restricted stock units withheld in net settlement for tax	—	—	(4,611)	—	(246)	—	—	(246)
Stock-based compensation	—	—	—	—	2,891	—	—	2,891
Net gain reclassified from accumulated other comprehensive income	—	—	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	—	—	(12,932)	(12,932)
Balance — September 30, 2020	—	$ —	34,236,165	$ 34	$ 464,812	$ —	$ (227,799)	$ 237,047

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	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	(Deficit)
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
Exercise of stock options	—	—	232,186	—	706	—	—	706
Stock-based compensation	—	—	—	—	1,106	—	—	1,106
Unrealized loss on available-for-sale securities	—	—	—	—	—	(18)	—	(18)
Net loss	—	—	—	—	—	—	(12,957)	(12,957)
Balance — September 30, 2019	—	$ —	28,255,893	$ 28	$ 271,394	$ 57	$ (163,229)	$ 108,250

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

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

	Nine Months Ended September 30,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (49,825)	$ (36,364)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,361	854
Stock-based compensation	7,108	2,336
Amortization of right-of-use assets	1,105	739
Accretion of discount on available-for-sale securities	289	(542)
Loss on write down of fixed assets	97	90
Change in fair value of warrant liability	—	609
Amortization of debt issuance costs	478	322
Changes in operating assets and liabilities:		
Accounts receivable	(3,334)	(2,701)
Inventory	(16,338)	(4,096)
Prepaid expenses and other current assets	(1,136)	(1,087)
Other assets	(161)	(1)
Accounts payable	(776)	884
Accrued and other current liabilities	2,841	4,169
Lease liabilities	(494)	(749)
Net cash used in operating activities	(58,785)	(35,537)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of available-for-sale securities	(16,020)	(106,347)
Proceeds from maturities of available-for-sale securities	72,000	32,300
Purchase of property and equipment	(9,846)	(2,287)
Net cash provided by (used in) investing activities	46,134	(76,334)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon initial public offering, net of issuance costs paid	—	100,547
Proceeds from issuance of common stock in private placement	—	10,000
Payments of offering costs	(179)	—
Proceed from issuance of common stock from public offering, net of issuance cost paid	83,368	—
Payments of taxes withheld on net settled vesting of restricted stock units	(862)	—
Principal payments of term loan	(1,111)	—
Net proceeds from term loan	3,265	—
Proceeds from stock option exercises	2,586	1,023
Proceeds from issuance of common stock under employee stock purchase plan	1,795	—
Proceeds from warrant exercises	—	110
Net cash provided by financing activities	88,862	111,680
Net increase in cash, cash equivalents and restricted cash	76,211	(191)
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	$ 216,706	$ 39,902
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	$ 403	$ 420
Income tax paid	$ 22	$ 120
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
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
Right-of-use asset obtained in exchange for lease liability	$ 121	$ 73
Property and equipment purchases included in accounts payable and accrued liabilities	$ 233	$ 204
Transfer of fixed assets to inventory	$ 197	$ —

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

1. Organization and Basis of Presentation

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

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

Need for Additional Capital

The Company has incurred significant losses and has negative cash flows from operations. As of September 30, 2020, the Company had an accumulated deficit of $227.8 million. Management expects to continue to incur additional substantial losses for the foreseeable future.

As of September 30, 2020, the Company had cash and cash equivalents of $215.3 million, which are available to fund future operations. The Company believes that its cash and cash equivalents as of September 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 nine months ended September 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 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 September 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:

	September 30, 2020	December 31, 2019
	(in thousands)	
Cash and cash equivalents	$ 215,256	$ 139,045
Restricted cash	1,450	1,450
Total cash, cash equivalents, and restricted cash	$ 216,706	$ 140,495

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.

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 nine months ended September 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.

3. Financial Instruments and Fair Value Measurements

As of September 30, 2020, our cash equivalent investments consisted of money market funds with a fair value of $213.3 million, which are valued using level 1 inputs. The following table summarizes the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy as of December 31, 2019:

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

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	$ —

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%

4. Cash Equivalents and Short-Term Investments

As of September 30, 2020, our cash equivalent investments consisted of money market funds with a fair value of $213.3 million, with no unrealized gains or losses. The following is a summary of the Company's cash equivalents and short-term investments as of December 31, 2019:

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

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

5. Balance Sheet Components

Inventory

Inventory consists of the following:

	September 30, 2020	December 31, 2019
	(in thousands)	
Raw material	$ 5,030	$ 2,501
Work in progress	4,425	1,364
Finished goods	17,601	6,642
Consigned inventory	1,812	1,567
Total inventory	$ 28,868	$ 12,074

Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2020	December 31, 2019
	(in thousands)	
Accrued employee compensation	$ 9,815	$ 8,139
Accrued asset purchases	660	—
Accrued research and development costs	3,449	3,090
Accrued professional services	1,271	804
Other	1,467	1,744
Total accrued liabilities	$ 16,662	$ 13,777

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 (a) the Wall Street Journal prime rate minus 1.75% and (b) 2.75%. There was a final payment equal to 6.75% of the original aggregate principal amount, or $1.0 million, of the term loan advances, which was being accrued over the 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 (a) the Prime Rate minus 1.25% and (b) 3.5%. The interest rate was 3.5% as of September 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 C2 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.

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:

	September 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	(49)	485
Term note, current and noncurrent	16,451	13,819
Less term note, current portion	(1,650)	(6,667)
Term note, noncurrent portion	$ 14,801	$ 7,152

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

Year ending December 31:	(in thousands)
2020 (remainder)	$ 146
2021	3,861
2022	6,961
2023	8,294
Total future payments	19,262
Less amounts representing interest	(1,194)
Less final payment	(1,568)
Total principal amount of term note payments	$ 16,500

7. Stock-Based Compensation

Total stock-based compensation was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
Cost of product revenue	$ 162	$ 81	$ 303	$ 156
Research and development	631	307	1,769	582
Sales and marketing	913	288	2,309	597
General and administrative	1,140	430	2,727	1,001
Total stock-based compensation	$ 2,846	$ 1,106	$ 7,108	$ 2,336

Stock-based compensation of $45,000 and $259,000 was capitalized into inventory for the three and nine months ended September 30, 2020, respectively. Stock-based compensation capitalized into inventory is recognized as cost of product revenue when the related product is sold.

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. During the nine months ended September 30, 2020, the Company granted no new options. The assumptions for the Black-Scholes model for the nine months ended September 30, 2019 were as follows:

	Nine Months Ended September 30,
	2019
Expected term (in years)	6.08
Expected volatility	42.4% - 42.9%
Risk-free interest rate	2.4% - 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 commencing on January 1, 2020 and ending on January 1, 2028, in an amount equal to three percent of the total number of shares of the Company's capital stock outstanding on the last day of the preceding year, or a lesser number of shares determined by the Company's Board of Directors. As of September 30, 2020, there were 2,685,328 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	Aggregate Intrinsic Value
				(in years)	(in thousands)
Balance, December 31, 2019	1,704,244	3,315,001	$ 5.08	7.28	$ 128,774
Awards authorized	943,345	—			
Options exercised	—	(747,829)	3.46		
Options forfeited	37,739	(37,739)	4.41		
Balance, September 30, 2020	2,685,328	2,529,433	$ 5.57	6.96	$ 177,632
Vested and exercisable, September 30, 2020		1,620,762	$ 4.36	6.56	$ 115,785
Vested and expected to vest, September 30, 2020		2,529,433	$ 5.57	6.96	$ 177,632

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.

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	601,183	44.69
RSUs vested	(54,004)	37.83
RSUs forfeited	(29,375)	41.36
Balance, September 30, 2020	798,708	$ 42.96

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. In addition, the number of shares of common stock reserved for issuance under the ESPP will automatically increase on the first day of January commencing on January 1, 2020 and ending January 1, 2028, in an amount equal to one percent of the total number of shares of the Company's capital stock outstanding on the last day of the preceding year, or such lesser number of shares as determined by the Company's Board of Directors. At September 30, 2020, a total of 562,486 shares were available for issuance 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 $118,000 and $516,000 of stock-based compensation expense related to the ESPP for the three and nine months ended September 30, 2020, respectively. The Company recorded $64,000 of stock-based compensation expense related to the ESPP for the three and nine months ended September 30, 2019, respectively.

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:

	September 30,	
	2020	2019
Common stock options issued and outstanding	2,529,433	3,658,436
Restricted stock units	798,708	226,550
Total	3,328,141	3,884,986

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
United States	$ 11,144	$ 6,246	$ 24,450	$ 15,054
Germany	1,185	873	2,921	2,389
Rest of Europe	5,592	3,428	13,807	9,473
All other countries	1,669	786	3,895	1,699
Product revenue	$ 19,590	$ 11,333	$ 45,073	$ 28,615

As of September 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"), for the treatment of below the knee PAD, was cleared by the FDA in August 2019, and accepted by our EU notified body in May 2020.

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 have completed enrollment in 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 March 2020. This study is designed to support U.S. PMA approval for our C2 catheters. We have submitted CAD III data to the FDA to support PMA approval, with subsequent U.S. launch of our C2 catheter planned for the first half of 2021, subject to FDA approval. We began enrollment in the DISRUPT CAD IV Japan study in 2019 and completed enrollment in April 2020. We anticipate submitting CAD III and CAD IV data to support Shonin approval, with subsequent Japan launch planned for the first half of 2022, subject to applicable regulatory approvals.

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

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

We market our products to hospitals whose interventional cardiologists, vascular surgeons and interventional radiologists treat patients with PAD and CAD. We have dedicated meaningful resources to establish a direct sales capability in the United States, Germany, Austria and Switzerland, which we have complemented with distributors 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 September 30, 2020 and 2019, we generated product revenue of $19.6 million and $11.3 million, respectively, and a loss from operations of $12.8 million and $13.1 million, respectively. For the three months ended September 30, 2020 and 2019, 43% and 45%, respectively, of our product revenue was generated from customers located outside of the United States.

For the nine months ended September 30, 2020 and 2019, we generated product revenue of $45.1 million and $28.6 million, respectively, and a loss from operations of $49.8 million and $36.5 million, respectively. For the nine months ended September 30, 2020 and 2019, 46% and 47%, 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 has had, and continues to have, far reaching impacts on our business, operations, and financial results and condition, directly and indirectly, including, without limitation, impacts on: the health of our management and employees; our manufacturing, distribution, marketing and sales operations; our research and development activities, including clinical activities; and customer and patient behaviors.

Access to many hospitals and other customer sites continues to be restricted to essential personnel, which negatively impacts our ability to promote the use of our products with physicians. Additionally, many hospitals and other therapeutic centers have in the past suspended, and may suspend or continue to suspend in the future, many elective procedures, resulting in a reduced volume of procedures using our products. Our customer behavior is impacted by the prevalence of COVID-19 and changes in the infection rates in the locations where our customers are located.

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

We have taken a variety of steps to address the impact of the COVID-19 pandemic, while attempting to minimize business disruption. Essential staff in manufacturing and limited support functions have continued to work from our Santa Clara headquarters following appropriate hygiene and social distancing protocols. To reduce the risk to our employees and their families from potential exposure to COVID-19, all other staff in our Santa Clara headquarters have been required to work from home. We have restricted non-essential travel to protect the health and safety of our employees and customers.

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

The ultimate extent of the impact of the COVID-19 pandemic on us remains highly uncertain and will depend on future developments and factors that continue to evolve, including the ability of various regions to effectively manage COVID-19 and the extent of the continuing resurgence of COVID-19. Most of these developments and factors are outside of our control and could exist for an extended period of time even after the pandemic might end.

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. We saw an increase in sales volume in the third quarter of 2020 as opposed to the second quarter of 2020. However, we are continuing to monitor the impact of COVID-19 on our product sales and on elective procedures using our products in the U.S. and international markets where our products are sold, particularly given the resurgence of COVID-19 during the fourth 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. The impact of the COVID-19 pandemic on our sales and procedures using our products in the fourth 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.

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 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 fourth quarter of 2020 as compared to the third quarter of 2020, such as travel and related expenses, to the extent 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 fourth 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. In addition, we incur expenses associated

with operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance and investor relations. As we continue to grow, we expect general and administrative expenses to increase in absolute dollars in future periods.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

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

	Three Months Ended September 30,			
	2020	2019	Change $	Change %
	(in thousands, except percentages)			
Revenue:				
Product revenue	$ 19,590	$ 11,333	$ 8,257	73%
Cost of revenue:				
Cost of product revenue	5,277	4,401	876	20%
Gross profit	14,313	6,932	7,381	106%
Operating expenses:				
Research and development	7,891	8,368	(477)	(6)%
Sales and marketing	13,619	8,192	5,427	66%
General and administrative	5,610	3,437	2,173	63%
Total operating expenses	27,120	19,997	7,123	36%
Loss from operations	(12,807)	(13,065)	258	(2)%
Interest expense	(314)	(251)	(63)	25%
Other income, net	218	385	(167)	(43)%
Net loss before taxes	(12,903)	(12,931)	28	(0)%
Income tax provision	29	26	3	12%
Net loss	$ (12,932)	$ (12,957)	$ 25	(0)%

Product revenue

Product revenue increased by $8.3 million, or 73%, from $11.3 million during the three months ended September 30, 2019 to $19.6 million during the three months ended September 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 three months ended September 30, 2020 as compared to the three months ended September 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 $11.1 million within the United States and $8.5 million for all other countries in the three months ended September 30, 2020 compared to $6.2 million within the United States and $5.1 million for all other countries in the three months ended September 30, 2019.

Cost of product revenue, gross profit and gross margin percentage

Cost of product revenue increased by $0.9 million, or 20%, from $4.4 million during the three months ended September 30, 2019 to $5.3 million during the three months ended September 30, 2020. Gross margin percentage improved to 73.1% for the three months ended September 30, 2020, compared to 61.2% for the three months ended September 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:

	Three Months Ended September 30,	
	2020	2019
	(in thousands)	
Compensation and personnel-related costs	$ 4,181	$ 3,316
Clinical-related costs	1,896	3,526
Material and supplies	556	580
Facilities and other allocated costs	621	494
Outside consultants	443	340
Other research and development costs	194	112
Total research and development expenses	$ 7,891	$ 8,368

R&D expenses decreased by $0.5 million, or 6%, from $8.4 million during the three months ended September 30, 2019 to $7.9 million during the three months ended September 30, 2020. The change was primarily due to a $1.6 million decrease in clinical-related costs due to the lifecycle of current clinical trials. This was partially offset by a $0.9 million increase in compensation and personnel-related costs due to increase in head count to support clinical trials during the three months ended September 30, 2020.

Sales and marketing expenses

Sales and marketing expenses increased by $5.4 million, or 66%, from $8.2 million during the three months ended September 30, 2019 to $13.6 million during the three months ended September 30, 2020. The change was primarily due to a $5.0 million increase in compensation and personnel-related costs, which includes a $1.9 million increase in commission expense, as a result of increased headcount and revenue in the third quarter of 2020.

General and administrative expenses

General and administrative expenses increased by $2.2 million, or 63%, from $3.4 million during the three months ended September 30, 2019 to $5.6 million during the three months ended September 30, 2020. The change was primarily due to a $1.4 million increase in compensation and personnel-related costs and a $0.5 million increase in professional services and consulting cost.

Comparison of the Nine Months Ended September 30, 2020 and 2019

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

	Nine Months Ended September 30,		Change	Change
	2020	2019	$	%
	(in thousands, except percentages)			
Revenue:				
Product revenue	$ 45,073	$ 28,615	$ 16,458	58%
Cost of revenue:				
Cost of product revenue	14,520	11,606	2,914	25%
Gross profit	30,553	17,009	13,544	80%
Operating expenses:				
Research and development	27,882	22,778	5,104	22%
Sales and marketing	35,236	21,023	14,213	68%
General and administrative	17,232	9,684	7,548	78%
Total operating expenses	80,350	53,485	26,865	50%
Loss from operations	(49,797)	(36,476)	(13,321)	37%
Interest expense	(897)	(746)	(151)	20%
Change in fair value of warrant liability	—	(609)	609	(100)%
Other income, net	942	1,518	(576)	(38)%
Net loss before taxes	(49,752)	(36,313)	(13,439)	37%
Income tax provision	73	51	22	43%
Net loss	$ (49,825)	$ (36,364)	$ (13,461)	37%

Product revenue

Product revenue increased by $16.5 million, or 58%, from $28.6 million during the nine months ended September 30, 2019 to $45.1 million during the nine months ended September 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 nine months ended September 30, 2020 as compared to the nine months ended September 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 $24.5 million within the United States and $20.6 million for all other countries in the nine months ended September 30, 2020 compared to $15.1 million within the United States and $13.5 million for all other countries in the nine months ended September 30, 2019.

Cost of product revenue and gross margin percentage

Cost of product revenue increased by $2.9 million, or 25% from $11.6 million during the nine months ended September 30, 2019 to $14.5 million during the nine months ended September 30, 2020. The increase was primarily due to growth in sales volume. Gross margin percentage improved to 67.8% for the nine months ended September 30, 2020, compared to 59.4% for the nine months ended September 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:

	Nine Months Ended September 30,	
	2020	2019
	(in thousands)	
Compensation and personnel-related costs	$ 12,500	$ 9,202
Clinical-related costs	8,502	8,515
Material and supplies	1,855	1,546
Facilities and other allocated costs	2,033	1,769
Outside consultants	1,367	1,130
Other research and development costs	1,625	616
Total research and development expenses	$ 27,882	$ 22,778

R&D expenses increased by $5.1 million, or 22%, from $22.8 million during the nine months ended September 30, 2019 to $27.9 million during the nine months ended September 30, 2020. The change was primarily due to a $3.3 million increase in compensation and personnel-related costs due to an increase in headcount to support clinical trials. Clinical-related costs during the nine months ended September 30, 2020, were primarily related to the CAD III, CAD IV and PAD III clinical trials. There was also a $1.0 million increase in software license expense related to R&D, a $0.3 million increase in material and supplies, and a $0.3 million increase in other allocated costs due to increased rent and building expenditures.

Sales and marketing expenses

Sales and marketing expenses increased by $14.2 million, or 68%, from $21.0 million during the nine months ended September 30, 2019 to $35.2 million during the nine months ended September 30, 2020. The change was primarily due to a $12.2 million increase in compensation and personnel-related costs, which included a $3.7 million increase in commission expense, as a result of increased headcount and increased sales of our products. There was also a $0.7 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 $0.4 million increase in general corporate expense, a $0.3 million increase marketing and promotional expenses to support the commercialization of our products and a $0.2 million increase in recruitment and training expense.

General and administrative expenses

General and administrative expenses increased by $7.5 million, or 78%, from $9.7 million during the nine months ended September 30, 2019 to $17.2 million during the nine months ended September 30, 2020. The change was primarily due to a $3.6 million increase in compensation and personnel-related costs, a $1.1 million increase general corporate expense (includes tax and license fees, supplies, software, and bad debt expense), a $2.3 million increase in professional services and consulting cost, a $0.4 million increase in other allocated costs due to increased rent and building expenditures, and a $0.2 million increase in recruitment and training expense. These increases were partially offset by a $0.1 million decrease in travel related 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 and cash equivalents as of September 30, 2020 will be sufficient to fund our operations for at least the next 12 months from the date of this filing. As of September 30, 2020, we had $215.3 million in cash and cash equivalents and an accumulated deficit of $227.8 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 may limit our hiring in response to the COVID-19 pandemic, 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.

Cash Flows

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

	Nine Months Ended September 30,	
	2020	**2019**
	(in thousands)	
Cash used in operating activities	$ (58,785)	$ (35,537)
Cash provided by (used in) investing activities	46,134	(76,334)
Cash provided by financing activities	88,862	111,680
Net increase in cash, cash equivalents and restricted cash	$ 76,211	$ (191)

Operating activities

During the nine months ended September 30, 2020, cash used in operating activities was $58.8 million, attributable to a net loss of $49.8 million and a net change in our net operating assets and liabilities of $19.4 million, partially offset by non-cash charges of $10.4 million. Non-cash charges primarily consisted of $7.1 million in stock-based compensation, $1.4 million in depreciation and amortization, $1.1 million in amortization of right-of-use assets, $0.5 million in amortization of debt issuance costs, $0.3 million in accretion of discount on available-for-sale securities, and $0.1 million in loss on write down of fixed assets. The change in our net operating assets and liabilities was primarily due to a $16.3 million increase in inventory, a $3.3 million increase in accounts

receivable due to an increase in sales, a $1.1 million increase in prepaid expenses and other current assets, a $0.2 million increase in other assets, a $0.8 million decrease in accounts payable and a $0.5 million decrease in lease liability. These changes were partially offset by a $2.8 million increase in accrued and other current liabilities resulting primarily from expansion in our operating activities and accrued professional services fees.

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

Investing activities

During the nine months ended September 30, 2020, cash provided by investing activities was $46.1 million, attributable to proceeds from maturities of available-for-sale investments of $72.0 million, partially offset by purchase of available-for-sale investments of $16.0 million and purchase of property and equipment of $9.9 million.

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

Financing activities

During the nine months ended September 30, 2020, cash provided by financing activities was $88.9 million, attributable to net proceeds of $83.4 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 $2.6 million from stock option exercises and proceeds of $1.8 million from issuance of shares under our employee stock purchase plan, partially offset by principal payment on our term loan of $1.1 million, a $0.9 million payment of taxes withheld on net settled vesting of restricted stock units and payment of offering costs of $0.2 million.

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

Contractual Obligations and Commitments

Except as noted below, during the nine months ended September 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.

In February 2020, we amended our existing term loan. Under the amendment, 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. The principal amount outstanding of $16.5 million under the amended term loan accrues interest at a floating per annum rate equal to the greater of (i) the Prime Rate minus 1.25% and (ii) 3.5%. The interest rate was 3.5% as of September 30, 2020. The amended term loan matures on December 1, 2023. The amended term loan provides an interest-only payment period which will end on (a) June 30, 2021, if our revenue for the trailing 12-month period ended June 30, 2021 is not at least 75% of our projections; (b) December 31, 2021, if we achieve the financial performance target referred to in clause (a), but do not obtain premarket approval of our C2 catheters from the FDA by such date and/or our trailing 12-month revenue for the period ending December 31, 2021 is not at least 75% of our projections; or (c) June 30, 2022, if we achieve the milestones referred to in clauses (a) and (b). The additional final payment for the amended loan is $1.6 million.

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 nine months ended September 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 September 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 California, with our sales representatives, with our third-party logistics provider in the Netherlands, and on consignment at hospital locations. Each reporting period, we update provisions for excess and obsolete inventory based on our estimates of forecast demand and, where applicable, product expiration. As of September 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 September 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 and cash equivalents as of September 30, 2020 consisted of $215.3 million in bank deposits and money market funds. Such interest-earning instruments carry a degree of interest rate risk. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents.

As of September 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 September 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 nine months ended September 30, 2020 and 2019, approximately 27% and 28% 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 $0.5 million and $1.2 million in foreign currency cash and accounts receivable as of September 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.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Petitions for inter partes review ("IPR") of U.S. Pat. Nos. 9,642,673, 8,956,371 and 8,728,091 (the "IPR Patents"), which are three of our issued U.S. patents that relate to our current IVL Technology, were filed in December 2018 at the USPTO's Patent Trial and Appeal Board (the "PTAB") by Cardiovascular Systems, Inc., one of our competitors. The PTAB instituted IPR proceedings for all three patents. The PTAB held oral hearings on April 15-16, 2020. On July 8, 2020, the PTAB ruled that one claim in U.S. Pat No. 8,956,371 (the "'371 patent") is valid, and ruled that all other claims in the '371 patent are invalid and that all claims of U.S. Pat No. 8,728,091 are invalid, and on July 20, 2020, the PTAB ruled that all claims of U.S. Pat. No. 9,642,673 are invalid.

On August 27, 2020, further briefing by the parties was requested by the PTAB judge in the '371 patent proceeding to assess whether recent guidance from the USPTO relating to "applicant admitted prior art" impacted the PTAB decision in the '371 patent proceeding. In addition, the PTAB judge reset the time for commencement of an appeal in the '371 patent proceeding pending the entry of a final decision after the requested briefing. On October 13, 2020, we submitted the last of the requested briefing, and the PTAB decision is pending. Subject to the final PTAB decision regarding the '371 patent proceeding, we anticipate appealing this ruling to the U.S. Court of Appeals for the Federal Circuit. In the meantime, we have appealed the rulings in the other two IPR proceedings. All claims of the IPR Patents remain valid and enforceable until such appeals have been exhausted. Upon the conclusion of such appeals, if we are unsuccessful in whole or in part, the IPR proceedings could result in the loss or narrowing in scope of the IPR Patents, which could limit our ability to stop others from using or commercializing products and technology similar or identical to ours. For more information regarding the risks presented by such proceedings, please see the section of 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 an initial public offering price of $17.00 per share for an aggregate offering price of approximately $111.4 million. The underwriters of the offering were Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated. Following the sale of the shares in connection with the closing of our 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.

There has been no material change in the actual or planned use of the proceeds from our IPO from that described in the prospectuses dated March 6, 2019, filed with the SEC pursuant to Rule 424(b)(4).

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Number	Description	Form	File No.	Exhibit(s)	Filing Date
10.1*†	Amended and Restated Non-Employee Director Compensation Policy	S-1/A	333-229590	10.11	February 25, 2019
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.

† Indicates a management contract or compensatory plan or arrangement.

SIGNATURES

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

Shockwave Medical, Inc.

Date: November 10, 2020 By: /s/ Douglas Godshall

Douglas Godshall
President and Chief Executive Officer

Date: November 10, 2020 By: /s/ Dan Puckett

Dan Puckett
Chief Financial Officer

SHOCKWAVE MEDICAL, INC.
AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION PLAN

This Shockwave Medical, Inc. Amended and Restated Non-Employee Director Compensation Plan (this "Plan") was adopted by the Board of Directors (the "Board") of Shockwave Medical, Inc. (the "Company") on February 20, 2019, and became effective on February 20, 2019. As amended and restated below, this Plan was adopted by the Compensation Committee of the Board on September 30, 2020 and became effective on such date.

1. Eligibility. Each member of the Board who is not a full- or part- time officer or employee of the Company (a "Non-Employee Director") is eligible to participate in this Plan during the period of the Non-Employee Director's service as a member of the Board.

2. Annual Cash Fees.

a. *Annual Board Member Fee*. Each Non-Employee Director will earn cash compensation for service as member of the Board at an annual rate of $40,000 (such compensation, the "Annual Board Member Fee").

b. *Annual Non-Executive Chair Fee*. Any Non-Employee Director serving as "Non-Executive Chair" of the Board will earn additional cash compensation for such service at an annual rate of $45,000 (such additional compensation, the "Annual Non-Executive Chair Fee").

c. *Annual Committee Chair Fees*. Each Non-Employee Director serving as the chair of one or more of the following committees of the Board will earn cash compensation for such service at the annual rate set forth here (such compensation, the "Annual Committee Chair Fee"):

i. $20,000 for the chair of the Audit Committee;

ii. $15,000 for the chair of the Compensation Committee; and

iii. $10,000 for the chair of the Nominating and Corporate Governance Committee.

d. *Annual Committee Member Fee*. Each Non-Employee Director serving as a non-chair member of one or more of the following committees of the Board will earn cash compensation for such service at the annual rate set forth here (such compensation, the "Annual Committee Member Fee"):

i. $10,000 for each member of the Audit Committee;

ii. $7,500 for each member of the Compensation Committee; and

iii. $5,000 for each member of the Nominating and Corporate Governance Committee.

e. *Payment*. The Annual Board Member Fee, Annual Non-Executive Chair Fee, Annual Committee Chair Fee and Annual Committee Member Fee (together, the "Annual Fees") earned by each Non-Employee Director will be paid quarterly in arrears on the last business day of each calendar quarter. In the event that a Non-Employee Director serves on the Board, as Non-Executive Chair or as a chair or member of a committee for less than an entire quarter, the portion of the applicable Annual Fees earned and

payable for such quarter will be prorated based on the number of days in such quarter for which such Non-Employee Director provided such service.

3. Initial Equity-Based Compensation for New Non-Employee Directors. Upon the election of a Non-Employee Director to the Board who has not previously served on the Board, such director shall receive an award (an "Initial Award") of restricted stock units ("RSUs") under the Shockwave Medical Inc., 2019 Equity Incentive Plan (the "Equity Plan"), with a value equal to $180,000, based on the grant date closing price of the Company's common stock, par value $0.001 per share (the "Common Stock"). The grant date of the Initial Award shall be the date of such director's election to the Board, or the earliest practicable date thereafter, as determined by the Company's Chief Executive Officer or Chief Financial Officer. The Initial Award shall vest in equal annual installments over three years from the date of grant, subject to the applicable director's continued service on the Board through the applicable vesting date. The Initial Award shall be granted pursuant to the Company's standard form RSU award agreement, and subject to the terms and conditions therein.

4. Annual Equity-Based Compensation for Non-Employee Directors. An annual grant of RSUs (an "Annual Award") shall be made under the Equity Plan to each Non-Employee Director following each annual meeting of stockholders of the Company. The Annual Award shall have a value equal to $120,000, based on the grant date closing price of the Common Stock. The grant date of the Annual Award shall be the date of such annual meeting of stockholders of the Company, or as the earliest practicable date thereafter, as determined by the Company's Chief Executive officer or Chief Financial Officer. The Annual Award shall vest in full on the earlier of (i) one year following the date of grant or (ii) the following year's annual meeting of stockholders, subject to the applicable director's continued service on the Board through the vesting date. The Annual Award shall be granted pursuant to the Company's standard form RSU award agreement, and subject to the terms and conditions therein.

5. Cash Equivalent for Equity Award. In each case where an Non-Employee Director is an equity partner or service provider of a private equity sponsor of the Company, and such sponsor has informed the Company in writing that it does not allow its equity partners or service providers, as the case may be, to accept awards of equity for compensation for services rendered to boards of directors of its portfolio companies, then such Non-Employee Director shall be eligible to receive a cash award in lieu of any Initial Award or Annual Award (each, a "Cash Equivalent Award") with a value equal to the designated value of the equity award that would otherwise be provided hereunder, but otherwise subject to the same terms and conditions applicable to such award.

6. Administration. This Plan will be administered by the Board, or if the Board so determines in its discretion, by the Compensation Committee of the Board (the "Committee"). The Board (or the Committee, as the case may be) will have the power to construe this Plan, to determine all questions hereunder, and to adopt and amend such rules and regulations for the administration of this Plan as it may deem desirable. All decisions, determinations and interpretations of the Board (or the Committee, as the case may be) with respect to this Plan will be final and binding.

7. Transfer and Assignment. The right of a Non-Employee Director to receive the payment of all or a portion of an Annual Fee or to be granted an Initial Award or Annual Award may not be assigned, transferred, pledged or encumbered, other than by will or the laws of descent and distribution and any attempted assignment or transfer will be null and void.

8. Governing Law. This Plan will be administered, interpreted and enforced under the internal laws of the State of Delaware without regard to conflicts of laws thereof.

9. Amendment and Termination. The Board (or the Committee, if so authorized by the Board) may amend, modify or terminate this Plan for any reason at any time; *provided*, that no amendment, modification or termination, without the consent of the applicable Non-Employee Director, will materially adversely affect any then issued and outstanding Initial Award or Annual Award held by such Non-Employee Director.

Exhibit 31.1

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

I, Douglas Godshall, certify that:

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

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

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

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

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

   (b) *Reserved*;

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

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

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

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

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

Date: November 10, 2020

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

Exhibit 31.2

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

I, Dan Puckett, certify that:

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

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

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

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

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

   (b) *Reserved*;

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

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

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

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

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

Date: November 10, 2020

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

Exhibit 32.1

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

In connection with the Quarterly Report of Shockwave Medical, Inc. (the "Company") on Form 10-Q for the period ending September 30, 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: November 10, 2020

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

Exhibit 32.2

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

In connection with the Quarterly Report of Shockwave Medical, Inc. (the "Company") on Form 10-Q for the period ending September 30, 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: November 10, 2020

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