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, 2021

OR

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

For the transition period from ___________to __________

Commission File Number: 001-38829

Shockwave Medical, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**27-0494101** **(I.R.S. Employer Identification No.)**
5403 Betsy Ross Drive **Santa Clara, California** **(Address of principal executive offices)**	**95054** **(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 2, 2021, the registrant had 35,304,469 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 statements relating to our expectations, projections, beliefs, and prospects, which are 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 “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “might”, “plan,” “expect,” “predict,” “could,” “potentially” or the negative of these terms or similar expressions. You should read these statements carefully because they may relate to future expectations around growth, strategy, and anticipated trends in our business, contain projections of future results of operations or financial condition, or state other “forward-looking” information. These statements are only predictions based on our current expectations, estimates, assumptions, and projections about future events and are applicable only as of the dates of such statements. These forward-looking statements are subject to certain risks and uncertainties 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. Factors that might cause such a difference include, but are not limited to the following:

- the impact of the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including due to the pandemic’s impact on our 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 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 factors and others are discussed in more detail in the section entitled “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2020, together with any updates in the section entitled “Risk Factors” of our Quarterly Report on Form 10-Q for the quarters ended March 31, 2021 and June 30, 2021 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. There may also be additional risks of which we are not presently aware or that we currently believe are immaterial which could have an adverse impact on our business. 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2021	December 31, 2020
		(1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 91,195	$ 50,423
Short-term investments	91,759	151,931
Accounts receivable, net	29,966	11,689
Inventory	38,744	29,859
Prepaid expenses and other current assets	4,364	2,398
Total current assets	256,028	246,300
Operating lease right-of-use assets	11,790	7,568
Property and equipment, net	23,085	16,362
Equity method investment	6,408	—
Other assets	1,684	1,812
TOTAL ASSETS	$ 298,995	$ 272,042
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,632	$ 1,466
Term notes, current portion	2,750	3,300
Accrued liabilities	33,017	19,942
Lease liability, current portion	867	873
Total current liabilities	40,266	25,581
Lease liability, noncurrent portion	11,939	7,488
Term notes, noncurrent portion	14,226	13,319
Related party contract liability, noncurrent portion	12,273	—
TOTAL LIABILITIES	78,704	46,388
STOCKHOLDERS' EQUITY:		
Preferred stock	—	—
Common stock	35	35
Additional paid-in capital	486,014	469,283
Accumulated other comprehensive income (loss)	(7)	9
Accumulated deficit	(265,751)	(243,673)
TOTAL STOCKHOLDERS' EQUITY	220,291	225,654
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 298,995	$ 272,042

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

(1) The consolidated balance sheet as of December 31, 2020 is derived from the audited consolidated financial statements as of that date.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Product revenue	$ 65,155	$ 19,590	$ 152,963	$ 45,073
Cost of revenue:				
Cost of product revenue	10,949	5,277	28,775	14,520
Gross profit	54,206	14,313	124,188	30,553
Operating expenses:				
Research and development	13,735	7,891	35,827	27,882
Sales and marketing	28,393	13,619	78,098	35,236
General and administrative	9,265	5,610	25,117	17,232
Total operating expenses	51,393	27,120	139,042	80,350
Income (loss) from operations	2,813	(12,807)	(14,854)	(49,797)
Share in net loss of equity method investment	(342)	—	(5,865)	—
Interest expense	(165)	(314)	(795)	(897)
Other income (expense), net	(280)	218	(369)	942
Net income (loss) before taxes	2,026	(12,903)	(21,883)	(49,752)
Income tax provision	78	29	195	73
Net income (loss)	$ 1,948	$ (12,932)	$ (22,078)	$ (49,825)
Other comprehensive income (loss):				
Unrealized gain/(loss) on available-for-sale securities	(17)	—	(16)	(14)
Adjustment for net gain realized and included in other income, net	—	(21)	—	(21)
Total other comprehensive income (loss)	(17)	(21)	(16)	(35)
Total comprehensive income (loss)	$ 1,931	$ (12,953)	$ (22,094)	$ (49,860)
Net income (loss) per share				
Basic	$ 0.06	$ (0.38)	$ (0.63)	$ (1.53)
Diluted	$ 0.05	$ (0.38)	$ (0.63)	$ (1.53)
Shares used in computing net income (loss) per share				
Basic	35,207,276	34,078,726	35,013,072	32,631,715
Diluted	37,567,176	34,078,726	35,013,072	32,631,715

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)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity
Balance — December 31, 2020	34,684,337	$ 35	$ 469,283	$ 9	$ (243,673)	$ 225,654
Exercise of stock options	159,325	—	773	—	—	773
Unrealized gain on available-for-sale securities	—	—	—	7	—	7
Issuance of common stock under employee stock purchase plan	20,594	—	1,141	—	—	1,141
Issuance of common stock in connection with vesting of restricted stock units	107,237	—	—	—	—	—
Taxes withheld on net settled vesting of restricted stock units	(42,529)	—	(5,114)	—	—	(5,114)
Stock-based compensation	—	—	5,394	—	—	5,394
Net loss	—	—	—	—	(23,601)	(23,601)
Balance — March 31, 2021	34,928,964	35	471,477	16	(267,274)	204,254
Exercise of stock options	149,101	—	1,085	—	—	1,085
Unrealized loss on available-for-sale securities	—	—	—	(6)	—	(6)
Issuance of common stock in connection with vesting of restricted stock units	71,761	—	—	—	—	—
Taxes withheld on net settled vesting of restricted stock units	(20,537)	—	(3,223)	—	—	(3,223)
Stock-based compensation	—	—	6,662	—	—	6,662
Net loss	—	—	—	—	(425)	(425)
Balance — June 30, 2021	35,129,289	35	476,001	10	(267,699)	208,347
Exercise of stock options	122,615	—	691	—	—	691
Unrealized loss on available-for-sale securities	—	—	—	(17)	—	(17)
Issuance of common stock under employee stock purchase plan	16,239	—	1,696	—	—	1,696
Issuance of common stock in connection with vesting of restricted stock units	26,809	—	—	—	—	—
Stock-based compensation	—	—	7,626	—	—	7,626
Net income	—	—	—	—	1,948	1,948
Balance — September 30, 2021	35,294,952	$ 35	$ 486,014	$ (7)	$ (265,751)	$ 220,291

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)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity
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 Cash Flows
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (22,078)	$ (49,825)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,685	1,361
Share in net loss of equity method investment	5,865	—
Stock-based compensation	19,049	7,108
Amortization of right-of-use assets	1,184	1,105
Accretion of discount on available-for-sale securities	1,022	289
Loss on write down of fixed assets	—	97
Amortization of debt issuance costs	357	478
Changes in operating assets and liabilities:		
Accounts receivable	(18,277)	(3,334)
Inventory	(7,982)	(16,338)
Prepaid expenses and other current assets	(1,966)	(1,136)
Other assets	128	(161)
Accounts payable	2,168	(776)
Accrued and other current liabilities	13,011	2,841
Lease liabilities	(961)	(494)
Net cash used in operating activities	(5,795)	(58,785)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of available-for-sale securities	(75,566)	(16,020)
Proceeds from maturities of available-for-sale securities	134,700	72,000
Purchase of property and equipment	(9,616)	(9,846)
Net cash provided by investing activities	49,518	46,134
CASH FLOWS FROM FINANCING ACTIVITIES:		
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	(8,337)	(862)
Principal payments of term loan	—	(1,111)
Net proceeds from term loan	—	3,265
Proceeds from stock option exercises	2,549	2,586
Proceeds from issuance of common stock under employee stock purchase plan	2,837	1,795
Net cash provided by (used in) financing activities	(2,951)	88,862
Net increase in cash, cash equivalents and restricted cash	40,772	76,211
Cash, cash equivalents and restricted cash at beginning of period	51,873	140,495
Cash, cash equivalents and restricted cash equivalents at end of period	$ 92,645	$ 216,706
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	$ 440	$ 403
Income tax paid	$ 114	$ 22
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Right-of-use asset obtained in exchange for lease liability	$ 5,406	$ 121
Property and equipment purchases included in accounts payable and accrued liabilities	$ 2,510	$ 233
Equity method investment obtained in exchange for related party contract liability	$ 12,273	$ —
Transfer of fixed assets to inventory	$ 270	$ 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 subsidiaries in Germany, the United Kingdom, Japan and France.

Need for Additional Capital

The Company has incurred significant losses to date, and as of September 30, 2021, had an accumulated deficit of $265.8 million. Although the Company had positive net income for the quarter ended September 30, 2021, it had a net loss for the nine months ended September 30, 2021. The Company may continue to incur losses in the future, which may vary significantly from period to period. The Company expects to continue to incur significant expenses as it (i) expands its marketing efforts to increase adoption of its products, (ii) expands existing relationships with its customers, (iii) obtains regulatory clearances or approvals for its planned or future products, (iv) conducts clinical trials on its existing and planned or future products, and (v) develops new products or adds new features to its existing products. The Company will need to continue to generate significant revenue in order to sustain profitability as it continues to grow its business. Even if it achieves profitability for any period, the Company cannot be sure that it will remain profitable for any substantial period of time.

As of September 30, 2021, the Company had cash, cash equivalents and short-term investments of $183.0 million, which are available to fund future operations. The Company believes that its cash and cash equivalents as of September 30, 2021, 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 continuing risks and uncertainties as a result of the COVID-19 pandemic, and is closely monitoring the impact of the pandemic on all aspects of its business, including the impacts on its customers, patients that would benefit from procedures utilizing the Company’s products, employees, suppliers, vendors, business partners and distribution channels. Specifically, the Company has recently seen some disruptions in the operations of certain of its third-party suppliers, resulting in increased lead-times, higher component costs and lower allocations for our purchase of some components and, in certain cases, requiring the Company to procure materials from alternate suppliers or incur higher logistical expenses. The Company is continuing to work closely with its manufacturing partners and suppliers to enable the Company to source key components and maintain appropriate inventory levels to meet customer demand. The Company, however, has not experienced material disruptions in its supply chain to date. Economies worldwide continue to be negatively impacted by the COVID-19 pandemic and the Company anticipates these disruptions will continue. As such the Company's future results of operations and liquidity could be adversely impacted by a variety of factors related to the COVID-19 pandemic, including those discussed in the section entitled “Risk Factors” of the Company’s Annual Report on Form 10-K for the year ended December 31, 2020. 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 remains uncertain.

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 the 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 three and nine months ended September 30, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2020 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, 2020, filed with the SEC on February 26, 2021.

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, 2021 and December 31, 2020 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, 2021	December 31, 2020
	(in thousands)	
Cash and cash equivalents	$ 91,195	$ 50,423
Restricted cash	1,450	1,450
Total cash, cash equivalents, and restricted cash	$ 92,645	$ 51,873

Equity Method Investments

Entities which the Company has significant influence over activities of the entity, but does not control, are accounted for under the equity method of accounting in accordance with Topic 323, *Investments - Equity Method and Joint Ventures*. The Company's carrying value in the equity method investment is reported as equity method investment on the Company's consolidated balance sheet. The Company records its proportionate share of the underlying income or loss which is recognized in share in net loss of equity method investment. For the three and nine months ended September 30, 2021, the Company's share in the losses incurred by the equity method investee was $0.3 and $5.9 million, respectively. The Company eliminates any intra-entity profits to the extent of the Company's beneficial interest.

We assess our equity method investment for impairment when events or circumstances suggest that the carrying amount of the investment may be impaired. We consider all available evidence in assessing whether a decline in fair value is other than temporary. If the decline in fair value is determined to be other than temporary, the difference between the carrying amount of the investment and estimated fair value is recognized as an impairment charge.

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

To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, *Revenue from Contracts with Customers*, 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.

Product 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 portion of the Company's revenue is generated through a consignment model under which inventory is maintained at hospitals.

Product 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.

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. The Company elected to account for shipping and handling activities that occur after the customer has obtained control as a fulfillment activity, and not a separate performance obligation.

The Company may provide 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.

License Revenue

For arrangements that contain a license of our functional intellectual property with a customer, we consider whether the license grant is distinct from other performance obligations in the arrangement. A license grant of functional intellectual property is generally considered to be capable of being distinct if a customer can benefit from the license on its own or together with other readily available resources. License revenue for licenses of functional intellectual property is recognized at a point in time when the Company satisfies its performance obligation of transferring the license to the customer.

Consideration received in advance of the satisfaction of a performance obligation is recognized as a contract liability. No license revenues have been recognized for the three and nine months ended September 30, 2021.

3. Financial Instruments and Fair Value Measurements

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

	September 30, 2021			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
U.S. Treasury securities	$ 65,235	$ —	$ —	$ 65,235
Money market funds	67,705	—	—	67,705
Commercial paper	—	21,385	—	21,385
Corporate bonds	—	5,139	—	5,139
Total assets	$ 132,940	$ 26,524	$ —	$ 159,464

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
U.S. Treasury securities	$ 126,363	$ —	$ —	$ 126,363
Money market funds	35,053	—	—	35,053
Commercial paper	—	31,968	—	31,968
Total assets	$ 161,416	$ 31,968	$ —	$ 193,384

4. Cash Equivalents and Short-Term Investments

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

	September 30, 2021			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury securities	$ 65,242	$ 2	$ (9)	$ 65,235
Money market funds	67,705	—	—	67,705
Commercial paper	21,385	—	—	$ 21,385
Corporate bonds	5,139	—	—	5,139
Total	$ 159,471	$ 2	$ (9)	$ 159,464
Reported as:				
Cash equivalents				$ 67,705
Short-term investments				91,759
Total				$ 159,464

	December 31, 2020			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury securities	$ 126,354	$ 11	$ (2)	$ 126,363
Money market funds	35,053	—	—	35,053
Commercial paper	31,968	—	—	31,968
Total	$ 193,375	$ 11	$ (2)	$ 193,384
Reported as:				
Cash equivalents				$ 41,453
Short-term investments				151,931
Total				$ 193,384

The Company recognized no material gains or losses on its cash equivalents and short-term investments in the periods presented. The remaining contractual maturities for available-for-sale securities were as follows:

	September 30, 2021
	Fair Value
One year or less	$ 134,384
Greater than one year and less than two years	25,080
Total	$ 159,464

5. Balance Sheet Components

Inventory

Inventory consists of the following:

	September 30, 2021	December 31, 2020
	(in thousands)	
Raw material	$ 6,781	$ 4,995
Work in progress	11,066	6,051
Finished goods	19,000	16,952
Consigned inventory	1,897	1,861
Total inventory	$ 38,744	$ 29,859

Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2021	December 31, 2020
	(in thousands)	
Accrued employee compensation	$ 20,713	$ 10,885
Accrued research and development costs	3,839	3,057
Accrued asset purchases	3,451	2,527
Accrued professional services	1,819	1,325
Other	3,195	2,148
Total accrued liabilities	$ 33,017	$ 19,942

6. Commitments and Contingencies

Operating Leases

In May 2018, the Company entered into a lease agreement for office, laboratory, and manufacturing space located at 5403 Betsy Ross Drive in Santa Clara, California, which consists of approximately 35,000 square feet (the “5403 Lease”). The term of the 5403 Lease commenced in September 2018 and ends in August 2022. In connection with the 5403 Lease, the Company maintains a letter of credit for the benefit of the landlord in the amount of $0.5 million, which is secured by restricted cash recorded as other assets on the consolidated balance sheets. In connection with the 5403 Lease, the Company has an operating lease right-of-use asset of $0.7 million as of September 30, 2021 and an aggregate lease liability of $0.8 million on its consolidated balance sheet. The remaining lease term is eleven months.

In December 2019, the Company entered into a lease agreement (i) for additional office, laboratory and manufacturing space located at 5353 Betsy Ross Drive in Santa Clara, California, which consists of approximately 50,200 square feet (the “5353 Lease”); and (ii) to modify the terms of the 5403 Lease. The 5403 Lease will continue in its existing terms (and with no changes to its terms, including its base rent) until its expiration on August 31, 2022, at which point the leased space under the 5403 Lease will become subject to the terms of the 5353 Lease. The initial term of the 5353 Lease began in December 2019 and was initially for 96 months.

The base rent of the first floor of the premises for the 5353 Betsy Ross building shall be abated for the first 19 months, and the base rent for the second floor of the 5353 Betsy Ross building shall be abated for the first four months. The landlord provided the Company with a tenant improvement allowance of up to $1.8 million for both 5403 and 5353 Betsy Ross buildings. In connection with the 5353 Lease, the Company provided an initial security deposit of $1.0 million in the form of a letter of credit, which is secured by restricted cash recorded as other assets on the consolidated balance sheets. While this amount will increase to $1.5 million on September 1, 2022 when the office, laboratory and manufacturing space of the 5403 Lease is included under the terms of the 5353 Lease, the letter of credit will be reduced annually from and after September 1, 2022 until the expiration of the 5353 Lease.

In September 2021, the Company amended the 5353 Lease (the “Amended Lease”), which extended the initial lease terms for both 5403 and 5353 Betsy Ross buildings by approximately 48.5 months to December 31, 2031. The Company accounted for this amendment as a lease modification for the lease of the 5353 Building. As of September 30, 2021, the lease of the 5403 Betsy Ross building under the modified terms has not yet commenced. The Amended Lease also contains an expansion option, which can be exercised after June 1, 2023, to lease an adjacent building consisting of approximately 35,000 square feet.

In connection with the lease of the 5353 Betsy Ross building, the Company has recorded an operating lease right-of-use asset of $10.9 million as of September 30, 2021 and an aggregate lease liability of $11.9 million on its consolidated balance sheet. The remaining lease term is ten years and three months.

Additionally, in September 2021, the Company entered into a ten-year lease for additional office space located at 3003 Bunker Hill Lane in Santa Clara, California which consists of approximately 81,000 square feet (the “3003 Lease”). The base rent for the premises of the 3003 Bunker Hill building shall be abated for the first six months. The landlord provided the Company with a tenant improvement allowance of up to $5.5 million. In connection with the lease, the Company shall provide an initial security deposit of $0.2 million in the form of a letter of credit and a prepayment for the same amount which will be applied to the first month's rent. The lease is due to expire in December 2031, and contains two optional extension periods of sixty months each at the then fair market rent for the space. As of September 30, 2021, the Company has not taken control of the leased facility and anticipates that it will take control of the leased facility in the fourth quarter of 2021.

The Company also leases vehicles for use by certain of its employees. In connection with the vehicle leases, the Company has an operating lease right-of-use asset and an aggregate lease liability of $0.2 million as of September 30, 2021 on its consolidated balance sheet. The weighted average remaining lease term for these vehicle leases is one year and seven months.

The weighted average incremental borrowing rate used to measure the operating lease liability is 5.14%. As of September 30, 2021, the Company has no material finance leases.

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

The following are minimum future rental payments owed under these agreements which have commenced as of September 30, 2021:

Year ending December 31,	**(in thousands)**
2021 (remainder)	$ 602
2022	2,128
2023	1,535
2024	1,552
2025	1,600
2026	1,643
Thereafter	8,787
Total minimum lease payments	$ 17,847
Less: imputed interest and adjustments	(5,041)
Total lease liability	$ 12,806

The following are minimum undiscounted future rental payments owed for the modified 5403 Betsy Ross Lease and 3003 Bunker Hill Lease which have not yet commenced as of September 30, 2021:

Year ending December 31,	**(in thousands)**
2021 (remainder)	$ 215
2022	1,420
2023	3,704
2024	3,815
2025	3,926
2026	4,047
Thereafter	22,004
Total minimum lease payments	$ 39,131

Operating lease cost for the three and nine months ended September 30, 2021 and 2020 was $0.5 million and $1.5 million, respectively, and $0.5 million and $1.5 million, respectively.

7. 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, 2021.

The supplemental term loan matures on December 1, 2023. The Amended Credit Facility provides an interest-only payment period through June 30, 2022.

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.

Current and noncurrent debt and net discount or premium balances are as follows:

	September 30, 2021	December 31, 2020
	(in thousands)	
Principal amount of term note	$ 16,500	$ 16,500
Net premium associated with accretion of final payment, and other debt issuance costs	476	119
Term note, current and noncurrent	16,976	16,619
Less term note, current portion	(2,750)	(3,300)
Term note, noncurrent portion	$ 14,226	$ 13,319

Future minimum payments of principal and estimated payments of interest on the Company's outstanding variable rate borrowings as of September 30, 2021 are as follows:

Year ending December 31:	(in thousands)
2021 (remainder)	146
2022	6,045
2023	12,779
Total future payments	18,970
Less amounts representing interest	(902)
Less final payment	(1,568)
Total principal amount of term note payments	$ 16,500

8. Stock-Based Compensation

Total stock-based compensation was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Cost of product revenue	$ 263	$ 162	$ 718	$ 303
Research and development	1,686	631	4,343	1,769
Sales and marketing	3,051	913	7,693	2,309
General and administrative	2,387	1,140	6,295	2,727
Total stock-based compensation	$ 7,387	$ 2,846	$ 19,049	$ 7,108

Stock-based compensation of $239,000 and $45,000 was capitalized into inventory for the three months ended September 30, 2021 and 2020, respectively. Stock-based compensation of $633,000 and $259,000 was capitalized into inventory for the nine months ended September 30, 2021 and 2020, respectively. Stock-based compensation capitalized into inventory is recognized as cost of product revenue when the related product is sold.

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 initial public offering (the "IPO"). As a result, effective as of March 6, 2019, the Company may not grant any additional awards under the 2009 Plan. The 2009 Plan will continue to govern outstanding equity awards granted thereunder. The Company initially reserved 2,000,430 shares of common stock for the issuance of a variety of awards under the 2019 Plan, including stock options, stock appreciation rights, awards of restricted stock and awards of restricted stock units. In addition, the number of shares of common stock reserved for issuance under the 2019 Plan will automatically increase on the first day of January for a period of up to ten years, which commenced on January 1, 2020, in an amount equal to 3% of the total number of shares of the Company's capital stock outstanding on the last day of the preceding year, or a lesser number of shares determined by the Company's Board of Directors. As of September 30, 2021, there were 3,745,216 shares available for issuance under the 2019 Plan.

Stock Options

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

	Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance, December 31, 2020	2,689,624	2,087,202	$ 5.92	6.77	$ 204,137
Awards authorized	1,040,530	—			
Options exercised	—	(431,041)	5.91		
Options forfeited	15,062	(15,062)	9.33		
Balance, September 30, 2021	3,745,216	1,641,099	$ 5.88	5.98	$ 328,212
Vested and exercisable, September 30, 2021		1,339,978	$ 4.88	5.72	$ 269,338
Vested and expected to vest, September 30, 2021		1,641,099	$ 5.88	5.98	$ 328,212

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, 2020	859,577	$ 48.50
RSUs granted	557,355	137.41
RSUs vested	(205,807)	42.98
RSUs forfeited	(47,266)	75.16
Balance, September 30, 2021	1,163,859	$ 90.97

Employee Stock Purchase Plan

In February 2019, the Company adopted the 2019 Employee Stock Purchase Plan ("ESPP"), which became effective in connection with the IPO on March 6, 2019. The Company initially reserved 300,650 shares of common stock for purchase under the ESPP. Each offering under the ESPP to Company employees to purchase stock under the ESPP begins on each September 1 and March 1 and ends on the following February 28 or 29 and August 31, respectively. On each purchase date, which falls on the last date of each offering period, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the offering date or (2) the fair market value of the common stock on the purchase date. The occurrence and duration of offering periods under the ESPP are subject to the determinations of the Company's Compensation Committee, in its sole discretion.

The fair value of the ESPP shares is estimated using the Black-Scholes option pricing model. The Company recorded $333,000 and $890,000 of stock-based compensation expense related to the ESPP for the three and nine months ended September 30, 2021, respectively. 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. At September 30, 2021, a total of 872,496 shares were available for issuance under the ESPP.

9. Net Income (Loss) Per Share

The components of basic and diluted net income (loss) per share are as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net income (loss)	$ 1,948	$ (12,932)	$ (22,078)	$ (49,825)
Denominator:				
Basic:				
Weighted average number of common shares outstanding - basic	35,207,276	34,078,726	35,013,072	32,631,715
Diluted:				
Weighted average number of common shares outstanding - basic	35,207,276	34,078,726	35,013,072	32,631,715
Dilutive effect of outstanding common stock options	1,645,968	—	—	—
Dilutive effect of restricted stock units	708,788	—	—	—
Dilutive effect of common stock pursuant to employee stock purchase plan	5,144	—	—	—
Weighted average number of common shares outstanding - diluted	37,567,176	34,078,726	35,013,072	32,631,715
Net income (loss) per share:				
Basic	$ 0.06	$ (0.38)	$ (0.63)	$ (1.53)
Diluted	$ 0.05	$ (0.38)	$ (0.63)	$ (1.53)

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net income (loss) per share for the periods presented due to their anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Common stock options issued and outstanding	—	2,529,433	1,641,099	2,529,433
Restricted stock units	18,539	798,708	1,163,859	798,708
Employee stock purchase plan	596	3,911	1,976	3,911
Total	19,135	3,332,052	2,806,934	3,332,052

10. Revenue

The following table represents the Company's product revenue based on product line:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Coronary	$ 47,165	$ 6,983	$ 99,175	$ 16,403
Peripheral	17,725	12,337	52,659	27,927
Other	265	270	1,129	743
Product revenue	$ 65,155	$ 19,590	$ 152,963	$ 45,073

Coronary product revenue encompasses sales of the Company's C^2 catheters. Peripheral product revenue encompasses sales of the Company's M^5 and S^4 IVL catheters. Other product revenue encompasses sales of the Company's generators and related accessories.

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,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
United States	$ 52,771	$ 11,144	$ 116,729	$ 24,450
Europe	8,624	6,370	27,266	15,962
All other countries	3,760	2,076	8,968	4,661
Product revenue	$ 65,155	$ 19,590	$ 152,963	$ 45,073

11. Equity Method Investments

Genesis Shockwave Private Limited

On March 19, 2021, the Company entered into the Joint Venture Deed (or "JV Agreement") with Genesis MedTech International Private Limited ("Genesis") to establish a long-term strategic partnership to develop, manufacture and commercialize certain of the Company's interventional products in the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau ("PRC"). Under the JV Agreement, Genesis Shockwave Private Ltd. (the "JV") was formed under the laws of Singapore to serve as a joint venture of Genesis and the Company for the purpose of establishing and managing such a strategic partnership.

On the same date, Genesis and the Company entered into a Share Subscription Agreement pursuant to which, among other things, the JV issued (i) 54,900 ordinary shares which represents 55% of total equity of the JV, to Genesis in exchange for a cash contribution of $15.0 million, of which 50% was paid upon signing and the remaining 50% will be due within one year of signing, and (ii) 45,000 ordinary shares which represents 45% of total equity, to the Company as consideration for the Shockwave License Agreement (or "License Agreement"). Under the License Agreement, the Company has agreed to contribute to the JV an exclusive license under certain of the Company's intellectual property rights to develop, manufacture, distribute and commercialize certain products in the PRC and is entitled to receive royalties on the sales of the licensed products in the PRC. Further, the Company entered into a Distribution Agreement, pursuant to which the Company has agreed to sell certain Company-manufactured products to the JV and/or a to-be formed PRC subsidiary of the JV for commercialization and distribution in the PRC.

The Company has accounted for its investment in the JV under the equity method of accounting. As of September 30, 2021, the carrying value of the Company's investment in the JV was $6.4 million. The Company's share of losses generated by the JV for the three and nine months ended September 30, 2021 was $0.3 and $5.9 million, respectively, which was recorded in share in net loss of equity method investment. The JV has not generated any revenues to date.

The following table summarizes the unaudited balance sheet for the JV:

	September 30, 2021
Balance sheet:	(in thousands)
Current assets	$ 14,991
Current liabilities	(757)
Net assets	$ 14,234

The following table summarizes the unaudited results of operations for the JV:

	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
	(in thousands)	
Revenues	$ —	$ —
Loss from operations	758	13,033
Net loss	$ 758	$ 13,033

Upon execution of the License Agreement, on March 19, 2021, the Company received a 45% equity stake in the JV. The Company determined that the JV met the definition of a customer under Topic 606, and that the promised goods and services of the contribution of the license of intellectual property and associated manufacturing technology transfer to the JV were considered to be a single performance obligation. The transaction price of $12.3 million was estimated by reference to the cash value of the shares which were issued at the formation of the JV.

As of September 30, 2021, the contribution of the license of intellectual property and associated manufacturing technology transfer to the JV has not yet been completed. The Company maintains a related party contract liability, noncurrent, of $12.3 million for the outstanding performance obligation. The Company will satisfy the outstanding performance obligation upon the completion of training provided by the Company to the JV, and successful regulatory approval from the PRC National Medical Products Administration.

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, 2020. 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 this Quarterly Report on Form 10-Q and in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2020, and our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2021 and June 30, 2021, 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. We are currently selling the following products in a number of countries around the world where we have applicable regulatory approvals:

Products for the Treatment of Peripheral Artery Disease ("PAD"):

- Our Shockwave M^5 IVL catheter ("M^5 catheter"), which 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 PAD.

- Our Shockwave M^{5+} IVL catheter, for which we are currently initiating a limited market release in the U.S and select international locations, was CE-Marked in November 2020 and cleared by the U.S. Food and Drug Administration ("FDA") in April 2021 for use in our IVL System for the treatment of PAD.

- The second version of our Shockwave S^4 IVL catheter ("S^4 catheter"), which was cleared by the FDA in August 2019 and accepted by our EU notified body in May 2020 for use in our IVL System for the treatment of below the knee PAD.

Product for the Treatment of Coronary Artery Disease ("CAD"):

- Our Shockwave C^2 IVL catheter ("C^2 catheter") was CE-Marked in June 2018 and approved by the FDA in February 2021 for use in our IVL System for the treatment of CAD.

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, in October 2020, we announced the results of our DISRUPT CAD III global study. The data from DISRUPT CAD III supported our pre-market application ("PMA") in the United States for our C^2 catheters, and a Shonin submission in Japan for our C^2 catheters. In addition, we began enrollment in the DISRUPT CAD IV Japan study in 2019 and completed enrollment in April 2020. In March of 2021, we submitted 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 actively selling our products in over 50 countries in North and South America, Europe, the Middle East, Asia, Africa and Australia/New Zealand. We are actively expanding our international field presence through new distributors, as well as additional sales and clinical personnel. In addition, we are adding new U.S. sales territories.

For the three months ended September 30, 2021 and 2020, we generated product revenue of $65.2 million and $19.6 million, respectively, and income from operations of $2.8 million and a loss of operations of $12.8 million, respectively. For the three months ended September 30, 2021 and 2020, 19% and 43%, respectively, of our product revenue was generated from customers located outside of the United States.

For the nine months ended September 30, 2021 and 2020, we generated product revenue of $153.0 million and $45.1 million, respectively, and a loss from operations of $14.9 million and $49.8 million, respectively. For the nine months ended September 30, 2021 and 2020, 24% and 46%, respectively, of our product revenue was generated from customers located outside of the United States.

Since inception, we have incurred significant net losses. Although we had positive net income for the quarter ended September 30, 2021, we had a net loss for the nine months ended September 30, 2021. We may continue to incur losses in the future, which may vary significantly from period to period. We expect to continue to incur significant expenses as we (i) expand our marketing efforts to increase adoption of our products, (ii) expand existing relationships with our customers, (iii) obtain regulatory clearances or approvals for our planned or future products, (iv) conduct clinical trials on our existing and planned or future products, and (v) develop new products or add new features to our existing products. We will need to continue to generate significant revenue in order to sustain profitability as we continue to grow our business. Even if we achieve profitability for any period, we cannot be sure that we will remain profitable for any substantial period of time.

To date, our principal sources of liquidity have been the net proceeds we received through the sale of our common stock in our public offerings, private sales of equity securities and payments received from customers using our products. As of September 30, 2021, we had $183.0 million in cash, cash equivalents and short-term investments and an accumulated deficit of $265.8 million.

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 may be or may periodically be, depending on the current COVID-19 infection rates in the applicable location, 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.

In addition, we have recently seen some disruptions in the operations of certain of our third-party suppliers, resulting in increased lead-times, higher component costs and lower allocations for our purchase of some components and, in certain cases, requiring us to procure materials from alternate suppliers or incur higher logistical expenses. We are continuing to work closely with our manufacturing partners and suppliers to enable us to source key components and maintain appropriate inventory levels to meet customer demand. We, however, have not experienced material disruptions in our supply chain to date.

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 continued to work from our Santa Clara headquarters following appropriate hygiene and social distancing protocols. To reduce the risk to our other employees and their families from potential exposure to COVID-19, until recently all other staff in our Santa Clara headquarters were required to work from home. Certain of these other employees had begun to return to our headquarters full or part-time during the second quarter of 2021, although we continue to review the impact of the delta variant of COVID-19 on employee safety. We continue to limit 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, the extent of the continuing resurgence of COVID-19, the efficacy and extent of distribution of vaccines, and the impact of mutations of COVID-19, and the ability of various economies and supply-chains to recover from the COVID-19 pandemic. 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 selected 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 portion of our revenue is generated through a consignment model under which inventory is maintained at hospitals. For consignment inventory, control is transferred at the time the catheters are consumed in a procedure.

Cost of product revenue

Cost of product revenue consists primarily of costs of components for use in our products, the materials and labor that are used to produce our products, the manufacturing overhead that directly supports production and the depreciation relating to the equipment used in our IVL System to the extent that we loan generators 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 costreduction strategies. We expect our gross margin percentage to increase over the long term to the extent we are successful in increasing our sales volume and are therefore able to leverage our fixed costs. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which, if successful, we believe will reduce costs and enable us to increase our gross margin percentage. While we expect gross margin percentage to increase over the long term, it will likely fluctuate from quarter to quarter as we continue to introduce new products and adopt new manufacturing processes and technologies.

Research and development expenses

Research and development ("R&D") expenses consist of applicable personnel, consulting, materials, and clinical trial expenses. R&D expenses include:

- certain personnel-related expenses, including salaries, benefits, bonus, travel, and stock-based compensation;
- cost of clinical studies to support new products and product enhancements, including expenses for clinical research organizations, 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 continue to grow our sales force and increase marketing efforts as we continue commercializing products based on our IVL Technology. As a result, we expect sales and marketing expenses to increase in absolute dollars over the long term.

General and administrative expenses

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

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

The following table shows our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Change $	Change %
	(in thousands, except percentages)			
Revenue:				
Product revenue	$ 65,155	$ 19,590	$ 45,565	233%
Cost of revenue:				
Cost of product revenue	10,949	5,277	5,672	107%
Gross profit	54,206	14,313	39,893	279%
Operating expenses:				
Research and development	13,735	7,891	5,844	74%
Sales and marketing	28,393	13,619	14,774	108%
General and administrative	9,265	5,610	3,655	65%
Total operating expenses	51,393	27,120	24,273	90%
Income (loss) from operations	2,813	(12,807)	15,620	122%
Share in net loss of equity method investment	(342)	—	(342)	(100)%
Interest expense	(165)	(314)	149	(47)%
Other income (expense), net	(280)	218	(498)	(228)%
Net income (loss) before taxes	2,026	(12,903)	14,929	116%
Income tax provision	78	29	49	169%
Net income (loss)	$ 1,948	$ (12,932)	$ 14,880	115%

Product revenue

Product revenue increased by $45.6 million, or 233%, from $19.6 million during the three months ended September 30, 2020 to $65.2 million during the three months ended September 30, 2021.

The following table represents our product revenue based on product line:

	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Change $	Change %
	(in thousands, except percentages)			
Coronary	$ 47,165	$ 6,983	$ 40,182	575%
Peripheral	17,725	12,337	5,388	44%
Other	265	270	(5)	(2)%
Product revenue	$ 65,155	$ 19,590	$ 45,565	233%

Coronary product revenue increased by $40.2 million, or 575%, from $7.0 million for the three months ended September 30, 2020 to $47.2 million for the three months ended September 30, 2021. In February 2021, we received U.S. FDA approval for our C2 catheters. The increase in coronary product revenue was primarily due to the commencement of sales in the United States, increased adoption of our products internationally, and continued recovery from the pandemic impact in the prior year. All coronary product revenue was from international customers for three months ended September 30, 2020.

Peripheral product revenue increased by $5.4 million, or 44%, from $12.3 million for the three months ended September 30, 2020 to $17.7 million for the three months ended September 30, 2021. The change was due to an increase in purchase volume of our M5 and S4 IVL catheters within the United States and internationally driven by increased adoption of our products and recovery from the pandemic impact in the prior year.

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, 2021 as compared to the three months ended September 30, 2020. Product revenue, classified by the major geographic areas in which our products are shipped, was $52.8 million within the United States and $12.4 million for all other countries in the three months ended September 30, 2021 compared to $11.1 million within the United States and $8.5 million for all other countries in the three months ended September 30, 2020.

Cost of product revenue, gross profit and gross margin percentage

Cost of product revenue increased by $5.7 million, or 107%, from $5.3 million during the three months ended September 30, 2020 to $10.9 million during the three months ended September 30, 2021. Gross margin percentage improved to 83.2% for the three months ended September 30, 2021, compared to 73.1% for the three months ended September 30, 2020. This change in gross margin percentage was primarily due to higher average selling price and 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:

	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Change $	Change %
	(in thousands)			
Compensation and personnel-related costs	$ 7,835	$ 4,181	$ 3,654	87%
Clinical-related costs	1,762	1,896	$ (134)	(7)%
Material and supplies	1,187	556	$ 631	113%
Facilities and other allocated costs	1,504	621	$ 883	142%
Outside consultants	1,124	443	$ 681	154%
Other research and development costs	323	194	$ 129	66%
Total research and development expenses	$ 13,735	$ 7,891	$ 5,844	74%

R&D expenses increased by $5.8 million, or 74%, from $7.9 million during the three months ended September 30, 2020 to $13.7 million during the three months ended September 30, 2021. The change was primarily due to a $3.7 million increase in compensation and personnel-related costs due to an increase in headcount, a $0.9 million increase in facilities and other allocated costs, a $0.7 million increase in outside consultants, a $0.6 million increase in materials and supplies, and a $0.1 million increase in other research and development costs. This was partially offset by a decrease in clinical-related costs of $0.1 million due to completion of patient enrollment for the majority of clinical trials.

Sales and marketing expenses

Sales and marketing expenses increased by $14.8 million, or 108%, from $13.6 million during the three months ended September 30, 2020 to $28.4 million during the three months ended September 30, 2021. The change was primarily due to a $10.1 million increase in compensation and personnel-related costs, resulting from increased headcount and commissions driven by increased sales of our products. There was also a $1.3 million increase in travel related costs, a $1.0 million increase in marketing and promotional costs, a $0.8 million increase in facilities and other allocated costs, a $0.6 million increase in professional services and consulting costs, a $0.6 million increase in materials and supplies, a $0.2 million increase in general corporate costs, and a $0.2 million increase in recruiting and training costs.

General and administrative expenses

General and administrative expenses increased by $3.7 million, or 65%, from $5.6 million during the three months ended September 30, 2020 to $9.3 million during the three months ended September 30, 2021. The change was primarily due to a $2.2 million increase in compensation and personnel-related costs, a $0.7 million increase in general corporate costs, a $0.3 million increase in professional services and consulting costs, a $0.3 million increase in facilities and other allocated costs, a $0.1 million increase in recruiting and training costs, and a $0.1 million increase in travel related costs.

Other income (expense), net

Other income (expense), net decreased by $0.5 million, or 228%, from $0.2 million in other income, net during the three months ended September 30, 2021 to $0.3 million in other expense, net during the three months ended September 30, 2021. The decrease in other income was primarily due to a decrease in interest income attributable to the decreased interest rate environment in the comparable period and the timing of the maturities of marketable securities. Also included in other income (expense), net are the net impact of foreign exchange gains and losses.

Share in net loss of equity method investment

The increase in share in net loss of equity method investment of $0.3 million for the three months ended September 30, 2021 was due to our 45% ownership in the JV which was acquired in March 2021.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table shows our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,			
	2021	**2020**	**Change $**	**Change %**
	(in thousands, except percentages)			
Revenue:				
Product revenue	$ 152,963	$ 45,073	$ 107,890	239%
Cost of revenue:				
Cost of product revenue	28,775	14,520	14,255	98%
Gross profit	124,188	30,553	93,635	306%
Operating expenses:				
Research and development	35,827	27,882	7,945	28%
Sales and marketing	78,098	35,236	42,862	122%
General and administrative	25,117	17,232	7,885	46%
Total operating expenses	139,042	80,350	58,692	73%
Loss from operations	(14,854)	(49,797)	34,943	(70)%
Share in net loss of equity method investment	(5,865)	—	(5,865)	(100)%
Interest expense	(795)	(897)	102	(11)%
Other income (expense), net	(369)	942	(1,311)	(139)%
Net loss before taxes	(21,883)	(49,752)	27,869	(56)%
Income tax provision	195	73	122	167%
Net loss	$ (22,078)	$ (49,825)	$ 27,747	(56)%

Product revenue

Product revenue increased by $107.9 million, or 239%, from $45.1 million during the nine months ended September 30, 2020 to $153.0 million during the nine months ended September 30, 2021.

The following table represents our product revenue based on product line:

	Nine Months Ended September 30,			
	2021	**2020**	**Change $**	**Change %**
	(in thousands, except percentages)			
Coronary	$ 99,175	$ 16,403	$ 82,772	505%
Peripheral	52,659	27,927	24,732	89%
Other	1,129	743	386	52%
Product revenue	$ 152,963	$ 45,073	$ 107,890	239%

Coronary product revenue increased by $82.8 million, or 505%, from $16.4 million for the nine months ended September 30, 2020 to $99.2 million for the nine months ended September 30, 2021. In February 2021, we received U.S. FDA approval for our C^2 catheters. The increase in coronary product revenue was primarily due to the commencement of sales in the United States, increased adoption of our products internationally, and continued recovery from the pandemic impact in the prior year. All coronary product revenue was from international customers for nine months ended September 30, 2020.

Peripheral product revenue increased by $24.7 million, or 89%, from $27.9 million for the nine months ended September 30, 2020 to $52.7 million for the nine months ended September 30, 2021. The change was due to an increase in purchase volume of our M5 and S4 IVL catheters within the United States and internationally driven by increased adoption of our products and recovery from the pandemic impact in the prior year.

Other product revenue increased by $0.4 million, or 52%, from $0.7 million for the nine months ended September 30, 2020 to $1.1 million for the nine months ended September 30, 2021. The change was due to an increase in the purchase volume of our IVL generators and other accessories 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, 2021 as compared to the nine months ended September 30, 2020. Product revenue, classified by the major geographic areas in which our products are shipped, was $116.7 million within the United States and $36.3 million for all other countries in the nine months ended September 30, 2021 compared to $24.5 million within the United States and $20.6 million for all other countries in the nine months ended September 30, 2020.

Cost of product revenue and gross margin percentage

Cost of product revenue increased by $14.3 million, or 98% from $14.5 million during the nine months ended September 30, 2020 to $28.8 million during the nine months ended September 30, 2021. The increase was primarily due to growth in sales volume. Gross margin percentage improved to 81.2% for the nine months ended September 30, 2021, compared to 67.8% for the nine months ended September 30, 2020. This change in gross margin percentage was primarily due to higher average selling price and 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,			
	2021	2020	Change $	Change %
	(in thousands)			
Compensation and personnel-related costs	$ 20,873	$ 12,500	$ 8,373	67%
Clinical-related costs	6,086	8,502	$ (2,416)	(28)%
Material and supplies	2,149	1,855	$ 294	16%
Facilities and other allocated costs	3,862	2,033	$ 1,829	90%
Outside consultants	2,145	1,367	$ 778	57%
Other research and development costs	712	1,625	$ (913)	(56)%
Total research and development expenses	$ 35,827	$ 27,882	$ 7,945	28%

R&D expenses increased by $7.9 million, or 28%, from $27.9 million during the nine months ended September 30, 2020 to $35.8 million during the nine months ended September 30, 2021. The change was primarily due to a $8.4 million increase in compensation and personnel-related costs due to an increase in headcount, a $1.8 million increase in facilities and other allocated costs due to increased rent and building expenditures, a $0.8 million increase in outside consulting costs, and a $0.3 million increase in materials and supplies. This was partially offset by a $2.4 million decrease in clinical-related costs due to completion of patient enrollment for the majority of clinical trials, and a $0.9 million decrease in other research and development costs due to software license costs in the prior year not incurred in the current year.

Sales and marketing expenses

Sales and marketing expenses increased by $42.9 million, or 122%, from $35.2 million during the nine months ended September 30, 2020 to $78.1 million during the nine months ended September 30, 2021. The change was primarily due to a $31.8 million increase in compensation and personnel-related costs, as a result of increased headcount and commissions driven by increased sales of our products. There was also a $3.8 million increase in marketing and promotional expenses to support the commercialization of our products, a $2.8 million increase in travel related costs, a $1.7 million increase in facilities and other allocated costs due to increased rent and building expenditures, a $1.2 million increase in materials and supplies, a $0.7 million increase in professional services and consulting costs, a $0.7 million increase in general corporate costs, and a $0.2 million increase in recruitment and training costs.

General and administrative expenses

General and administrative expenses increased by $7.9 million, or 46%, from $17.2 million during the nine months ended September 30, 2020 to $25.1 million during the nine months ended September 30, 2021. The change was primarily due to a $5.8 million increase in compensation and personnel-related costs driven by an increase in headcount, a $1.1 million increase general corporate costs which includes supplies, software, etc., a $0.5 million increase in other allocated costs due to increased rent and building expenditures, a $0.3 million increase in recruitment and training costs, a $0.1 million increase in professional services and consulting costs, and a $0.1 million increase in travel related costs.

Other income (expense), net

Other income (expense), net decreased by $1.3 million, or 139%, from $0.9 million in other income, net during the nine months ended September 30, 2021 to $0.4 million in other expense, net during the nine months ended September 30, 2021. The decrease in other income was primarily due to a decrease in interest income attributable to the decreased interest rate environment in the comparable period and the timing of the maturities of marketable securities. Also included in other income (expense), net are the net impact of foreign exchange gains and losses.

Share in net loss of equity method investment

The increase in share in net loss of equity method investment of $5.9 million for the nine months ended September 30, 2021 was due to our 45% ownership in the JV which was acquired in March 2021.

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 using our products and to a lesser extent proceeds from our debt financings. On March 11, 2019, upon completion of our IPO, we received net proceeds of $99.9 million, after deducting underwriting discounts and commissions and offering expenses. Concurrent with the IPO, we completed a private placement for net proceeds of $10.0 million. On November 15, 2019, we completed a follow-on offering for net proceeds of $96.7 million, after deducting underwriting discounts and commissions and offering expenses. On June 19, 2020, we completed an offering for 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 was 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 have a number of ongoing clinical trials and expect to continue to make substantial investments in these trials and in additional clinical trials that are designed to provide clinical evidence of the safety and efficacy of our products. We intend to continue to make significant investments in our sales and marketing organization by increasing the number of U.S. sales representatives and expanding our international marketing programs to help facilitate further adoption among existing hospital accounts and physicians as well as broaden awareness of our products to new hospitals. We also expect to continue to make investments in R&D, regulatory affairs, and clinical studies to develop future generations of products based on our IVL Technology, support regulatory submissions, and demonstrate the clinical efficacy of our products. Moreover, we expect to 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, although we had positive net income for the quarter ended September 30, 2021, we had a net loss for the nine-months ended September 30, 2021 and we may incur net losses and have negative cash flows from operations in the future.

As of September 30, 2021, we had cash, cash equivalents and short-term investments of $183.0 million, which are available to fund future operations. We believe that our cash and cash equivalents as of September 30, 2021, will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months.

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

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost of our research and development activities for new and modified products;
- 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,	
	2021	2020
	(in thousands)	
Cash used in operating activities	$ (5,795)	$ (58,785)
Cash provided by investing activities	49,518	46,134
Cash provided by (used in) financing activities	(2,951)	88,862
Net increase in cash, cash equivalents and restricted cash	$ 40,772	$ 76,211

Operating activities

During the nine months ended September 30, 2021, cash used in operating activities was $5.8 million, attributable to a net loss of $22.1 million, non-cash charges of $30.2 million, partially offset by a net change in our net operating assets and liabilities of $13.9 million. Non-cash charges primarily consisted of $19.0 million in stock-based compensation, $5.9 million in share in net loss of equity method investment, $2.7 million in depreciation and amortization, $1.2 million in amortization of right-of-use assets, $1.0 million in accretion of discount on available-for-sale securities, and $0.4 million in amortization of debt issuance costs. The change in our net operating assets and liabilities was primarily due to a $18.3 million increase in accounts receivable due to an increase in sales, a $8.0 million increase in inventory driven by an increase in work in progress inventory, a $2.0 million increase in prepaid expenses and other current assets, and a $1.0 million decrease in lease liability. These changes were partially offset by a $13.0 million increase in accrued and other current liabilities resulting from expansion in our operating activities and accrued employee compensation driven by increased headcount, a $2.2 million increase in accounts payable due to the timing of vendor billings and payments, and a decrease in other assets of $0.1 million.

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.

Investing activities

During the nine months ended September 30, 2021, cash provided by investing activities was $49.5 million, attributable to proceeds from maturities of available-for-sale investments of $134.7 million, partially offset by purchase of available-for-sale investments of $75.6 million and purchases of property and equipment of $9.6 million.

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 purchases of property and equipment of $9.9 million.

Financing activities

During the nine months ended September 30, 2021, cash used in financing activities was $3.0 million, attributable to $8.3 million of payment of taxes withheld on net settled vesting of restricted stock units, partially offset by proceeds of $2.5 million from stock option exercises and proceeds of $2.8 million from issuance of shares under our employee stock purchase plan.

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.

Contractual Obligations and Commitments

Debt, Principal, and Interest

Our debt, principal and interest commitments consist of our debt obligations under the Amended Credit Facility. As of September 30, 2021, we had debt, principal, and interest commitments of $19.0 million.

Manufacturing Purchase Obligations

We have engaged a contract manufacturer to produce and supply us with certain products. We have fixed commitments of approximately $7.1 million within the next twelve months.

Operating Leases

Our operating lease commitments mostly consist of our lease obligations for our Santa Clara headquarter office spaces. During the nine months ended September 30, 2021, we entered into a lease amendment and executed a lease for an additional facility. Our total operating lease commitments as of September 30, 2021 are approximately $57.0 million, of which $3.1 million is expected to be paid within the next twelve months.

There were no other material changes during the three months ended September 30, 2021 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, 2020.

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.

With the exception of the accounting of equity method investments and license revenue as described below, herein, there have been no significant changes in our critical accounting policies and assumptions associated with the greatest potential impact on our consolidated financial statements as disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Equity Method Investment

Entities which we have significant influence over activities of the entity, but does not control, are accounted for under the equity method of accounting in accordance with Topic 323, Investments - Equity Method and Joint Ventures. On March 19, 2021, we entered into the Joint Venture Deed (or "JV Agreement") with Genesis MedTech International Private Limited ("Genesis") to establish a long-term strategic partnership to develop, manufacture and commercialize certain of our interventional products in the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau ("PRC"). Under the JV Agreement, Genesis Shockwave Private Ltd. (the "JV") was formed under the laws of Singapore to serve as a joint venture with Genesis for the purpose of establishing and managing such a strategic partnership.

Our carrying value in the equity method investment is reported as equity method investment on our consolidated balance sheet. We record our proportionate share of the underlying income or loss which is recognized in share in net loss of equity method investment. For the three and nine months ended September 30, 2021, our share in the losses incurred by the equity method investee was $0.3 and $5.9 million, respectively. We eliminate any intra-entity profits to the extent of our beneficial interest.

We assess our equity method investment for impairment when events or circumstances suggest that the carrying amount of the investment may be impaired. We consider all available evidenced in assessing whether a decline in fair value is other than temporary. If the decline in fair value is determined to be other than temporary, the difference between the carrying amount of the investment and estimated fair value is recognized as an impairment charge.

License Revenue

For arrangements that contain a license of our functional intellectual property with a customer, we consider whether the license grant is distinct from other performance obligations in the arrangement. A license grant of functional intellectual property is generally considered to be capable of being distinct if a customer can benefit from the license on its own or together with other readily available resources. License revenue for licenses of functional intellectual property is recognized at a point in time when we satisfy our performance obligation of transferring the license to the customer.

In connection with the formation of the JV on March 19, 2021, we received a 45% equity stake in the JV in exchange for the contribution of intellectual property. We determined that the JV met the definition of a customer under Topic 606, and that the promised goods and services of the contribution of the license of intellectual property and associated manufacturing technology transfer to the JV were considered to be a single performance obligation. The transaction price of $12.3 million was estimated by reference to the cash value of the shares which were issued at the formation of the JV.

As of September 30, 2021, the contribution of the license of intellectual property and associated manufacturing technology transfer to the JV has not yet been completed. We recorded a related party contract liability, noncurrent, of $12.3 million for the outstanding performance obligation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest rate risk

Our cash, cash equivalents and short-term investments as of September 30, 2021 consisted of $183.0 million in bank deposits, money market funds and available-for-sale securities. Such interest-earning instruments carry a degree of interest rate risk. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents.

As of September 30, 2021, we had $16.5 million of principal amount of variable rate debt outstanding with an interest-only payment period through June 30, 2022. The debt 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, 2021.

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, 2021 and 2020, approximately 14% and 27% 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 $1.5 million and $0.6 million in foreign currency cash and accounts receivable as of September 30, 2021 and December 31, 2020, 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. 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 and the briefing of these two cases is completed. The parties are awaiting the scheduling of the hearings before the Federal Circuit. All claims of the IPR Patents remain valid and enforceable until such appeals have been exhausted. Upon the conclusion of such appeals, if we are unsuccessful in whole or in part, the IPR proceedings could result in the loss or narrowing in scope of the IPR Patents, which could limit our ability to stop others from using or commercializing products and technology similar or identical to ours. For more information regarding the risks presented by such proceedings, please see the section of our Annual Report on Form 10-K for the year ended December 31, 2020, entitled "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.

The following risk factors supplement and, to the extent inconsistent, supersede the risk factors disclosed in Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2020 (the "2020 Annual Report"), filed with the Securities and Exchange Commission on February 26, 2021.

We depend upon third-party suppliers, including single source component suppliers, making us vulnerable to supply problems and price fluctuations.

We rely on third-party suppliers, including some single source suppliers for certain components of our products, to provide us with a portion of our demand for one of our products as well as components used in the manufacturing of our products. In some cases, we purchase supplies through purchase orders and do not have long-term supply agreements with, or guaranteed commitments from, our component suppliers, including single source suppliers. Many of our suppliers and contract manufacturers are not obligated to perform services or supply products for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. We depend on our suppliers to provide us and our customers with materials or products in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers may encounter problems during manufacturing for a variety of reasons, including as a result of the ongoing COVID-19 pandemic, any of which could delay or impede their ability to meet our demand. These suppliers may cease producing the products or components we purchase from them or otherwise decide to cease doing business with us. Further, we maintain limited volumes of inventory from most of our suppliers and contract manufacturers. If we inaccurately forecast demand for finished goods, we may be unable to meet customer demand which could harm our competitive position and reputation. In addition, if we fail to effectively manage our relationships with our suppliers and contract manufacturers, we may be required to change suppliers or contract manufacturers. While we believe alternate suppliers exist for all materials, components and services necessary to manufacture our products, establishing additional or replacement suppliers for any of these materials, components or services, if required, could be time-consuming, expensive and may result in interruptions in our operations and product delivery. Even if we are able to find replacement suppliers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Any of these events could require that we obtain a new regulatory authority approval before we implement the change, which could result in further delay or which may not be obtained at all. If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost, volumes and quality on a timely basis, the continued commercialization of our products, the supply of our products to customers and the development of any future products will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition and results of operations.

For example, the COVID-19 pandemic has disrupted the operations of certain of our third-party suppliers, resulting in increased lead-times for our purchases of some components and, in certain cases, requiring us to procure materials from alternate suppliers or incur higher logistics expenses. We have worked closely with our manufacturing partners and suppliers to enable us to source key components and maintain appropriate inventory levels to meet customer demand and have not experienced disruptions in our supply chain to date. However, there is no assurance that we will not experience more significant disruptions in our supply chain in the future, particularly if the operations of our contract manufacturing partners or any of our critical single source component providers are more severely impacted by the pandemic and associated containment measures. Any supply interruption from our suppliers or failure to obtain additional suppliers for products or any of the components used in our products would limit our ability to manufacture our products and could have a material adverse effect on our business, financial condition and results of operations.

Other than the foregoing, there have been no material changes from the risk factors disclosed in Part I, Item 1A. “Risk Factors” of the 2020 Annual Report, as updated by the risk factors discussed in Part II, “Item 1A. Risk Factors” in our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2021 (“Q2 2021 Quarterly Report”). The risk factors described in our 2020 Annual Report, as updated by our Q2 2021 Quarterly Report and supplemented by the foregoing risk factors 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 herein, in the 2020 Annual Report and in the Q2 2021 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.

None.

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	Office Lease (Net), dated as of September 27, 2021, between Bunker Hill Lane Property, LLC, a Delaware limited liability company, as Landlord, and Shockwave Medical, Inc., a Delaware Corporation, as Tenant, for 3003 Bunker Hill Lane, Santa Clara, California.	8-K	001-38829	10.1	September 28, 2021
10.2	First Amendment to Office Lease (Net), dated as of September 27, 2021, by and between Betsy Ross Property, LLC, a Delaware limited liability company, and Shockwave Medical, Inc., a Delaware corporation, relating to 5353 Betsy Ross Drive, and 5403 Betsy Ross Drive, Santa Clara, California.	8-K	001-38829	10.2	September 28, 2021
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*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline Taxonomy Extension Presentation Linkbase Document				

104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 has been formatted in Inline XBRL and contained in Exhibit 101

* Filed herewith.

SIGNATURES

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

		Shockwave Medical, Inc.
Date: November 8, 2021	By:	/s/ Douglas Godshall
		Douglas Godshall
		President and Chief Executive Officer
Date: November 8, 2021	By:	/s/ Dan Puckett
		Dan Puckett
		Chief Financial Officer

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2021

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2021

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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 8, 2021

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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 8, 2021

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