UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

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

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

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

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

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

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

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

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

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

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

As of August 4, 2021, the registrant had 35,150,341 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 quarter ended March 31, 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.

Item 1. Financial Statements.

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

	June 30, 2021	December 31, 2020
		(1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 84,268	$ 50,423
Short-term investments	90,478	151,931
Accounts receivable, net	24,955	11,689
Inventory	36,149	29,859
Prepaid expenses and other current assets	3,781	2,398
Total current assets	239,631	246,300
Operating lease right-of-use assets	6,825	7,568
Property and equipment, net	21,467	16,362
Equity method investment	6,750	—
Other assets	1,686	1,812
TOTAL ASSETS	$ 276,359	$ 272,042
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 2,633	$ 1,466
Term notes, current portion	4,125	3,300
Accrued liabilities	28,317	19,942
Lease liability, current portion	920	873
Total current liabilities	35,995	25,581
Lease liability, noncurrent portion	6,911	7,488
Term notes, noncurrent portion	12,833	13,319
Related party contract liability, noncurrent portion	12,273	—
TOTAL LIABILITIES	68,012	46,388
STOCKHOLDERS' EQUITY:		
Preferred stock	—	—
Common stock	35	35
Additional paid-in capital	476,001	469,283
Accumulated other comprehensive income	10	9
Accumulated deficit	(267,699)	(243,673)
TOTAL STOCKHOLDERS' EQUITY	208,347	225,654
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 276,359	$ 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 Loss
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Product revenue	$ 55,908	$ 10,286	$ 87,808	$ 25,483
Cost of revenue:				
Cost of product revenue	9,934	3,592	17,826	9,243
Gross profit	45,974	6,694	69,982	16,240
Operating expenses:				
Research and development	11,815	8,101	22,092	19,991
Sales and marketing	25,713	11,206	49,705	21,617
General and administrative	8,626	5,398	15,852	11,622
Total operating expenses	46,154	24,705	87,649	53,230
Loss from operations	(180)	(18,011)	(17,667)	(36,990)
Share in net loss of equity method investment	—	—	(5,523)	—
Interest expense	(318)	(306)	(630)	(583)
Other income (expense), net	146	220	(89)	724
Net loss before taxes	(352)	(18,097)	(23,909)	(36,849)
Income tax provision	73	21	117	44
Net loss	$ (425)	$ (18,118)	$ (24,026)	$ (36,893)
Unrealized gain/(loss) on available-for-sale securities	(6)	(82)	1	(14)
Total comprehensive loss	$ (431)	$ (18,200)	$ (24,025)	$ (36,907)
Net loss per share, basic and diluted	$ (0.01)	$ (0.56)	$ (0.69)	$ (1.16)
Shares used in computing net loss per share, basic and diluted	35,030,036	32,156,476	34,914,361	31,900,259

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 Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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

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

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

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

	Six Months Ended June 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (24,026)	$ (36,893)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,597	877
Share in net loss of equity method investment	5,523	—
Stock-based compensation	11,662	4,262
Amortization of right-of-use assets	791	734
Accretion of discount on available-for-sale securities	397	201
Amortization of debt issuance costs	339	313
Changes in operating assets and liabilities:		
Accounts receivable	(13,266)	1,012
Inventory	(5,676)	(10,965)
Prepaid expenses and other current assets	(1,383)	(1,220)
Other assets	126	(116)
Accounts payable	1,270	(282)
Accrued and other current liabilities	8,107	(41)
Lease liabilities	(578)	(237)
Net cash used in operating activities	(15,117)	(42,355)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of available-for-sale securities	(27,243)	(16,020)
Proceeds from maturities of available-for-sale securities	88,300	59,000
Purchase of property and equipment	(6,757)	(8,952)
Net cash provided by investing activities	54,300	34,028
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments of offering costs	—	(179)
Proceed from issuance of common stock from public offering, net of issuance cost paid	—	83,784
Principal payments of term loan	—	(1,111)
Net proceeds from term loan	—	3,265
Payments of taxes withheld on net settled vesting of restricted stock units	(8,337)	(616)
Proceeds from stock option exercises	1,858	1,593
Proceeds from issuance of common stock under employee stock purchase plan	1,141	842
Net cash provided by (used in) financing activities	(5,338)	87,578
Net increase in cash, cash equivalents and restricted cash	33,845	79,251
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	$ 85,718	$ 219,746
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	$ 292	$ 256
Income tax paid	$ 17	$ 10
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Offering costs included in accounts payable and accrued liabilities	$ —	$ 402
Right-of-use asset obtained in exchange for lease liability	$ 48	$ 39
Property and equipment purchases included in accounts payable and accrued liabilities	$ 2,613	$ 501
Equity method investment obtained in exchange for related party contract liability	$ 12,273	$ —
Transfer of fixed assets to inventory	$ 220	$ 174

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 and has negative cash flows from operations. As of June 30, 2021, the Company had an accumulated deficit of $267.7 million. Management expects to continue to incur additional substantial losses for the foreseeable future.

As of June 30, 2021, the Company had cash, cash equivalents and short-term investments of $174.7 million, which are available to fund future operations. The Company believes that its cash, cash equivalents and short-term investments as of June 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. Economies worldwide continue to be negatively impacted by the COVID-19 pandemic, in particular with recurrent outbreaks and mutations of the virus, despite advances in vaccines, and we anticipate 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 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 six months ended June 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 June 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:

	June 30, 2021	December 31, 2020
	(in thousands)	
Cash and cash equivalents	$ 84,268	$ 50,423
Restricted cash	1,450	1,450
Total cash, cash equivalents, and restricted cash	$ 85,718	$ 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 six months ended June 30, 2021, the Company's share in the losses incurred by the equity method investee was nil and $5.5 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 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.

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 six months ended June 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:

	June 30, 2021			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
U.S. Treasury securities	$ 60,421	$ —	$ —	$ 60,421
Money market funds	68,974	—	—	68,974
Commercial paper	—	24,777	—	24,777
Corporate bonds	—	5,280	—	5,280
Total assets	$ 129,395	$ 30,057	$ —	$ 159,452

	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:

	June 30, 2021			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury securities	$ 60,412	$ 9	$ —	$ 60,421
Money market funds	68,974	—	—	68,974
Commercial paper	24,777	—	—	$ 24,777
Corporate bonds	5,279	1	—	5,280
Total	$ 159,442	$ 10	$ —	$ 159,452
Reported as:				
Cash equivalents				$ 68,974
Short-term investments				90,478
Total				$ 159,452

	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. As of June 30, 2021, the remaining contractual maturities for available-for-sale securities were less than one year.

5. Balance Sheet Components

Inventory

Inventory consists of the following:

	June 30, 2021	December 31, 2020
	(in thousands)	
Raw material	$ 6,555	$ 4,995
Work in progress	7,905	6,051
Finished goods	19,893	16,952
Consigned inventory	1,796	1,861
Total inventory	$ 36,149	$ 29,859

Accrued Liabilities

Accrued liabilities consist of the following:

	June 30, 2021	December 31, 2020
	(in thousands)	
Accrued employee compensation	$ 16,069	$ 10,885
Accrued research and development costs	4,005	3,057
Accrued asset purchases	3,185	2,527
Accrued professional services	1,722	1,325
Other	3,336	2,148
Total accrued liabilities	$ 28,317	$ 19,942

6. Term Notes

Loan and Security Agreement

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

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

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

In February 2020, the Company entered into a First Amendment to its Loan and Security Agreement (the “Amended Credit Facility”) to, among other things, refinance its existing term loan, which is accounted for as a modification of the Loan and Security Agreement. Under the Amended Credit Facility, the existing revolving line of credit of $2.0 million was terminated and the termination fee of less than $0.1 million was waived. The Amended Credit Facility provides the Company with a supplemental term loan in the amount of $16.5 million. After repayment of the outstanding amount of the term loan, the Company received net proceeds of $3.3 million, which reflects an additional $4.3 million in principal as of the date of the modification less the final balloon payment fee of $1.0 million. The principal amount outstanding under the supplemental term loan accrues interest at a floating per annum rate equal to the greater of the Prime Rate minus 1.25% and 3.5% (3.5% as of June 30, 2021).

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

On June 30, 2021, the Company achieved the milestone referred to in clause (a) which extended the interest-only payment period by an additional six months to December 31, 2021.

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

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

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

	June 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	458	119
Term note, current and noncurrent	16,958	16,619
Less term note, current portion	(4,125)	(3,300)
Term note, noncurrent portion	$ 12,833	$ 13,319

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

Year ending December 31:	(in thousands)
2021 (remainder)	$ 294
2022	8,701
2023	9,976
Total future payments	18,971
Less amounts representing interest	(903)
Less final payment	(1,568)
Total principal amount of term note payments	$ 16,500

7. Stock-Based Compensation

Total stock-based compensation was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Cost of product revenue	$ 317	$ 39	$ 455	$ 141
Research and development	1,490	650	2,657	1,138
Sales and marketing	2,585	837	4,642	1,396
General and administrative	2,131	924	3,908	1,587
Total stock-based compensation	$ 6,523	$ 2,450	$ 11,662	$ 4,262

Stock-based compensation of $139,000 and $155,000 was capitalized into inventory for the three months ended June 30, 2021 and 2020, respectively. Stock-based compensation of $394,000 and $215,000 was capitalized into inventory for the six months ended June 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 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 June 30, 2021, there were 3,742,997 shares available for issuance under the 2019 Plan.

Stock Options

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

	Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Term	Aggregate Intrinsic Value
				(in years)	(in thousands)
Balance, December 31, 2020	2,689,624	2,087,202	$ 5.92	6.77	$ 204,137
Awards authorized	1,040,530	—			
Options exercised	—	(308,426)	6.02		
Options forfeited	12,843	(12,843)	9.87		
Balance, June 30, 2021	3,742,997	1,765,933	$ 5.87	6.23	$ 324,688
Vested and exercisable, June 30, 2021		1,386,994	$ 4.77	5.91	$ 256,540
Vested and expected to vest, June 30, 2021		1,765,933	$ 5.87	6.23	$ 324,688

Restricted Stock Units

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

RSU activity under the 2019 Plan is set forth below:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance, December 31, 2020	859,577	$ 48.50
RSUs granted	498,315	127.82
RSUs vested	(178,998)	41.27
RSUs forfeited	(41,705)	72.84
Balance, June 30, 2021	1,137,189	$ 83.50

Employee Stock Purchase Plan

In February 2019, the Company adopted the 2019 Employee Stock Purchase Plan ("ESPP"), which became effective in connection with the Company's 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 $290,000 and $557,000 of stock-based compensation expense related to the ESPP for the three and six months ended June 30, 2021, respectively. The Company recorded $207,000 and $398,000 of stock-based compensation expense related to the ESPP for the three and six months ended June 30, 2020, respectively. At June 30, 2021, a total of 888,735 shares were available for issuance under the ESPP.

8. Net Loss Per Share

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

	June 30,	
	2021	2020
Common stock options issued and outstanding	1,765,933	2,798,083
Restricted stock units	1,137,189	743,440
Employee stock purchase plan	11,760	20,079
Total	2,914,882	3,561,602

9. Revenue

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Peripheral	$ 18,793	$ 6,509	$ 34,934	$ 15,590
Coronary	36,702	3,653	52,010	9,420
Other	413	124	864	473
Product revenue	$ 55,908	$ 10,286	$ 87,808	$ 25,483

Peripheral product revenue encompasses sales of the Company's M5 and S4 IVL catheters. Coronary product revenue encompasses sales of the Company's C2 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
United States	$ 42,913	$ 5,537	$ 63,958	$ 13,306
Europe	10,420	3,817	18,642	9,592
All other countries	2,575	932	5,208	2,585
Product revenue	$ 55,908	$ 10,286	$ 87,808	$ 25,483

10. 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 Shockwave'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 Shockwave-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 June 30, 2021, the carrying value of the Company's investment in the JV was $6.8 million. The Company's share of losses generated by the JV for the three and six months ended June 30, 2021 was nil and $5.5 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:

	June 30, 2021
Balance sheet:	(in thousands)
Current assets	$ 14,994
Total assets	14,994
Total liabilities	—
Net assets	$ 14,994

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 June 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, non-current, of $12.3 million for the outstanding performance obligation.

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, 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 M5 IVL catheter ("M5 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 M5+ 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 S4 IVL catheter ("S4 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 C2 IVL catheter ("C2 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 C2 catheters, and a Shonin submission in Japan for our C2 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 June 30, 2021 and 2020, we generated product revenue of $55.9 million and $10.3 million, respectively, and a loss from operations of $0.2 million and $18.0 million, respectively. For the three months ended June 30, 2021 and 2020, 23% and 46%, respectively, of our product revenue was generated from customers located outside of the United States.

For the six months ended June 30, 2021 and 2020, we generated product revenue of $87.8 million and $25.5 million, respectively, and a loss from operations of $17.7 million and $37.0 million, respectively. For the six months ended June 30, 2021 and 2020, 27% and 48%, respectively, of our product revenue was generated from customers located outside of the United States.

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. 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 June 30, 2021, we had $174.7 million in cash, cash equivalents and short-term investments and an accumulated deficit of $267.7 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.

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 are reviewing 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. 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 significant portion of our revenue is generated through a consignment model under which inventory is maintained at hospitals. For consignment inventory, control is transferred at the time the catheters are consumed in a procedure.

Cost of product revenue

Cost of product revenue consists primarily of costs of components for use in our products, the materials and labor that are used to produce our products, the manufacturing overhead that directly supports production and the depreciation relating to the equipment used in our IVL System that we loan to our hospital customers without charge to facilitate the use of our IVL catheters in their procedures. We depreciate equipment over a three-year period. We expect cost of product revenue to increase in absolute terms as our revenue grows.

Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, the cost of direct materials, product mix, geographic mix, discounting practices, manufacturing costs, product yields, headcount and cost-reduction strategies. We expect our gross margin percentage to increase over the long term to the extent we are successful in increasing our sales volume and are therefore able to leverage our fixed costs. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which, if successful, we believe will reduce costs and enable us to increase our gross margin percentage. While we expect gross margin percentage to increase

over the long term, it will likely fluctuate from quarter to quarter as we continue to introduce new products and adopt new manufacturing processes and technologies.

Research and development expenses

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

- certain personnel-related expenses, including salaries, benefits, bonus, travel, and stock-based compensation;
- cost of clinical studies to support new products and product enhancements, including expenses for clinical research organizations, 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 June 30, 2021 and 2020

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

	Three Months Ended June 30,			
	2021	2020	Change $	Change %
	(in thousands, except percentages)			
Revenue:				
Product revenue	$ 55,908	$ 10,286	$ 45,622	444%
Cost of revenue:				
Cost of product revenue	9,934	3,592	6,342	177%
Gross profit	45,974	6,694	39,280	587%
Operating expenses:				
Research and development	11,815	8,101	3,714	46%
Sales and marketing	25,713	11,206	14,507	129%
General and administrative	8,626	5,398	3,228	60%
Total operating expenses	46,154	24,705	21,449	87%
Loss from operations	(180)	(18,011)	17,831	(99)%
Share in net loss of equity method investment	—	—	—	—
Interest expense	(318)	(306)	(12)	4%
Other income, net	146	220	(74)	(34)%
Net loss before taxes	(352)	(18,097)	17,745	(98)%
Income tax provision	73	21	52	248%
Net loss	$ (425)	$ (18,118)	$ 17,693	(98)%

Product revenue

Product revenue increased by $45.6 million, or 444%, from $10.3 million during the three months ended June 30, 2020 to $55.9 million during the three months ended June 30, 2021.

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

	Three Months Ended June 30,			
	2021	2020	Change $	Change %
	(in thousands, except percentages)			
Peripheral	$ 18,793	$ 6,509	$ 12,284	189%
Coronary	36,702	3,653	33,049	905%
Other	413	124	289	233%
Product revenue	$ 55,908	$ 10,286	$ 45,622	444%

Peripheral product revenue increased by $12.3 million, or 189% from $6.5 million for the three months ended June 30, 2020 to $18.8 million for the three months ended June 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.

Coronary product revenue increased by $33.0 million, or 905% from $3.7 million for the three months ended June 30, 2020 to $36.7 million for the three months ended June 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. All coronary product revenue was international for three months ended June 30, 2020.

Other product revenue increased by $0.3 million, or 233% from $0.1 million for the three months ended June 30, 2020 to $0.4 million for the three months ended June 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 three months ended June 30, 2021 as compared to the three months ended June 30, 2020. Product revenue, classified by the major geographic areas in which our products are shipped, was $42.9 million within the United States and $13.0 million for all other countries in the three months ended June 30, 2021 compared to $5.5 million within the United States and $4.8 million for all other countries in the three months ended June 30, 2020.

Cost of product revenue, gross profit and gross margin percentage

Cost of product revenue increased by $6.3 million, or 177%, from $3.6 million during the three months ended June 30, 2020 to $9.9 million during the three months ended June 30, 2021. The increase was primarily due to growth in sales volume. Gross margin percentage improved to 82.2% for the three months ended June 30, 2021, compared to 65.1% for the three months ended June 30, 2020. This change in gross margin percentage was primarily due to higher average selling price and lower per unit manufacturing costs due to manufacturing volume efficiencies.

Research and development expenses

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

	Three Months Ended June 30,		Change	Change
	2021	2020	$	%
	(in thousands)			
Compensation and personnel-related costs	$ 6,940	$ 4,344	$ 2,596	60%
Clinical-related costs	1,805	2,010	(205)	(10)%
Material and supplies	935	445	490	110%
Facilities and other allocated costs	1,326	743	583	78%
Outside consultants	554	425	129	30%
Other research and development costs	255	134	121	90%
Total research and development expenses	$ 11,815	$ 8,101	$ 3,714	46%

R&D expenses increased by $3.7 million, or 46%, from $8.1 million during the three months ended June 30, 2020 to $11.8 million during the three months ended June 30, 2021. The change was primarily due to a $2.6 million increase in compensation and personnel-related costs due to increase in headcount, a $0.6 million increase in facilities and other allocated costs due to increased rent and building expenditures, a $0.5 million increase in material and supplies, a $0.1 million increase in outside consultant costs, and a $0.1 million increase in other research and development costs. This was partially offset by a $0.2 million decrease in clinical-related costs due to completion of patient enrollment for the majority of clinical trials during the three months ended June 30, 2021.

Sales and marketing expenses

Sales and marketing expenses increased by $14.5 million, or 129%, from $11.2 million during the three months ended June 30, 2020 to $25.7 million during the three months ended June 30, 2021. The change was primarily due to a $10.2 million increase in compensation and personnel-related costs as a result of increased headcount and sales. There was also a $2.0 million increase in marketing and promotional costs to support the commercialization of our products, a $1.3 million increase in travel related costs, a $0.5 million increase in facilities and other allocated costs due to increased rent and building expenditures and a $0.5 million increase in consulting and general corporate costs.

General and administrative expenses

General and administrative expenses increased by $3.2 million, or 60%, from $5.4 million during the three months ended June 30, 2020 to $8.6 million during the three months ended June 30, 2021. The change was primarily due to a $1.9 million increase in compensation and personnel-related costs driven by increased headcount, a $0.9 million increase in consulting, professional and general corporate costs, a $0.2 million increase in recruiting and training costs, a $0.1 million increase in other allocated costs due to increased rent and building expenditures, and a $0.1 million increase in travel related costs.

Comparison of the Six Months Ended June 30, 2021 and 2020

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

	Six Months Ended June 30,			
	2021	2020	Change $	Change %
	(in thousands, except percentages)			
Revenue:				
Product revenue	$ 87,808	$ 25,483	$ 62,325	245%
Cost of revenue:				
Cost of product revenue	17,826	9,243	8,583	93%
Gross profit	69,982	16,240	53,742	331%
Operating expenses:				
Research and development	22,092	19,991	2,101	11%
Sales and marketing	49,705	21,617	28,088	130%
General and administrative	15,852	11,622	4,230	36%
Total operating expenses	87,649	53,230	34,419	65%
Loss from operations	(17,667)	(36,990)	19,323	(52)%
Share in net loss of equity method investment	(5,523)	—	(5,523)	100%
Interest expense	(630)	(583)	(47)	8%
Other income (expense), net	(89)	724	(813)	(112)%
Net loss before taxes	(23,909)	(36,849)	12,940	(35)%
Income tax provision	117	44	73	166%
Net loss	$ (24,026)	$ (36,893)	$ 12,867	(35)%

Product revenue

Product revenue increased by $62.3 million, or 245%, from $25.5 million during the six months ended June 30, 2020 to $87.8 million during the six months ended June 30, 2021.

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

	Six Months Ended June 30,			
	2021	2020	Change $	Change %
	(in thousands, except percentages)			
Peripheral	$ 34,934	$ 15,590	$ 19,344	124%
Coronary	52,010	9,420	42,590	452%
Other	864	473	391	83%
Product revenue	$ 87,808	$ 25,483	$ 62,325	245%

Peripheral product revenue increased by $19.3 million, or 124% from $15.6 million for the six months ended June 30, 2020 to $34.9 million for the six months ended June 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.

Coronary product revenue increased by $42.6 million, or 452% from $9.4 million for the six months ended June 30, 2020 to $52.0 million for the for the six months ended June 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. All coronary product revenue was international for the six months ended June 30, 2020.

Other product revenue increased by $0.4 million, or 83% from $0.5 million for the six months ended June 30, 2020 to $0.9 million for the six months ended June 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 six months ended June 30, 2021 as compared to the six months ended June 30, 2020. Product revenue, classified by the major geographic areas in which our products are shipped, was $64.0 million within the United States and $23.8 million for all other countries in the six

months ended June 30, 2021 compared to $13.3 million within the United States and $12.2 million for all other countries in the six months ended June 30, 2020.

Cost of product revenue and gross margin percentage

Cost of product revenue increased by $8.6 million, or 93% from $9.2 million during the six months ended June 30, 2020 to $17.8 million during the six months ended June 30, 2021. The increase was primarily due to growth in sales volume. Gross margin percentage improved to 79.7% for the six months ended June 30, 2021, compared to 63.7% for the six months ended June 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:

	Six Months Ended June 30,		Change	Change
	2021	2020	$	%
	(in thousands)			
Compensation and personnel-related costs	$ 13,038	$ 8,319	$ 4,719	57%
Clinical-related costs	4,324	6,598	(2,274)	(34)%
Material and supplies	962	1,297	(335)	(26)%
Facilities and other allocated costs	2,358	1,440	918	64%
Outside consultants	1,021	924	97	10%
Other research and development costs	389	1,413	(1,024)	(72)%
Total research and development expenses	$ 22,092	$ 19,991	$ 2,101	11%

R&D expenses increased by $2.1 million, or 11%, from $20.0 million during the six months ended June 30, 2020 to $22.1 million during the six months ended June 30, 2021. The change was primarily due to a $4.7 million increase in compensation and personnel-related costs due to an increase in headcount, a $0.9 million increase in other allocated costs due to increased rent and building expenditures, and a $0.1 million increase in outside consulting costs. This was partially offset by a $2.3 million decrease in clinical-related costs due to completion of patient enrollment for the majority of clinical trials, a $1.0 million decrease in other research and development costs due to software license costs in the prior year, and a $0.3 million decrease in materials and supplies costs.

Sales and marketing expenses

Sales and marketing expenses increased by $28.1 million, or 130%, from $21.6 million during the six months ended June 30, 2020 to $49.7 million during the six months ended June 30, 2021. The change was primarily due to a $21.7 million increase in compensation and personnel-related costs as a result of increased headcount and increased sales. There was also a $2.8 million increase in marketing and promotional expenses to support the commercialization of our products, a $1.5 million increase in travel related costs, a $0.9 million increase in facilities and other allocated costs due to increased rent and building expenditures, a $0.6 million increase in consulting and general corporate expenses, and a $0.6 million increase in materials and supplies costs.

General and administrative expenses

General and administrative expenses increased by $4.2 million, or 36%, from $11.6 million during the six months ended June 30, 2020 to $15.9 million during the six months ended June 30, 2021. The change was primarily due to a $3.6 million increase in compensation and personnel-related costs, a $0.3 million increase in consulting, professional and general corporate costs, a $0.2 million increase in facilities and other allocated costs due to increased rent and building expenditures, and a $0.1 million increase in recruitment and training costs.

Other income (expense), net

Other income (expense), net decreased by $813,000, or 112%, from $724,000 in other income, net during the six months ended June 30, 2020 to $89,000 in other expense, net during the six months ended June 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 $5.5 million for the six months ended June 30, 2021 was due to the Company's 45% ownership in the JV. Refer to Note 10 of the interim condensed consolidated financial statements for further discussion.

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, we expect to continue to incur substantial net losses and negative cash flows from operations for the foreseeable future.

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

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

We believe that our cash, cash equivalents and short-term investments as of June 30, 2021 will be sufficient to fund our operations for at least the next 12 months from the date of this filing. As of June 30, 2021, we had $174.7 million in cash, cash equivalents and short-term investments and an accumulated deficit of $267.7 million.

Cash Flows

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

	Six Months Ended June 30,	
	2021	2020
	(in thousands)	
Cash used in operating activities	$ (15,117)	$ (42,355)
Cash provided by investing activities	54,300	34,028
Cash provided by (used in) financing activities	(5,338)	87,578
Net increase in cash, cash equivalents and restricted cash	$ 33,845	$ 79,251

Operating activities

During the six months ended June 30, 2021, cash used in operating activities was $15.1 million, attributable to a net loss of $24.0 million and a net change in our net operating assets and liabilities of $11.4 million, partially offset by non-cash charges of $20.3 million. Non-cash charges primarily consisted of $11.7 million in stock-based compensation, $5.5 million in share in net loss of equity method investment, $1.6 million in depreciation and amortization, $0.8 million in amortization of right-of-use assets, $0.4 million in accretion of discount on available-for-sale securities, and $0.3 million in amortization of debt issuance costs. The change in our net operating assets and liabilities was primarily due to a $13.3 million increase in accounts receivable, $5.7 million increase in inventory, $1.4 million increase in prepaid expenses and other current assets, a $0.6 million decrease in lease liability. These changes were partially offset by a $8.1 million increase in accrued and other current liabilities, $1.3 million increase in accounts payable, and $0.1 million increase in other assets.

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

Investing activities

During the six months ended June 30, 2021, cash provided by investing activities was $54.3 million, attributable to proceeds from maturities of available-for-sale investments of $88.3 million, partially offset by purchase of available-for-sale investments of $27.2 million and purchase of property and equipment of $6.8 million.

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

Financing activities

During the six months ended June 30, 2021, cash used in financing activities was $5.3 million, attributable to $8.3 million in payment of taxes withheld on net settled vesting of restricted stock units, partially offset by proceeds of $1.9 million from stock option exercises and proceeds of $1.1 million from issuance of shares under our employee stock purchase plan.

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

Contractual Obligations and Commitments

Debt, Principal, and Interest

The Company's debt, principal and interest commitments consist of our debt obligations under the Amended Credit Facility. On June 30, 2021, the Company achieved a milestone specified in the Amended Credit Facility which extended the interest-only payment period by an additional six months to December 31, 2021. As of June 30, 2021, the Company had debt, principal, and interest commitments of $19.0 million.

Manufacturing Purchase Obligations

The Company has engaged a contract manufacturer to produce and supply the Company with certain products. The Company has fixed commitments of approximately $7.2 million over the next fiscal year.

There were no other material changes during the three months ended June 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 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. 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 Shockwave'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.

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 six months ended June 30, 2021, the Company's share in the losses incurred by the equity method investee was nil and $5.5 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 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 the Company satisfies its performance obligation of transferring the license to the customer.

In connection with the formation of the Genesis Shockwave Private Ltd. joint venture on March 19, 2021, the Company received a 45% equity stake in the JV in exchange for the contribution of intellectual property. 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 June 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 recorded a related party contract liability, non-current, 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 June 30, 2021 consisted of $174.7 million in bank deposits, money market funds and available-for-sale securities. Such interest-earning instruments carry a degree of interest rate risk. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents.

As of June 30, 2021, we had $16.5 million of principal amount of variable rate debt outstanding. In February 2020, we refinanced our existing term loan by means of a supplemental term loan in the amount of $16.5 million. The supplemental term loan requires monthly repayments of principal, subject to a contingent deferral if certain milestones are met. On June 30, 2021, the Company achieved a milestone which extended the interest-only payment period by an additional six months to December 31, 2021. The supplemental term loan matures on December 1, 2023 and accrues interest at a floating per annum rate equal to the greater of the Prime Rate minus 1.25% and 3.5%. The interest rate on the term loan was 3.5% as of June 30, 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 six months ended June 30, 2021 and 2020, approximately 16% and 26% 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 $1.1 million and $0.6 million in foreign currency cash and accounts receivable as of June 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 have limited commercial manufacturing experience and may experience development or manufacturing problems or delays in producing our products and planned or future products that could limit the potential growth of our revenue or increase our losses.

We are continuing to develop our expertise in commercially manufacturing our products and our ability to manufacture these products in the volume that we anticipate will be required if we achieve planned levels of commercial sales. The forecasts of demand we use to determine order quantities and lead times for components purchased from outside suppliers may be incorrect. Our failure to obtain required components or sub-assemblies when needed and at a reasonable cost would adversely affect our business. As a result, we may not be able to develop and implement efficient, low-cost manufacturing capabilities and processes that will enable us to manufacture our existing, planned, or future products in significant volumes, while meeting the legal, regulatory, quality, price, durability, engineering, design and production standards required to market our products successfully.

We may encounter unforeseen situations in the manufacturing and assembly of our products that would result in delays or shortfalls in our production. For example, our production processes and assembly methods may have to change in order to accommodate any significant future expansion of our manufacturing capacity, which may increase our manufacturing costs, delay production of our products, reduce our product margin and adversely impact our business. Conversely, if demand for our products shifts such that a manufacturing facility is operated below its capacity for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.

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

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

We 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 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. We rely on single source suppliers for certain components of our products. In some cases, we do not have long-term supply agreements with, or guaranteed commitments from, our component suppliers, including single source suppliers. 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, 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.

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.

We and our suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have an adverse effect on our business, financial condition, and results of operations.

As a medical device manufacturer, we must register with the FDA and non-U.S. regulatory agencies, and we are subject to periodic inspection by the FDA and foreign regulatory agencies, for compliance with certain good manufacturing practices, including design controls, product validation and verification, in process testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA and foreign regulatory agencies. Our product and component suppliers are also required to meet certain standards applicable to their manufacturing processes.

We cannot assure you that we or our product or component suppliers comply or can continue to comply with all regulatory requirements. The failure by us or one of our suppliers to achieve or maintain compliance with these requirements or quality standards may disrupt our ability to supply products sufficient to meet demand until compliance is achieved or, until a new supplier has been identified and evaluated. Our or any product or component supplier's failure to comply with applicable regulations could cause sanctions to be imposed on us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals or clearances, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, which could harm our business. We cannot assure you that if we need to engage new suppliers to satisfy our business requirements, we can locate new suppliers in compliance with regulatory requirements at a reasonable cost and in an acceptable timeframe. Our failure to do so could have a material adverse effect on our business, financial condition, and results of operations.

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

We depend on a third party to manufacture a portion of the demand for certain of our products and we may engage additional third-party manufacturers in the future. If any of these manufacturers fail to meet our requirements and strict regulatory standards, we may be unable to develop, commercialize or market our products.

We depend on one third-party to manufacture a certain portion of the demand for one of our products and we may in the future need to depend upon additional third parties to manufacture our products. Reliance on third-party manufacturers entails risks to which we are not be subject if we manufactured products ourselves, including:

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

Any of these factors could cause delay or suspension of clinical trials, regulatory submissions, required approvals, commercialization or marketing of our products or cause us to incur higher costs. Furthermore, if our contract manufacturers fail to

deliver the required commercial quantities of finished products on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenue. Any difficulties in locating and hiring third-party manufacturers, or in the ability of third-party manufacturers to supply quantities of our products at the times, and in the quantities, we need, could have a material adverse effect on our business. It may take a significant amount of time and resources (including costs) to establish an alternative source of supply for our products and to have any such new source approved by the FDA.

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. The risk factors described in our 2020 Annual Report, as supplemented by the foregoing risk factors 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 and in the 2020 Annual 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†	Amended and Restated Non-Employee Director Compensation Policy	10-Q	001-38829	10.1	May 10, 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 XBRL Taxonomy Extension Presentation Linkbase Document				
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 has been formatted in Inline XBRL and contained in Exhibit 101				

* Filed herewith.

† Indicates management contract or compensatory plan.

SIGNATURES

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

Shockwave Medical, Inc.

Date: August 9, 2021 By: /s/ Douglas Godshall

Douglas Godshall
President and Chief Executive Officer

Date: August 9, 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: August 9, 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: August 9, 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 June 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: August 9, 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 June 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: August 9, 2021

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