UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

OR

o 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 x No o

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 x No o

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	x	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	o
Emerging growth company	o		

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. o

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

As of May 2, 2023, the registrant had 36,626,211 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

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. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- 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 ability to successfully execute our commercialization strategy for our approved or cleared products;
- 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;
- the impact of government laws and 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 ability to scale our organizational culture of cooperative product development and commercial execution;
- the expected benefits of our recent acquisition of Neovasc Inc., a corporation existing under the Canada Business Corporations Act;
- the development, regulatory approval, efficacy and commercialization of competing products;
- our ability to develop and maintain our corporate infrastructure, including our internal controls;
- our estimates regarding expenses, future financial performance and capital requirements;
- 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; and
- the impact of macroeconomic conditions, including inflation, rising interest rates, instability in the global banking system and volatile market conditions, and global events, including the COVID-19 pandemic, on our operations, financial results, liquidity and capital resources, sales, expenses, supply chain, manufacturing, research and development activities, clinical trials and employees.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Quarterly Report on Form 10-Q. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions and other factors that could cause our actual results, level of activity, performance, or achievements to differ materially from the results, level of activity, performance or achievements

expressed or implied by the forward-looking statements, including those described in the section titled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022, together with any updates in the section titled “Risk Factors” in this Quarterly Report on Form 10-Q, and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Quarterly Report on Form 10-Q. 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. Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Except to the extent required by law, we undertake no obligation to update any of these forward-looking statements after the date of this Quarterly Report on Form 10-Q to conform our prior statements to actual results or revised expectations.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	March 31, 2023	December 31, 2022[1]
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 280,932	$ 156,586
Short-term investments	135,929	147,907
Accounts receivable, net	84,309	71,366
Inventory	83,256	75,112
Prepaid expenses and other current assets	6,399	8,292
Total current assets	590,825	459,263
Operating lease right-of-use assets	31,623	32,365
Property and equipment, net	54,057	48,152
Equity method investment	2,689	3,512
Deferred tax assets	97,941	97,568
Other assets	6,112	5,229
TOTAL ASSETS	$ 783,247	$ 646,089
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 11,050	$ 6,721
Debt, current portion	80,000	—
Accrued liabilities	49,640	55,375
Lease liability, current portion	1,308	1,278
Total current liabilities	141,998	63,374
Lease liability, noncurrent portion	34,058	34,928
Debt, noncurrent portion	24,231	24,198
Related party contract liability, noncurrent portion	12,273	12,273
TOTAL LIABILITIES	212,560	134,773
STOCKHOLDERS' EQUITY:		
Preferred stock	—	—
Common stock	37	36
Additional paid-in capital	568,705	548,960
Accumulated other comprehensive loss	(367)	(867)
Retained earnings (accumulated deficit)	2,312	(36,813)
TOTAL STOCKHOLDERS' EQUITY	570,687	511,316
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 783,247	$ 646,089

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

[1] The condensed consolidated balance sheet as of December 31, 2022 is derived from the audited consolidated financial statements as of that date.

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

	Three Months Ended March 31,	
	2023	**2022**
Revenue:		
Product revenue	$ 161,066	$ 93,631
Cost of revenue:		
Cost of product revenue	21,066	12,890
Gross profit	140,000	80,741
Operating expenses:		
Research and development	26,971	17,019
Sales and marketing	54,011	35,961
General and administrative	19,204	12,389
Total operating expenses	100,186	65,369
Income from operations	39,814	15,372
Loss from equity method investment	(823)	(47)
Interest expense	(636)	(297)
Other income (expense), net	2,382	(310)
Net income before taxes	40,737	14,718
Income tax provision	1,612	197
Net income	$ 39,125	$ 14,521
Unrealized gain (loss) on available-for-sale securities	505	(815)
Adjustment for net gain realized and included in other income	(5)	—
Total comprehensive income	$ 39,625	$ 13,706
Net income per share		
Basic	$ 1.07	$ 0.41
Diluted	$ 1.03	$ 0.39
Shares used in computing net income per share		
Basic	36,427,263	35,587,337
Diluted	37,979,448	37,623,477

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 Loss	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount				
Balance — December 31, 2022	36,235,546	$ 36	$ 548,960	$ (867)	$ (36,813)	$ 511,316
Exercise of stock options	77,230	1	319	—	—	320
Unrealized gain on available-for-sale securities, net of tax	—	—	—	505	—	505
Net gain reclassified from accumulated other comprehensive income	—	—	—	(5)	—	(5)
Issuance of common stock under employee stock purchase plan	19,124	—	3,092	—	—	3,092
Issuance of common stock in connection with vesting of restricted stock units	257,624	—	—	—	—	—
Taxes withheld on net settled vesting of restricted stock units	(19)	—	(3)	—	—	(3)
Stock-based compensation	—	—	16,337	—	—	16,337
Net income	—	—	—	—	39,125	39,125
Balance — March 31, 2023	36,589,505	$ 37	$ 568,705	$ (367)	$ 2,312	$ 570,687

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance — December 31, 2021	35,444,472	$ 35	$ 494,806	$ (202)	$ (252,809)	$ 241,830
Exercise of stock options	54,913	1	390	—	—	391
Unrealized loss on available-for-sale securities	—	—	—	(815)	—	(815)
Issuance of common stock under employee stock purchase plan	14,172	—	2,135	—	—	2,135
Issuance of common stock in connection with vesting of restricted stock units	210,835	—	—	—	—	—
Taxes withheld on net settled vesting of restricted stock units	(31)	—	(6)	—	—	(6)
Stock-based compensation	—	—	9,767	—	—	9,767
Net income	—	—	—	—	14,521	14,521
Balance — March 31, 2022	35,724,361	$ 36	$ 507,092	$ (1,017)	$ (238,288)	$ 267,823

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

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

	Three Months Ended March 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 39,125	$ 14,521
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,708	953
Loss from equity method investment	823	47
Stock-based compensation	15,967	9,510
Non-cash lease expense	748	767
Amortization of premium and discount on available-for-sale securities	(718)	210
Loss on write down of fixed assets	11	—
Deferred income taxes	(547)	—
Amortization of debt issuance costs	33	153
Foreign currency remeasurement	(689)	—
Changes in operating assets and liabilities:		
Accounts receivable	(13,004)	(10,407)
Inventory	(7,757)	(10,090)
Prepaid expenses and other current assets	1,896	600
Other assets	(861)	(119)
Accounts payable	4,734	4,911
Accrued and other current liabilities	(6,661)	(9,051)
Lease liabilities	(846)	(68)
Net cash provided by operating activities	33,962	1,937
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of available-for-sale securities	(21,130)	(42,128)
Proceeds from maturities of available-for-sale securities	34,500	18,000
Purchase of property and equipment	(7,188)	(3,286)
Net cash provided by (used in) investing activities	6,182	(27,414)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments of taxes withheld on net settled vesting of restricted stock units	(3)	(6)
Proceeds from stock option exercises	320	391
Proceeds from issuance of common stock under employee stock purchase plan	3,092	2,135
Proceeds from debt financing, net of issuance costs	80,000	—
Net cash provided by financing activities	83,409	2,520
Effect of exchange rate changes on cash and cash equivalents	792	—
Net increase (decrease) in cash, cash equivalents and restricted cash	124,345	(22,957)
Cash, cash equivalents and restricted cash at beginning of period	158,302	90,874
Cash, cash equivalents and restricted cash equivalents at end of period	$ 282,647	$ 67,917
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	$ 424	$ 144
Income tax paid	$ 322	$ 78
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment purchases included in accounts payable and accrued liabilities	$ 6,162	$ 3,159

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 eleven wholly-owned foreign subsidiaries as of March 31, 2023. The unaudited condensed financial statements include the accounts of Shockwave Medical, Inc. and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

As of March 31, 2023, the Company had cash, cash equivalents and short-term investments of $416.9 million, which are available to fund future working capital requirements, investments, acquisitions, or repayments of credit facilities. The Company believes that its cash, cash equivalents, and short-term investments as of March 31, 2023, will be sufficient for the Company to continue as a going concern for at least 12 months from the date the unaudited condensed consolidated financial statements are filed with the Securities and Exchange Commission ("SEC"). The Company's future capital requirements will depend on many factors, including its growth rate, the timing and extent of its spending to support research and development activities, and the timing and cost of establishing additional sales and marketing capabilities and the scope.

Risk and Uncertainties

The Company is subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including inflation, rising interest rates, and instability in the global banking system, geopolitical factors, including the ongoing conflict between Russia and Ukraine and the responses thereto, supply chain disruptions and the remaining effects of the COVID-19 pandemic. The Company is closely monitoring the impact of these factors on all aspects of its business, including the impacts on its customers, patients, employees, suppliers, vendors, business partners and distribution channels.

In particular, while the Company has not experienced material disruptions in its supply chain to date, the Company has been and continues to be impacted by disruptions in the operations of certain of its third-party suppliers, resulting in increased lead-times, higher component costs and lower allocations for the purchase of some components. In certain cases, the Company has incurred higher logistical expenses. The Company is continuing to work closely with its manufacturing partners and suppliers to source key components and maintain appropriate inventory levels to meet customer demand.

The Company's future results of operations and liquidity could be adversely impacted by a variety of factors, including those discussed in the section titled "Risk Factors" of the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 27, 2023 (the "2022 Annual Report"), together with any updates in the section titled "Risk Factors" in this Quarterly Report on Form 10-Q. As of the date of issuance of these condensed consolidated financial statements, the extent to which the current macroeconomic environment and the COVID-19 pandemic may materially impact the Company's financial condition, liquidity, or results of operations remains uncertain.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") and applicable rules and regulations of the SEC regarding interim financial reporting.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's consolidated financial position, results of operations and

cash flows. The results of operations for the three months ended March 31, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2022 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 2022 Annual Report.

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.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated statements of cash flows:

	March 31, 2023	March 31, 2022
	(in thousands)	
Cash and cash equivalents	$ 280,932	$ 66,252
Restricted cash	1,715	1,665
Total cash, cash equivalents, and restricted cash	$ 282,647	$ 67,917

Restricted cash as of March 31, 2023 and December 31, 2022 relates to letters of credit established for real property leases relating to the Company's office buildings, and is recorded as other assets on the condensed consolidated balance sheets.

See Note 12 for a discussion of the Company's subsequent payments related to the acquisition of Neovasc, Inc. and the repayment of the credit drawn on March 16, 2023 under the Credit Agreement.

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 sheets. The Company records its proportionate share of the underlying income or loss which is recognized in earnings or loss from the equity method investment. The Company eliminates a portion of intra-entity profit to the extent the goods sold by the Company have not yet been sold through by the equity method investee to an end customer at the end of the reporting period. The profit earned by the Company from the equity method investee for items not yet sold through is eliminated through equity method earnings or loss which is recognized in income (loss) from equity method investment.

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

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 has 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 generally 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 the Company's functional intellectual property with a customer, the Company considers 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 were recognized for the three months ended March 31, 2023 and 2022.

Stock-Based Compensation

The Company accounts for share-based payments at fair value. The fair value of stock options is measured using the Black-Scholes option-pricing model. For share-based awards that vest subject to the satisfaction of a service requirement, the fair value measurement date for stock-based compensation awards is the date of grant and the expense is recognized on a straight-line basis, over the vesting period. For share-based awards that vest upon the satisfaction of a performance target, the related compensation cost is recognized over the requisite service period based on the expected achievement of the performance target. The Company accounts for forfeitures as they occur.

3. Financial Instruments and Fair Value Measurements

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

	March 31, 2023			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
U.S. Treasury securities	$ 95,282	$ —	$ —	$ 95,282
Money market funds	10,070	—	—	10,070
Commercial paper	—	8,139	—	8,139
Corporate bonds	—	20,688	—	20,688
U.S. agency securities	—	11,820	—	11,820
Total assets	$ 105,352	$ 40,647	$ —	$ 145,999

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
U.S. Treasury securities	$ 111,631	$ —	$ —	$ 111,631
Money market funds	12,076	—	—	12,076
Commercial paper	—	8,039	—	8,039
Corporate bonds	—	18,808	—	18,808
U.S. agency securities	—	9,429	—	9,429
Total assets	$ 123,707	$ 36,276	$ —	$ 159,983

4. Cash Equivalents and Short-Term Investments

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

	March 31, 2023			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury securities	$ 95,784	$ 18	$ (520)	$ 95,282
Money market funds	10,070	—	—	10,070
Commercial paper	8,140	1	(2)	8,139
Corporate bonds	20,685	22	(19)	20,688
U.S. agency securities	11,804	16	—	11,820
Total	$ 146,483	$ 57	$ (541)	$ 145,999
Reported as:				
Cash equivalents				$ 10,070
Short-term investments				135,929
Total				$ 145,999

	December 31, 2022			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury securities	$ 112,719	$ 3	$ (1,091)	$ 111,631
Money market funds	12,076	—	—	12,076
Commercial paper	8,039	—	—	8,039
Corporate bonds	18,876	8	(76)	18,808
U.S. agency securities	9,432	4	(7)	9,429
Total	$ 161,142	$ 15	$ (1,174)	$ 159,983
Reported as:				
Cash equivalents				$ 12,076
Short-term investments				147,907
Total				$ 159,983

There were $76.4 million and $123.8 million of investments in unrealized loss positions of $0.5 million and $1.2 million as of March 31, 2023 and December 31, 2022, respectively. During the three months ended March 31, 2023 and 2022, the Company did not record any other-than-temporary impairment charges on its available-for-sale securities. Based on the Company's procedures under the expected credit loss model, including an assessment of unrealized losses on the portfolio, the Company concluded that the unrealized losses for its marketable securities were not attributable to credit and therefore an allowance for credit losses for these securities has not been recorded as of March 31, 2023 and December 31, 2022. Also, based on the scheduled maturities of the investments, the Company was more likely than not to hold these investments for a period of time sufficient for a recovery of the Company's cost basis.

For the three months ended March 31, 2023 and 2022, the Company recognized $5,000 and nil in realized gains on cash equivalents and short-term investments.

The remaining contractual maturities of the Company's cash equivalents and short-term investments were as follows:

	March 31, 2023
	Fair Value
	(in thousands)
Money market funds	$ 10,070
One year or less	112,680
Greater than one year and less than two years	23,249
Total	$ 145,999

5. Balance Sheet Components

Inventory

Inventory consists of the following:

	March 31, 2023	December 31, 2022
	(in thousands)	
Raw material	$ 21,504	$ 18,456
Work in progress	10,722	7,666
Finished goods	50,737	48,735
Consigned inventory	293	255
Total inventory	$ 83,256	$ 75,112

Accrued Liabilities

Accrued liabilities consist of the following:

	March 31, 2023	December 31, 2022
	(in thousands)	
Employee compensation	$ 22,070	$ 32,885
Asset purchases	6,882	4,600
Research and development costs	4,118	4,007
Professional services	3,862	4,044
Excise, sales, income and other taxes	5,123	4,036
Other	7,585	5,803
Total accrued liabilities	$ 49,640	$ 55,375

6. Debt

On October 19, 2022, the Company entered into a Credit Agreement (the “Credit Agreement”) with Wells Fargo Bank, National Association, as administrative agent, Wells Fargo Bank, National Association, as swingline lender and an issuing lender, Wells Fargo Securities, LLC and Silicon Valley Bank, as joint lead arrangers and joint bookrunners, Silicon Valley Bank, as syndication agent, and the several lenders party thereto. The Credit Agreement provides for a revolving credit facility in an aggregate principal amount of $175 million with the right to request increases to the revolving commitments (subject to certain conditions) of up to the greater of (x) $100 million or (y) the Company’s consolidated EBITDA for the four fiscal quarter period most recently ended prior to the date of such increase.

Concurrent with entering into the Credit Agreement, the Company drew down $25.0 million. On March 16, 2023, the Company drew down an additional $80.0 million under the Credit Agreement. See Note 12 for a discussion of the Company’s subsequent payment of the additional $80.0 million drawn under the Credit Agreement.

The revolving credit facility accrues for interest, at the election of the Company, at (A) the Base Rate (as defined below) plus a margin ranging from 0% to 1% depending on the Company's Consolidated Total Net Leverage Ratio (as defined in the Credit Agreement) (which rate is currently 0%) or (B) the applicable secured overnight financing rate (“SOFR”) plus a margin from 1% to 2%, depending on the Company's Consolidated Total Net Leverage Ratio (which rate is currently 1%). Base Rate means, at any time, the highest of (a) the Wells Fargo Bank, National Association's announced prime rate, (b) the federal funds rate plus 0.5% and (c) Term SOFR for a one-month tenor in effect on such day plus 1%. The Credit Agreement matures on October 19, 2027. The interest rate was 5.6% as of March 31, 2023.

The Company recorded interest expense of $0.6 million and $0.3 million for the three months ended March 31, 2023 and 2022, respectively.

Debt and debt issuance costs are as follows:

	March 31, 2023	December 31, 2022
	(in thousands)	
Principal amount of debt	$ 105,000	$ 25,000
Debt issuance costs	(769)	(802)
Debt	104,231	24,198
Less: debt, current portion	(80,000)	—
Debt, noncurrent portion	$ 24,231	$ 24,198

7. Stock-Based Compensation

Total stock-based compensation was as follows:

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Cost of product revenue	$ 954	$ 653
Research and development	3,795	2,238
Sales and marketing	6,466	3,932
General and administrative	4,752	2,687
Total stock-based compensation	$ 15,967	$ 9,510

Stock-based compensation of $0.4 million and $0.3 million was capitalized into inventory for the three months ended March 31, 2023 and 2022, 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 Company's Board of Directors (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 Company's initial public offering (the “IPO”). As a result, effective as of March 6, 2019, the Company may not grant any additional awards under the 2009 Plan. The 2009 Plan will continue to govern outstanding equity awards granted thereunder. The Company initially reserved 2,000,430 shares of common stock for the issuance of a variety of awards under the 2019 Plan, including stock options, stock appreciation rights, awards of restricted stock and awards of restricted stock units (“RSUs”). 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 Board. As of March 31, 2023, there were 3,765,125 shares available for issuance under the 2019 Plan.

Stock Options

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

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Term	Aggregate Intrinsic Value
			(in years)	(in thousands)
Balance, December 31, 2022	1,122,009	$ 5.87	4.60	$ 224,115
Awards authorized	—			
Options exercised	(77,230)	4.12		
Options cancelled	(6,133)	2.41		
Balance, March 31, 2023	1,038,646	$ 6.02	4.41	$ 218,961
Vested and exercisable, March 31, 2023	1,038,503	$ 6.01	4.41	$ 218,935
Vested and expected to vest, March 31, 2023	1,038,646	$ 6.02	4.41	$ 218,961

Restricted Stock Units

RSUs are share awards that entitle the holder to receive freely tradable shares of the Company's common stock upon vesting. 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. RSUs generally vest over a four-year period with straight-line quarterly vesting with a one year cliff or straight-line annual vesting, provided the employee remains continuously employed with the Company. The fair value of RSUs is equal to the closing price of the Company's common stock on the grant date.

In February 2022 and 2023, the Company granted performance-based restricted stock units ("PRSUs") to certain key executives. The vesting of these PRSUs is dependent on the achievement of certain performance targets related to the Company's compound annual growth rate of revenue over a two or three year performance period, provided the executives remain employed with the Company at the time of vesting. The number of PRSUs that vest will vary from 0% to 200% of the target which will be determined based on the level of performance attained for each performance period. The fair value of these PRSUs is equal to the closing price of the Company's common stock on the grant date. Compensation cost for PRSUs is recognized over the requisite service period based on the expected achievement of performance targets.

RSU and PRSU activity under the 2019 Plan is set forth below. Grant activity for all PRSUs is disclosed at target (100%):

	Restricted Stock Units		Performance-Based Restricted Stock Units	
	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance, December 31, 2022	1,125,991	$ 127.39	38,797	$ 165.74
RSUs granted	293,007	191.06	29,473	191.36
RSUs forfeited	(19,803)	145.72	(175)	278.52
RSUs vested	(257,624)	97.37	—	—
Balance, March 31, 2023	1,141,571	150.18	68,095	176.54

Employee Stock Purchase Plan

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

The fair value of the ESPP shares is estimated using the Black-Scholes option pricing model. The Company recorded $1.3 million and $0.4 million of stock-based compensation expense related to the ESPP for the three months ended March 31, 2023 and 2022, respectively. At March 31, 2023, a total of 1,540,527 shares were available for issuance under the ESPP.

8. Net Income Per Share

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

	Three Months Ended March 31,	
	2023	**2022**
Numerator:		
Net income	$ 39,125	$ 14,521
Denominator:		
Basic:		
Weighted average number of common shares outstanding - basic	36,427,263	35,587,337
Diluted:		
Weighted average number of common shares outstanding - basic	36,427,263	35,587,337
Dilutive effect of outstanding common stock options	1,039,985	1,437,748
Dilutive effect of restricted stock units	510,340	597,817
Dilutive effect of common stock pursuant to employee stock purchase plan	1,860	575
Weighted average number of common shares outstanding - diluted	37,979,448	37,623,477
Net income per share:		
Basic	$ 1.07	$ 0.41
Diluted	$ 1.03	$ 0.39

9. Revenue

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

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Coronary	$ 113,875	$ 70,337
Peripheral	46,130	22,852
Other	1,061	442
Product revenue	$ 161,066	$ 93,631

Coronary product revenue encompasses sales of the Company's C^2 catheter and C^{2+} catheter. Peripheral product revenue encompasses sales of the Company's M^5 catheter, M^{5+} catheter, S^4 IVL catheter, and L^6 IVL catheter. 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 March 31,	
	2023	2022
	(in thousands)	
United States	$ 131,623	$ 78,519
Europe	16,234	12,067
All other countries	13,209	3,045
Product revenue	$ 161,066	$ 93,631

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 the Company's interventional products in the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau (the "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 the 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 the total equity of the JV, to Genesis in exchange for a cash contribution of $15.0 million, of which 50% was due upon signing and the remaining 50% was due within one year of signing, and (ii) 45,000 ordinary shares, which represents 45% of the total equity of the JV, to the Company as consideration for the Shockwave License Agreement (the "License Agreement"). Under the License Agreement, the Company has agreed to contribute to the JV an exclusive license under certain of the Company's intellectual property rights to develop, manufacture, distribute and commercialize certain products in the PRC and is entitled to receive royalties on the sales of the licensed products in the PRC. Further, the Company entered into a Distribution Agreement, pursuant to which the Company has agreed to sell certain Company-manufactured products to the JV or a PRC subsidiary of the JV for commercialization and distribution in the PRC. In May 2022, the JV obtained regulatory approval from the China National Medical Products Administration to sell the Company-manufactured Shockwave IVL System with the Shockwave C^2 catheter, M^5 catheter and S^4 catheter in the PRC.

The Company has accounted for its investment in the JV under the equity method of accounting. As of March 31, 2023, the carrying value of the Company's investment in the JV was $2.7 million and the Company owned a 45% interest in the entity. During the three months ended March 31, 2023, the Company continued to recognize product revenue on sales to the JV and eliminate a portion of intra-entity profit to the extent the goods have not yet either been consumed by the JV for use in clinical trials, or sold by the JV to an end customer at the end of the reporting period. The profit earned by the Company from the JV for items not yet sold through to an end customer is eliminated through equity method earnings or loss which is recognized in income (loss) from equity method investment.

The Company's product revenue for products sold to the JV during the three months ended March 31, 2023 and related accounts receivable from the JV as of March 31, 2023 were immaterial. Intra-entity profit, which was recorded as a reduction to equity method investment as of and for the three months ended March 31, 2023, was also immaterial.

For the three months ended March 31, 2023 and 2022, the Company's loss from the equity method was $0.8 million and $47,000, respectively.

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 that were issued at the formation of the JV.

As of March 31, 2023, the associated manufacturing technology transfer to the JV has not yet been completed. The Company maintains a related party contract liability, noncurrent, of $12.3 million for the outstanding performance obligation. The Company will satisfy the outstanding performance obligation upon the completion of training provided by the Company to the JV, and successful regulatory approval for the JV manufactured product from the China National Medical Products Administration.

11. Income Taxes

On a quarterly basis, the Company provides for income taxes based upon an estimated annual effective income tax rate, adjusted for discrete items. The Company recognized income tax expense of $1.6 million and $0.2 million for the three months ended March 31, 2023 and 2022, respectively, representing an effective tax rate of 3.96% and 1.34%, respectively. The year-over-year increase in tax expense for the three-month period ended March 31, 2023 was primarily due to the valuation allowance on the U.S. federal and other-than-California state deferred tax assets as of March 31, 2022, which was released in the fourth quarter of fiscal year 2022. For the three months ended March 31, 2023, the effective tax rate differed from the U.S. federal statutory rate primarily due to stock-based compensation for tax purposes and research credits. For the three months ended March 31, 2022, the effective tax rate differed from the U.S. federal statutory rate primarily due to the valuation allowance on the U.S. deferred tax assets.

The Company's effective tax rate may be subject to fluctuation due to several factors, including the Company's ability to accurately predict the pre-tax earnings in the various jurisdictions, valuation allowances against deferred tax assets, the recognition or de-recognition of tax benefits related to uncertain tax positions and the effects of tax law changes.

During the fourth quarter of 2022, the Company determined that the positive evidence overcame any negative evidence, primarily due to the Company's transition from a cumulative loss in recent years to cumulative income in 2022 and concluded that it was more likely than not that the U.S. federal and other-than-California state deferred tax assets were realizable. As a result, the Company released the valuation allowance against all of the U.S. federal deferred tax assets and other-than-California state deferred tax assets during the fourth quarter of fiscal year 2022.

12. Subsequent Events

Acquisition of Neovasc, Inc.

On April 11, 2023, the Company completed the previously announced acquisition of Neovasc Inc. ("Neovasc"), a corporation existing under the Canada Business Corporations Act, in accordance with the Arrangement Agreement (the "Arrangement Agreement"). Pursuant to the Arrangement Agreement, the Company acquired all of the issued and outstanding common shares of Neovasc and Neovasc became a wholly owned subsidiary of the Company by means of a

plan of arrangement under the Canada Business Corporations Act. Each common share of Neovasc that was issued and outstanding immediately prior to April 11, 2023 was transferred to the Company in exchange for $27.25 per share in cash and one contingent value right entitling the holder to receive up to $12.00 per share in cash, with such receipt and amount contingent on whether the U.S. Food and Drug Administration grants marketing approval for the device known as the Neovasc Reducer for the treatment of angina within specified timeframes set forth in the Arrangement Agreement

Since the completion of the acquisition, the Company has paid a total of $107.2 million to Neovasc shareholders.

Pay-off of Credit Agreement Draw

On April 26, 2023, the Company repaid the $80.0 million drawn under the Credit Agreement in March 2023.

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, 2022, filed with the SEC on February 27, 2023 *(the "2022 Annual Report"). 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 2022 Annual Report, 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 outcomes for patients with calcified cardiovascular disease. We are currently selling the following products in a number of countries around the world where we have applicable regulatory approvals:

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

- Our Shockwave M^5 IVL catheter ("M^5 catheter") and Shockwave M^{5+} IVL catheter ("M^{5+} catheter") are five-emitter catheters for use in our IVL System in medium-diameter vessels for the treatment of PAD. The M^5 catheter was CE-Marked in April 2018 and cleared by the U.S. Food and Drug Administration ("FDA") in July 2018. The M^{5+} catheter was CE-Marked in November 2020 and cleared by the FDA in April 2021. In May 2022, we obtained regulatory approval, through our joint venture with Genesis MedTech International Private Limited ("Genesis"), from the China National Medical Products Administration ("NMPA") to sell our M^5 catheter in the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau (the "PRC").

- Our Shockwave S^4 IVL catheter ("S^4 catheter") is a four-emitter catheter for use in our IVL System in small-diameter vessels for the treatment of PAD. The S^4 catheter was CE-Marked in April 2018. The second version of our S^4 catheter was cleared by the FDA in August 2019 and accepted by our EU notified body in May 2020 for use in our IVL System. In May 2022, we obtained regulatory approval, through our joint venture with Genesis, from the NMPA to sell our S^4 catheter in the PRC.

- Our Shockwave L^6 IVL catheter ("L^6 catheter") is a six-emitter catheter for use in our IVL System in large diameter vessels for the treatment of PAD. Our L^6 catheter was cleared by the FDA in August 2022 for use in our IVL System. We commenced a U.S. limited market release for our L^6 catheter in the fourth quarter of 2022 followed by a full market release in March 2023.

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

- Our Shockwave C^2 IVL catheter ("C^2 catheter") and Shockwave C^{2+} IVL catheter ("C^{2+} catheter") are two-emitter catheters for use in our IVL System for the treatment of CAD. The C^2 catheter was CE-Marked in June 2018. In August 2019, we received the Breakthrough Device Designation from the FDA for our C^2 catheter using our IVL System for the treatment of CAD. We received FDA approval of our C^2 catheter in February 2021. In March 2022, we received regulatory approval in Japan for our C^2 catheter and commenced a limited market release in Japan in May 2022, followed by a full market release in January 2023. In May 2022, we obtained regulatory

approval, through our joint venture with Genesis, from the NMPA to sell our C^2 catheter in the PRC. The C^{2+} catheter was CE-Marked in August 2022 and approved by the FDA in December 2022. In the fourth quarter of 2022, we commenced a limited market release for our C^{2+} catheter in select international locations, followed by a full market release in those locations in March 2023.

Our differentiated range of IVL catheters enables delivery of IVL therapy to diseased vasculature throughout the body for calcium modification. Our IVL catheters resemble in form a standard balloon angioplasty catheter, the device most commonly used by interventionalists. This familiarity makes our IVL System easy to learn, adopt and use on a day-to-day basis.

Since inception, we have focused on generating clinical data to demonstrate the safety and effectiveness of our IVL Technology. These studies have consistently shown low rates of complications regardless of which vessel was being studied. In addition to supporting our regulatory approvals or clearances, the data from our clinical studies strengthen our ability to drive adoption of our IVL Technology across multiple therapies in existing and new market segments. Our studies have also guided optimal IVL procedure technique and informed the design of our IVL System and future products in development. In addition, we have ongoing clinical programs across several products and indications, which, if successful, could allow us to expand commercialization of our products into new geographies and indications.

The first two indications that our IVL System addresses 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 cardiac valvular disease, a condition where the heart's valves become increasingly calcified with age, causing them to narrow and obstruct blood flow from the heart.

We have adapted the use of lithotripsy, which has been used to successfully treat kidney stones (deposits of hardened calcium) for over 30 years, to the cardiovascular field with the aim of creating what we believe is the safest, most effective means of addressing the growing challenge of cardiovascular calcification. 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 both deep wall and thick calcium, not just at the thin, superficial most intimal layer. The shockwaves crack this calcium and enable the narrowed artery to expand at low pressures, thereby minimizing complications inherent to traditional balloon dilations, such as dissections or perforations. Preparing the vessel with IVL facilitates optimal outcomes with other adjacent therapies, including stents and drug-eluting technologies. Using IVL also avoids complications associated with atherectomy devices such as dissection, perforation, and embolism.

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, Switzerland, France, Ireland, Japan and the United Kingdom and are working to build out our direct sales teams in Spain, Portugal and Canada. We have complemented our direct sales capabilities with distributors actively selling our products in over 55 countries in North and South America, Europe, the Middle East, Asia, Africa, and Australia/New Zealand. We are continuing to add new U.S. sales territories and are actively expanding our international field presence through new distributors, as well as additional sales and clinical personnel and expanded direct sales territories.

For the three months ended March 31, 2023 and 2022, we generated product revenue of $161.1 million and $93.6 million, respectively, and income from operations of $39.8 million and $15.4 million, respectively. For the three months ended March 31, 2023 and 2022, 18% and 16%, respectively, of our product revenue was generated from customers located outside of the United States.

Although we had net income for the year ended December 31, 2022 and the three months ended March 31, 2023, we may incur net losses in the future which may vary significantly from period to period. We expect to continue to incur significant expenses as we (i) expand our marketing efforts to increase adoption of our products, (ii) expand existing relationships with our customers, (iii) obtain regulatory clearances or approvals for our planned or future products, (iv) conduct clinical trials on our existing and planned or future products, and (v) develop new products or add new features to our existing products. We will need to continue to generate significant revenue in order to sustain profitability as we continue to grow our business. Even if we achieve profitability for any period, we cannot be sure that we will remain profitable for any substantial period of time.

To date, our principal sources of liquidity have been the net proceeds we received through the private sales of our equity securities, payments received from customers purchasing our products and proceeds from our debt financings. For the three months ended March 31, 2023, we generated positive cash flows from operations of $34.0 million. As of March 31, 2023, we had $416.9 million in cash, cash equivalents and short-term investments and retained earnings of $2.3 million.

Impact of current global economic conditions

Uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including inflation and rising interest rates, geopolitical factors, including the ongoing conflict between Russia and Ukraine and the responses thereto, supply chain disruptions and the remaining effects of the COVID-19 pandemic. We are closely monitoring the impact of these factors on all aspects of our business, including the impacts on our customers, patients, employees, suppliers, vendors, business partners and distribution channels.

In particular, while we have not experienced material disruptions in our supply chain to date, we have been and continue to be impacted by disruptions in the operations of certain of our third-party suppliers, resulting in increased lead-times, higher component costs and lower allocations for our purchase of some components. In certain cases, we have incurred higher logistical expenses. We are continuing to work closely with our manufacturing partners and suppliers to source key components and maintain appropriate inventory levels to meet customer demand.

The ultimate extent of the impact of global economic conditions on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. Most of these developments and factors are outside of our control and could exist for an extended period of time. As a result, we are subject to continuing risks and uncertainties and continue to closely monitor the impact of the current conditions on our business. For more information regarding these risks and uncertainties, see the section titled “Risk Factors” in our 2022 Annual Report, together with any updates in the section titled “Risk Factors” in this Quarterly Report on Form 10-Q.

Components of Our Results of Operations

Product revenue

Product revenue is primarily from the sale of our IVL catheters.

We sell our products to hospitals, primarily through direct sales representatives, as well as through distributors in selected international markets. For products sold through direct sales representatives, control is transferred upon delivery to customers. For products sold to distributors internationally and products sold to customers that utilize stocking orders, control is transferred upon shipment or delivery to the customer’s named location, based on the contractual shipping terms. Additionally, a portion of our revenue is generated through a consignment model under which inventory is maintained at hospitals. For consignment inventory, control is transferred at the time the catheters are consumed in a procedure.

Cost of product revenue

Cost of product revenue consists primarily of the costs of the components for use in our products, the materials and labor that are used to produce our products, the manufacturing overhead that directly supports production and the depreciation relating to the equipment used in our IVL System to the extent that we loan generators to our hospital customers, without charge to facilitate the use of our IVL catheters in their procedures. We depreciate the equipment over a three-year period. We expect costs 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 marginally 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 expenses consist of applicable personnel, consulting, materials, and clinical trial expenses. Research and development expenses include, but are not limited to:

- 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 research and development 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.

Research and development costs are expensed as incurred. In the future, we expect research and development 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 Securities and Exchange Commission (“SEC”) compliance and investor relations.

Loss from equity method investment

Loss from equity method investment, represents our proportionate share of the underlying income or loss incurred in connection with our joint venture with Genesis. Also included in loss from equity method investment is the portion of intra-entity profit which is eliminated to the extent the goods have not yet either been consumed by the JV for use in clinical trials, or sold through by the JV to an end customer at the end of the reporting period.

Interest expense

Interest expense consists of the interest and amortization expense related to our debt.

Other income (expense), net

Other income (expense), net consists of interest earned on our cash equivalents and short-term investments and the net impact of foreign exchange gains and losses.

Income tax provision

Income tax provision consists of income taxes from the U.S. and foreign jurisdictions.

Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

The following table shows our results of operations for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,		Change	Change
	2023	2022	$	%
	(in thousands, except percentages)			
Revenue:				
Product revenue	$ 161,066	$ 93,631	$ 67,435	72%
Cost of revenue:				
Cost of product revenue	21,066	12,890	8,176	63%
Gross profit	140,000	80,741	59,259	73%
Operating expenses:				
Research and development	26,971	17,019	9,952	58%
Sales and marketing	54,011	35,961	18,050	50%
General and administrative	19,204	12,389	6,815	55%
Total operating expenses	100,186	65,369	34,817	53%
Income from operations	39,814	15,372	24,442	159%
Loss from equity method investment	(823)	(47)	(776)	1,651%
Interest expense	(636)	(297)	(339)	114%
Other income (expense), net	2,382	(310)	2,692	(868)%
Net income before taxes	40,737	14,718	26,019	177%
Income tax provision	1,612	197	1,415	718%
Net income	$ 39,125	$ 14,521	$ 24,604	169%

Product revenue

Product revenue increased by $67.4 million, or 72%, from $93.6 million during the three months ended March 31, 2022 to $161.1 million during the three months ended March 31, 2023.

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

	Three Months Ended March 31,		Change	Change
	2023	2022	$	%
	(in thousands, except percentages)			
Coronary	$ 113,875	$ 70,337	$ 43,538	62%
Peripheral	46,130	22,852	23,278	102%
Other	1,061	442	619	140%
Product revenue	$ 161,066	$ 93,631	$ 67,435	72%

Coronary product revenue increased by $43.5 million, or 62%, from $70.3 million for the three months ended March 31, 2022 to $113.9 million for the three months ended March 31, 2023. The increase in coronary product revenue was due an increase in the purchase volume of our C^2 catheters in the United States and increased adoption of our products internationally.

Peripheral product revenue increased by $23.3 million, or 102%, from $22.9 million for the three months ended March 31, 2022 to $46.1 million for the three months ended March 31, 2023 which was due to an increase in the purchase volume of our M^{5+} catheter, S^4 catheter, and L^6 catheter within the United States and internationally driven by increased adoption of our products.

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 March 31, 2023 as compared to the three months ended March 31, 2022. Product revenue, classified by the major geographic areas in which our products are shipped, was $131.6 million, or 82%, within the United States and $29.4 million, or 18%, for all other countries in the three months ended March 31, 2023 compared to $78.5 million, or 84%, within the United States and $15.1 million, or 16%, for all other countries in three months ended March 31, 2022.

Cost of product revenue, gross profit and gross margin percentage

Cost of product revenue increased by $8.2 million, or 63%, from $12.9 million during the three months ended March 31, 2022 to $21.1 million during the three months ended March 31, 2023. The increase was driven by higher product sales volume compared to the prior year. Gross margin percentage improved to 87% for the three months ended March 31, 2023, compared to 86% for the three months ended March 31, 2022. This change in gross margin percentage was primarily due to a higher average selling price and lower fixed costs per unit from increased sales volume of our IVL catheters and efficiencies from improvements to productivity and process efficiencies.

Research and development expenses

The following table summarizes our research and development expenses incurred during the periods presented:

	Three Months Ended March 31,		Change	Change
	2023	2022	$	%
	(in thousands)			
Compensation and personnel-related costs	$ 14,748	$ 10,534	$ 4,214	40%
Facilities and other allocated costs	5,320	2,023	3,297	163%
Materials and supplies	2,505	1,055	1,450	137%
Clinical-related costs	2,579	1,906	673	35%
Outside consultants	1,283	1,028	255	25%
Other research and development costs	536	473	63	13%
Total research and development expenses	$ 26,971	$ 17,019	$ 9,952	58%

Research and development expenses increased by $10.0 million, or 58%, from $17.0 million during the three months ended March 31, 2022 to $27.0 million during the three months ended March 31, 2023. The change was primarily due to a $4.2 million increase in compensation and personnel-related costs due to an increase in headcount, a $3.3 million increase in facilities and other allocated costs due to increased information technology, rent and building expenditures, a $1.4 million increase in materials and supplies, an increase in clinical-related costs of $0.7 million, a $0.3 million increase in outside consultants, and a $0.1 million increase in other research and development costs.

Sales and marketing expenses

Sales and marketing expenses increased by $18.0 million, or 50%, from $36.0 million during the three months ended March 31, 2022 to $54.0 million during the three months ended March 31, 2023. The change was primarily due to a $10.8 million increase in compensation and personnel-related costs, resulting from increased headcount and commissions driven by increased sales of our products. There was also a $3.9 million increase in travel related costs, a $1.3 million increase in marketing and promotional costs, a $1.0 million increase in facilities and other allocated costs, a $0.4 million increase in professional and consulting services, a $0.3 million increase in materials and supplies, a $0.2 million increase in general corporate costs, and a $0.1 million increase in recruiting and training fees.

General and administrative expenses

General and administrative expenses increased by $6.8 million, or 55%, from $12.4 million during the three months ended March 31, 2022 to $19.2 million during the three months ended March 31, 2023. The change was primarily due to a $3.4 million increase in compensation and personnel-related costs, a $2.1 million increase in professional services and consulting costs, a $0.8 million increase in general corporate costs, a $0.3 million increase in facilities and other allocated costs due to increased information technology, rent and building expenditures, and a $0.2 million increase in travel related costs.

Loss from equity method investment

The increase in loss from equity method investment of $0.8 million for the three months ended March 31, 2023 was due to increased sales by the JV to end customers following the NMPA approval of products in the PRC, and the elimination of intra-entity profit for goods sold by us to the JV that have not yet been sold through by the JV to an end customer at the end of the reporting period.

Interest expense

Interest expense increased by $0.3 million, or 114%, from $0.3 million during the three months ended March 31, 2022 to $0.6 million during the three months ended March 31, 2023. The increase in interest expense was related to the additional draw of $80 million under the Credit Agreement in March 2023.

Other income (expense), net

Other income (expense), net increased by $2.7 million, or 868%, from $0.3 million in other expense, net during the three months ended March 31, 2022 to $2.4 million in other income, net during the three months ended March 31, 2023. The increase in other income was primarily due to an increase in interest income from increased interest rates, partially offset by an increase in foreign exchange losses.

Income tax provision

Income tax provision of $1.6 million for the three months ended March 31, 2023 primarily consisted of U.S. federal, state, and foreign income taxes. The income tax expense for the three months ended March 31, 2023 reflected the impact of a change in U.S. tax law, effective January 1, 2022, which requires the capitalization and amortization of research and experimental expenditures incurred after December 31, 2022. Income tax provision of $0.2 million for the three months ended March 31, 2022 primarily consisted of foreign income taxes.

Liquidity and Capital Resources

To date, our principal sources of liquidity have been the net proceeds of $280.0 million that we received through the sale of our common stock in our public offerings, $10.0 million from private sales of our equity securities, payments received from customers using our products and proceeds from our debt financings.

On October 19, 2022, we entered into the Credit Agreement with Wells Fargo Bank, National Association, as administrative agent, Wells Fargo Bank, National Association, as swingline lender and an issuing lender, Wells Fargo Securities, LLC and Silicon Valley Bank, as joint lead arrangers and joint bookrunners, Silicon Valley Bank, as syndication agent, and the several lenders party thereto (the “Credit Agreement”). The Credit Agreement provides for a revolving credit facility in an aggregate principal amount of $175 million with the right to request increases to the revolving commitments (subject to certain conditions) of up to the greater of (x) $100 million or (y) our consolidated EBITDA for the four fiscal quarter period most recently ended prior to the date of such increase.

Concurrent with entering into a Credit Agreement, we drew down $25.0 million and prepaid in full all outstanding amounts and related expenses under the previous Credit Agreement with Silicon Valley Bank, totaling $14.6 million, and terminated the credit facility thereunder. We drew down an additional $80.0 million under the Credit Agreement during the three months ended March 31, 2023. On April 26, 2023, we repaid the $80.0 million drawn under the Credit Agreement in March 2023.

Since the completion of the acquisition, we have paid a total of $107.2 million to Neovasc shareholders.

We have a number of ongoing clinical trials and expect to continue to make substantial investments in these trials as well as additional clinical trials designed to provide clinical evidence of the safety and efficacy of our existing 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 research and development, regulatory affairs, and clinical studies to develop future generations of products based on our IVL Technology, support regulatory submissions, and demonstrate the clinical efficacy of our products. Moreover, we expect to continue to incur expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance, investor relations and other expenses. Because of these and other factors, although we had net income and generated cash flows from operations for the three months ended March 31, 2023 and for the year ended December 31, 2022, we may incur net losses and have negative cash flows from operations in the future.

As of March 31, 2023, we had $416.9 million in cash, cash equivalents and short-term investments and retained earnings of $2.3 million.

In the short term, we believe that our cash, cash equivalents and short-term investments will be sufficient for at least the next 12 months to meet our requirements and plans for cash, including supporting working capital, capital expenditure requirements, investments, acquisitions or repayments of credit facilities. In the long term, our ability to support our working capital and capital expenditure requirements will depend on many factors, including:

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost of our research and development activities for new and modified products;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish including any contract manufacturing arrangements;
- the timing, receipt and amount of sales from our current and potential products;
- the degree of success we experience in commercializing our products;
- the emergence of competing or complementary technologies;
- macroeconomic conditions, including a potential recession, inflation, rising interest rates and instability in the global banking system;
- 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.

To the extent that current and anticipated future sources of liquidity are insufficient to fund our future business activities and cash and other requirements, we may be required to seek additional equity or debt financing. The sale of additional equity would result in additional dilution to our stockholders. The incurrence of additional debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. In the event that additional financing is required from outside sources, there is a possibility we may not be able to raise it on terms acceptable to us or at all. Further, the current macroeconomic environment may make it difficult for us to raise capital on terms favorable to us or at all. If we are unable to raise additional capital when desired, our business, operating results, and financial condition could be adversely affected.

Our material cash requirements include the following contractual and other obligations:

Debt, Principal, and Interest

As of March 31, 2023, our debt, principal and interest commitments consist of our debt obligations under the Credit Agreement.

As discussed above, on October 19, 2022, we entered into the Credit Agreement, which provides for a revolving credit facility in an aggregate principal amount of $175 million with the right to request increases to the revolving commitments (subject to certain conditions) of up to the greater of (x) $100 million or (y) our consolidated EBITDA for the four fiscal quarter period most recently ended prior to the date of such increase.

Concurrent with entering into the Credit Agreement, we drew down $25.0 million. We drew down an additional $80.0 million under the Credit Agreement during the three months ended March 31, 2023.

The Credit Agreement is secured by all of our assets, excluding intellectual property and certain other assets. The Credit Agreement is subject to customary affirmative and restrictive covenants, including with respect to our ability to enter into fundamental transactions, incur additional indebtedness, grant liens, and pay any dividend or make any distributions to stockholders.

As of March 31, 2023, we had $104.2 million of outstanding principal, net of unamortized debt issuance costs which matures in October 2027. On April 26, 2023, we repaid the $80.0 million drawn under the Credit Agreement in March 2023.

Manufacturing Purchase Obligations

We have engaged a contract manufacturer to produce and supply us with certain products. We have fixed commitments of approximately $14.7 million within the next twelve months.

Operating Leases

Our operating lease commitments mostly consist of our lease obligations for our Santa Clara headquarter office spaces, as well as for laboratory and manufacturing space. Our total operating lease commitments as of March 31, 2023 are approximately $51.3 million, of which $5.3 million is expected to be paid within the next twelve months.

There were no other material changes during the three months ended March 31, 2023 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 2022 Annual Report.

We did not have during the periods presented, and we do not currently have, any commitments or obligations, including contingent obligations, arising from arrangements with unconsolidated entities or persons that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, cash requirements or capital resources.

Cash Flows

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

	Three Months Ended March 31,	
	2023	2022
Net cash provided by (used in):	(in thousands)	
Operating activities	$ 33,962	$ 1,937
Investing activities	6,182	(27,414)
Financing activities	83,409	2,520
Effect of exchange rate changes on cash and cash equivalents	792	—
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 124,345	$ (22,957)

Operating activities

During the three months ended March 31, 2023, cash provided by operating activities was $34.0 million, attributable to a net income of $39.1 million, and non-cash charges of $17.4 million, partially offset by a net change in our net operating assets and liabilities of $22.5 million. Non-cash charges of $17.4 million primarily consisted of $16.0 million in stock-based compensation, $1.7 million in depreciation and amortization, and $0.7 million in non-cash lease expense. The change in our net operating assets and liabilities of $22.5 million was primarily due to a $13.0 million increase in accounts receivable due to an increase in sales, a $7.8 million increase in inventory driven by an increase in raw materials and finished goods inventory, and a $6.7 million decrease in accrued and other current liabilities from payment of accrued bonuses and other compensation in the current quarter,

During the three months ended March 31, 2022, cash provided by operating activities was $1.9 million, attributable to a net income of $14.5 million and non-cash charges of $11.6 million, partially offset by a net change in our net operating assets and liabilities of $24.2 million. Non-cash charges of $11.6 million primarily consisted of $9.5 million in stock-based compensation, $1.0 million in depreciation and amortization, and $0.8 million in non-cash lease expense. The change in our net operating assets and liabilities of $24.2 million was primarily due to a $10.4 million increase in accounts receivable due to an increase in sales, a $10.1 million increase in inventory driven by an increase in raw materials and finished goods inventory, and a $9.1 million decrease in accrued and other current liabilities resulting from payment of accrued bonuses and other compensation in the three months ended March 31, 2022. These changes were partially offset by a $4.9 million increase in accounts payable due to the timing of vendor billings.

Investing activities

During the three months ended March 31, 2023, cash provided by investing activities was $6.2 million, attributable to proceeds from maturities of available-for-sale investments of $34.5 million, partially offset by purchases of available-for-sale investments of $21.1 million and purchases of property and equipment of $7.2 million.

During the three months ended March 31, 2022, cash used in investing activities was $27.4 million, attributable to purchases of available-for-sale investments of $42.1 million and purchases of property and equipment of $3.3 million, partially offset by proceeds from maturities of available-for-sale investments of $18.0 million.

Financing activities

During the three months ended March 31, 2023, cash provided by financing activities was $83.4 million, attributable to proceeds of $80.0 million from debt financing, net of issuance costs, $3.1 million from the issuance of shares under our employee stock purchase plan, and proceeds of $0.3 million from stock option exercises.

During the three months ended March 31, 2022, cash provided by financing activities was $2.5 million, attributable to proceeds of $2.1 million from the issuance of shares under our employee stock purchase plan and proceeds of $0.4 million from stock option exercises.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these condensed 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.

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 2022 Annual Report in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There have been no material changes to our quantitative and qualitative disclosures about market risk as compared to the quantitative and qualitative disclosures about market risk described in our 2022 Annual Report.

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.

A petition for inter partes review ("IPR") of U.S. Pat. No. 8,956,371 (the "'371 patent"), which is one of our issued U.S. patents that relates to our current IVL technology, was filed in December 2018 at the U.S. Patent and Trademark Office's (the "USPTO") Patent Trial and Appeal Board (the "PTAB") by Cardiovascular Systems, Inc. ("CSI"), one of our competitors. The PTAB instituted IPR proceedings for this patent and held oral hearings in April 2020. On July 8, 2020, the PTAB ruled that one claim ("Claim 5") in the '371 patent is valid and ruled that all other claims in the '371 patent are invalid. On August 27, 2020, further briefing by the parties was requested by the PTAB in the '371 patent proceeding to assess whether recent guidance from the USPTO relating to "applicant admitted prior art" impacted the PTAB's decision in the '371 patent proceeding. In addition, the PTAB reset the time for commencement of an appeal in the '371 patent proceeding pending the entry of a final decision after the requested briefing. The requested briefing is complete and the PTAB's decision is pending. On March 9, 2022, the PTAB issued an order authorizing us to file a motion for additional discovery. On March 23, 2022, we filed a motion for additional discovery, relating to additional information publicized by CSI after the PTAB's decision on the patents. On February 2, 2023, the PTAB denied the motion for additional discovery and issued a final decision, ruling again that Claim 5 is valid and that all other claims are invalid. We will be pursuing an appeal of this ruling. Accordingly, Claim 5 and all other claims remain valid and enforceable until all appeals have been exhausted. Upon the conclusion of such appeals, if we are unsuccessful in whole or in part, the '371 patent proceedings could result in the loss or narrowing in scope of the '371 patent, which could further 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 2022 Annual Report, titled "Risk Factors—Risks Related to Our Intellectual Property."

From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business. We have received, and may from time to time receive, letters from third parties alleging patent infringement, violation of employment practices or trademark infringement, and we may in the future participate in litigation to defend ourselves. We cannot predict the results of any such disputes, and despite the potential outcomes, the existence thereof may have an adverse material impact on us due to diversion of management time and attention as well as the financial costs related to resolving such disputes.

Item 1A. Risk Factors.

The following risk factor supplements and, to the extent inconsistent, supersedes, the risk factors disclosed in Part I, Item 1A. "Risk Factors" of our 2022 Annual Report. The risk factor included herein as well as the risk factors described in our 2022 Annual Report, and 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 or in the 2022 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.

Unfavorable global economic conditions could adversely affect our business, financial condition, or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets. If the conditions in the general economy deteriorate, including as a result of changes in gross domestic product growth, recent volatility and disruptions in the capital and credit markets, rising interest rates, increasing effects of inflation, the COVID-19 pandemic and the responses thereto, the ongoing conflict between Russia and Ukraine and the responses thereto, global supply-chain disruptions or the tightening of the global labor market, or otherwise, our business, financial condition, and operating results could be adversely affected. Moreover, there has been recent turmoil in the global banking system. For example, on March 10, 2023, Silicon Valley Bank, which was one of four lenders under the Credit Agreement, was closed by the California Department of Financial Protection & Innovation and the Federal Deposit Insurance Corporation (the "FDIC") was named receiver for Silicon Valley Bank. At the time of closing on March 10, 2023, we had cash, cash equivalents and short-term and long-term investments at Silicon Valley Bank or under Silicon Valley Bank management. While the majority of these assets were not restricted by the FDIC action to take control of Silicon Valley Bank as most of these assets resided in a custodial account with a third-party bank for which Silicon Valley Bank acted as advisor and the FDIC has taken steps to make whole all depositors of Silicon Valley Bank, there is no

assurance that similar guarantees will be made in the event of further bank closures and continued instability in the global banking system. Our ongoing cash management strategy is to maintain diversity in our deposit accounts across financial institutions, but deposits in these institutions may exceed the amount of insurance provided on such deposits and there can be no assurance that this strategy will be successful. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, then our ability to access our cash, cash equivalents and short-term and long-term investments may be threatened, which could have a material adverse effect on our business and financial condition. Moreover, events such as the closure of Silicon Valley Bank, in addition to other global macroeconomic conditions, may cause further turbulence and uncertainty in the capital markets. A severe or prolonged economic downturn, could result in a variety of risks to our business, including driving hospitals to tighten budgets and curtail spending, which would negatively impact our sales and business. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in their purchases and also in our receivable collections, and additional allowances may be required, which could adversely affect our business, financial condition and results of operations. Adverse worldwide economic conditions may also adversely impact our suppliers' ability to provide us with materials and components, which could have a material adverse effect on our business, financial condition, and results of operations.

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
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*#	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*#	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline Taxonomy Extension Presentation Linkbase Document				
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 has been formatted in Inline XBRL and contained in Exhibit 101				

* Filed herewith.

\# This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

SIGNATURES

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

Shockwave Medical, Inc.

Date: May 8, 2023 By: /s/ Douglas Godshall

Douglas Godshall
President, Chief Executive Officer and Director
(principal executive officer)

Date: May 8, 2023 By: /s/ Trinh Phung

Trinh Phung
Vice President of Finance
(principal accounting officer)

Exhibit 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

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 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 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: May 8, 2023

By: /s/ Douglas Godshall

Douglas Godshall

President, Chief Executive Officer and Director
(*Principal Executive Officer*)

Exhibit 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

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 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 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: May 8, 2023

By: /s/ Daniel K. Puckett

Daniel K. Puckett

Chief Financial Officer
(*Principal Financial Officer*)

Exhibit 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

In connection with the Quarterly Report of Shockwave Medical, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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, as amended; and

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

Date: May 8, 2023

By: /s/ Douglas Godshall

Douglas Godshall

President, Chief Executive Officer and Director
(*Principal Executive Officer*)

Exhibit 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

In connection with the Quarterly Report of Shockwave Medical, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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, as amended; and

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

Date: May 8, 2023

By: /s/ Daniel K. Puckett

Daniel K. Puckett

Chief Financial Officer
(*Principal Financial Officer*)