

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended **June 30, 2022**

OR

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

For the transition period from _____ to _____

Commission File Number: **001-38829**

Shockwave Medical, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

27-0494101

(I.R.S. Employer
Identification No.)

**5403 Betsy Ross Drive
Santa Clara, California**

(Address of principal executive offices)

95054

(Zip Code)

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

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

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

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

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

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

As of August 2, 2022, the registrant had 35,927,128 shares of common stock, \$0.001 par value per share, outstanding.

Table of Contents

	Page
PART I.	
	FINANCIAL INFORMATION
Item 1.	Financial Statements (Unaudited)
	Condensed Consolidated Balance Sheets
	Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
	Condensed Consolidated Statements of Stockholders' Equity
	Condensed Consolidated Statements of Cash Flows
	Notes to Unaudited Condensed Consolidated Financial Statements
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations
Item 3.	Quantitative and Qualitative Disclosures About Market Risk
Item 4.	Controls and Procedures
PART II.	OTHER INFORMATION
Item 1.	Legal Proceedings
Item 1A.	Risk Factors
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds
Item 3.	Defaults Upon Senior Securities
Item 4.	Mine Safety Disclosures
Item 5.	Other Information
Item 6.	Exhibits
Signatures	35

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:

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

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 sections titled “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2021, together with any updates in the section entitled “Risk Factors” in this Quarterly Report on Form 10-Q, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”. 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)

	June 30, 2022	December 31, 2021 ¹
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 99,913	\$ 89,209
Short-term investments	124,993	111,772
Accounts receivable, net	59,797	37,435
Inventory	60,028	42,978
Prepaid expenses and other current assets	7,275	4,508
Total current assets	352,006	285,902
Operating lease right-of-use assets	26,045	27,496
Property and equipment, net	32,253	24,361
Equity method investment	4,476	5,987
Other assets	2,365	1,936
TOTAL ASSETS	\$ 417,145	\$ 345,682
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 5,266	\$ 3,520
Term notes, current portion	11,000	5,500
Accrued liabilities	47,253	40,870
Lease liability, current portion	2,688	1,738
Total current liabilities	66,207	51,628
Lease liability, noncurrent portion	27,157	28,321
Term notes, noncurrent portion	6,440	11,630
Related party contract liability, noncurrent portion	12,273	12,273
TOTAL LIABILITIES	112,077	103,852
STOCKHOLDERS' EQUITY:		
Preferred stock	—	—
Common stock	36	35
Additional paid-in capital	519,096	494,806
Accumulated other comprehensive loss	(1,337)	(202)
Accumulated deficit	(212,727)	(252,809)
TOTAL STOCKHOLDERS' EQUITY	305,068	241,830
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 417,145	\$ 345,682

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

¹ The condensed consolidated balance sheet as of December 31, 2021 is derived from the audited consolidated financial statements as of that date.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Product revenue	\$ 120,746	\$ 55,908	\$ 214,377	\$ 87,808
Cost of revenue:				
Cost of product revenue	16,730	9,934	29,620	17,826
Gross profit	104,016	45,974	184,757	69,982
Operating expenses:				
Research and development	20,760	11,815	37,779	22,092
Sales and marketing	40,515	25,713	76,476	49,705
General and administrative	13,165	8,626	25,554	15,852
Total operating expenses	74,440	46,154	139,809	87,649
Income (loss) from operations	29,576	(180)	44,948	(17,667)
Loss from equity method investment	(1,464)	—	(1,511)	(5,523)
Interest expense	(304)	(318)	(601)	(630)
Other income (expense), net	(1,473)	146	(1,783)	(89)
Net income (loss) before taxes	26,335	(352)	41,053	(23,909)
Income tax provision	774	73	971	117
Net income (loss)	\$ 25,561	\$ (425)	\$ 40,082	\$ (24,026)
Unrealized gain (loss) on available-for-sale securities	(320)	(6)	(1,135)	1
Total comprehensive income (loss)	\$ 25,241	\$ (431)	\$ 38,947	\$ (24,025)
Net income (loss) per share				
Basic	\$ 0.71	\$ (0.01)	\$ 1.12	\$ (0.69)
Diluted	\$ 0.68	\$ (0.01)	\$ 1.06	\$ (0.69)
Shares used in computing net income (loss) per share				
Basic	35,825,947	35,030,036	35,707,301	34,914,361
Diluted	37,690,094	35,030,036	37,690,320	34,914,361

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	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
Exercise of stock options	111,601	\$ —	\$ 500	\$ —	\$ —	\$ 500
Unrealized loss on available-for-sale securities	—	—	—	(320)	—	(320)
Issuance of common stock in connection with vesting of restricted stock units	71,491	—	—	—	—	—
Stock-based compensation	—	—	11,504	—	—	11,504
Net income	—	—	—	—	25,561	25,561
Balance — June 30, 2022	35,907,453	\$ 36	\$ 519,096	\$ (1,337)	\$ (212,727)	\$ 305,068

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

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

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

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

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

	Six Months Ended June 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	\$ 40,082	\$ (24,026)
Adjustments to reconcile net income (loss) to net cash provided (used) in operating activities:		
Depreciation and amortization	2,060	1,597
Loss from equity method investment	1,511	5,523
Stock-based compensation	20,515	11,662
Non-cash lease expense	1,537	791
Accretion of discount on available-for-sale securities	354	397
Amortization of debt issuance costs	310	339
Foreign currency remeasurement	1,540	—
Changes in operating assets and liabilities:		
Accounts receivable	(22,477)	(13,266)
Inventory	(16,222)	(5,676)
Prepaid expenses and other current assets	(2,774)	(1,383)
Other assets	(430)	126
Accounts payable	1,160	1,270
Accrued and other current liabilities	3,942	8,107
Lease liabilities	(300)	(578)
Net cash provided by (used in) operating activities	<u>30,808</u>	<u>(15,117)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of available-for-sale securities	(52,633)	(27,243)
Proceeds from maturities of available-for-sale securities	37,923	88,300
Purchase of property and equipment	(6,888)	(6,757)
Net cash (used in) provided by investing activities	<u>(21,598)</u>	<u>54,300</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments of taxes withheld on net settled vesting of restricted stock units	(6)	(8,337)
Proceeds from stock option exercises	891	1,858
Proceeds from issuance of common stock under employee stock purchase plan	2,135	1,141
Net cash provided by (used in) financing activities	<u>3,020</u>	<u>(5,338)</u>
Effect of exchange rate changes on cash and cash equivalents	(1,526)	—
Net increase in cash, cash equivalents and restricted cash	10,704	33,845
Cash, cash equivalents and restricted cash at beginning of period	90,874	51,873
Cash, cash equivalents and restricted cash equivalents at end of period	<u>\$ 101,578</u>	<u>\$ 85,718</u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	\$ 292	\$ 292
Income tax paid	\$ 382	\$ 17
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment purchases included in accounts payable and accrued liabilities	\$ 5,059	\$ 2,613
Equity method investment obtained in exchange for related party contract liability	\$ —	\$ 12,273

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

Notes to Condensed Consolidated Financial Statements

1. Organization and Basis of Presentation

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

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

As of June 30, 2022, the Company had cash, cash equivalents and short-term investments of \$224.9 million, which are available to fund future working capital requirements. The Company believes that its cash and cash equivalents as of June 30, 2022, will be sufficient for the Company to continue as a going concern for at least 12 months from the date the unaudited condensed consolidated financial statements are filed with the Securities and Exchange Commission (“SEC”). The Company’s future capital requirements will depend on many factors, including its growth rate, the timing and extent of its spending to support research and development activities, the timing and cost of establishing additional sales and marketing capabilities and the scope, duration and continuing impact of the COVID-19 pandemic.

Risk and Uncertainties

The Company is subject to continuing risks and uncertainties as a result of the COVID-19 pandemic, and is closely monitoring the impact of the pandemic on all aspects of its business, including the impacts on its customers, patients, employees, suppliers, vendors, business partners and distribution channels. Specifically, the Company has recently seen some disruptions in the operations of certain of its third-party suppliers, resulting in increased lead-times, higher component costs and lower allocations for the Company’s purchase of some components. In certain cases, this has resulted in the Company being required to procure materials from alternate suppliers or incur higher logistical expenses. The Company is continuing to work closely with its manufacturing partners and suppliers to enable the Company to source key components and maintain appropriate inventory levels to meet customer demand. The Company, however, has not experienced material disruptions in its supply chain to date. The Company’s future results of operations and liquidity could be adversely impacted by a variety of factors related to the COVID-19 pandemic, including those discussed in the section entitled “Risk Factors” of the Company’s Annual Report on Form 10-K for the year ended December 31, 2021. As of the date of issuance of these condensed consolidated financial statements, the extent to which the COVID-19 pandemic may materially impact the Company’s financial condition, liquidity, or results of operations remains uncertain.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company’s consolidated financial position, results of operations and cash flows. The results of operations for the three and six months ended June 30, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2021 included herein was derived from the audited financial statements as of that date. The unaudited condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and related notes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 25, 2022.

SHOCKWAVE MEDICAL, INC.
Notes to Condensed Consolidated Financial Statements

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 balance sheets that sum to the total of the same amounts shown in the condensed consolidated statements of cash flows:

	June 30, 2022	December 31, 2021
	(in thousands)	
Cash and cash equivalents	\$ 99,913	\$ 89,209
Restricted cash	1,665	1,665
Total cash, cash equivalents, and restricted cash	\$ 101,578	\$ 90,874

Restricted cash as of June 30, 2022 and December 31, 2021 relates to a letter of credit established for the Company's office leases and is recorded as other assets on the condensed consolidated balance sheets.

Equity Method Investments

Entities which the Company has significant influence over activities of the entity, but does not control, are accounted for under the equity method of accounting in accordance with Topic 323, *Investments - Equity Method and Joint Ventures*. The Company's carrying value in the equity method investment is reported as equity method investment on the Company's consolidated balance sheet. The Company records its proportionate share of the underlying income or loss which is recognized in earnings or loss from 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 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.

SHOCKWAVE MEDICAL, INC.

Notes to Condensed Consolidated Financial Statements

For products sold through direct sales representatives, control is transferred upon delivery to customers. For products sold to distributors internationally and products sold to customers that utilize stocking orders, control is transferred upon shipment or delivery to the customer’s named location, based on the contractual shipping terms. For consignment inventory, control is transferred at the time the IVL catheters are consumed in a procedure. The Company elected to account for shipping and handling activities that occur after the customer has obtained control as a fulfillment activity, and not a separate performance obligation.

The Company may provide for the use of an IVL generator and connector cable under an agreement to customers at no charge to facilitate use of the IVL catheters. These agreements do not contain contractually enforceable minimum commitments and are generally cancellable by either party with 30 days notice.

License Revenue

For arrangements that contain a license of 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 and six months ended June 30, 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.

Internal-Use Software

The Company has internal-use software consisting of cloud-based hosting arrangements with service contracts. The Company capitalizes certain costs incurred to implement such software within prepaid expenses and other current assets, or within other assets. Eligible costs of internal use software and implementation costs of certain hosting arrangements are capitalized. Once the software is ready for its intended use, the Company starts amortizing the capitalized implementation costs on a straight-line basis over the estimated service term or associated hosting arrangement, as applicable.

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:

	June 30, 2022			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
U.S. Treasury securities	\$ 94,047	\$ —	\$ —	\$ 94,047
Money market funds	33,431	—	—	33,431
Commercial paper	—	13,492	—	13,492
Corporate bonds	—	17,454	—	17,454
Total assets	\$ 127,478	\$ 30,946	\$ —	\$ 158,424

SHOCKWAVE MEDICAL, INC.

Notes to Condensed Consolidated Financial Statements

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
U.S. Treasury securities	\$ 80,155	\$ —	\$ —	\$ 80,155
Money market funds	47,541	—	—	47,541
Commercial paper	—	20,472	—	20,472
Corporate bonds	—	11,145	—	11,145
Total assets	\$ 127,696	\$ 31,617	\$ —	\$ 159,313

4. Cash Equivalents and Short-Term Investments

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

	June 30, 2022			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury securities	\$ 95,284	\$ —	\$ (1,237)	\$ 94,047
Money market funds	33,431	—	—	33,431
Commercial paper	13,492	—	—	13,492
Corporate bonds	17,554	—	(100)	17,454
Total	\$ 159,761	\$ —	\$ (1,337)	\$ 158,424
Reported as:				
Cash equivalents				\$ 33,431
Short-term investments				124,993
Total				\$ 158,424

	December 31, 2021			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury securities	\$ 80,353	\$ —	\$ (198)	\$ 80,155
Money market funds	47,541	—	—	47,541
Commercial paper	20,472	—	—	20,472
Corporate bonds	11,149	—	(4)	11,145
Total	\$ 159,515	\$ —	\$ (202)	\$ 159,313
Reported as:				
Cash equivalents				\$ 47,541
Short-term investments				111,772
Total				\$ 159,313

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

SHOCKWAVE MEDICAL, INC.
Notes to Condensed Consolidated Financial Statements

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

	June 30, 2022
	Fair Value
	(in thousands)
Money market funds	\$ 33,431
One year or less	\$ 97,847
Greater than one year and less than two years	27,146
Total	\$ 158,424

5. Balance Sheet Components

Inventory

Inventory consists of the following:

	June 30, 2022	December 31, 2021
	(in thousands)	
Raw material	\$ 15,705	\$ 7,685
Work in progress	9,446	13,315
Finished goods	33,891	20,326
Consigned inventory	986	1,652
Total inventory	\$ 60,028	\$ 42,978

Accrued Liabilities

Accrued liabilities consist of the following:

	June 30, 2022	December 31, 2021
	(in thousands)	
Employee compensation	\$ 25,104	\$ 25,749
Research and development costs	4,501	4,605
Asset purchases	7,738	4,101
Professional services	2,853	2,636
Excise, sales, income and other taxes	3,210	1,232
Other	3,847	2,547
Total accrued liabilities	\$ 47,253	\$ 40,870

6. Commitments and Contingencies

Operating Leases

The Company's operating leases consist of leased facilities for the Company's headquarter offices, as well as for laboratory and manufacturing space. Also included in operating leases are leases for vehicles, for use by certain employees of the Company, which were not material for the periods presented.

SHOCKWAVE MEDICAL, INC.
Notes to Condensed Consolidated Financial Statements

The weighted average remaining lease term and discount rate used to measure the Company's operating lease liabilities were 9.5 years and 5.0%, respectively. The Company estimated the discount rate using the incremental borrowing rate as the rate implicit in the lease was not readily determinable.

Short-term leases are leases having a term of 12 months or less. The Company recognizes short-term leases on a straight-line basis and does not record a related lease asset or liability for such leases. As of June 30, 2022, the Company has no material finance leases. Operating lease cost was \$1.2 million and \$0.6 million, for the three months ended June 30, 2022 and 2021, respectively. Operating lease cost was \$2.4 million and \$1.1 million, for the six months ended June 30, 2022 and 2021, respectively

The following are minimum future rental payments owed under these agreements which have commenced as of June 30, 2022:

Years ending December 31,	(in thousands)
2022 (remainder)	\$ 2,000
2023	4,194
2024	4,289
2025	4,415
2026	4,545
Thereafter	24,664
Total minimum lease payments	\$ 44,107
Less: imputed interest and adjustments	(14,262)
Total lease liability	\$ 29,845

The total minimum future rental payments due for the 5403 Betsy Ross facility under the First Amendment to Office Lease (Net) entered into in September 2021, which have not yet commenced as of June 30, 2022, are \$10.8 million.

7. Term Notes

Loan and Security Agreement

In February 2020, the Company entered into a First Amendment to its Loan and Security Agreement with Silicon Valley Bank (the "Amended Credit Agreement") to, among other things, refinance its existing term loan, which is accounted for as a modification of the Loan and Security Agreement. The Amended Credit Agreement provides the Company with a supplemental term loan in the amount of \$16.5 million. The principal amount outstanding under the supplemental term loan accrues interest at a floating per annum rate equal to the greater of (i) the Prime Rate minus 1.25% and (ii) 3.5%. The interest rate was 3.5% as of June 30, 2022.

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

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

SHOCKWAVE MEDICAL, INC.
Notes to Condensed Consolidated Financial Statements

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

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

	June 30, 2022	December 31, 2021
	(in thousands)	
Principal amount of term note	\$ 16,500	\$ 16,500
Net premium associated with accretion of final payment, and other debt issuance costs	940	630
Term note, current and noncurrent	17,440	17,130
Less term note, current portion	(11,000)	(5,500)
Term note, noncurrent portion	<u>\$ 6,440</u>	<u>\$ 11,630</u>

8. Stock-Based Compensation

Total stock-based compensation was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands)		(in thousands)	
Cost of product revenue	\$ 518	\$ 317	\$ 1,171	\$ 455
Research and development	2,476	1,490	4,714	2,657
Sales and marketing	4,408	2,585	8,340	4,642
General and administrative	3,603	2,131	6,290	3,908
Total stock-based compensation	<u>\$ 11,005</u>	<u>\$ 6,523</u>	<u>\$ 20,515</u>	<u>\$ 11,662</u>

Stock-based compensation of \$0.5 million and \$0.1 million was capitalized into inventory for the three months ended June 30, 2022 and June 30, 2021, respectively. Stock-based compensation of \$0.8 million and \$0.4 million was capitalized into inventory for the six months ended June 30, 2022 and June 30, 2021, 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 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 June 30, 2022, there were 4,809,697 shares available for issuance under the 2019 Plan.

SHOCKWAVE MEDICAL, INC.
Notes to Condensed Consolidated Financial Statements

Stock Options

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

	Shares Available for Grant	Number of Shares	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance, December 31, 2021	3,745,216	1,524,985	\$ 6.01	5.76	\$ 262,793
Awards authorized	1,063,334	—			
Options exercised	—	(166,514)	5.35		
Options cancelled	1,147	(1,147)	10.17		
Balance, June 30, 2022	<u>4,809,697</u>	<u>1,357,324</u>	\$ 6.08	5.24	\$ 251,224
Vested and exercisable, June 30, 2022		<u>1,267,566</u>	\$ 5.62	5.15	\$ 235,197
Vested and expected to vest, June 30, 2022		<u>1,357,324</u>	\$ 6.08	5.24	\$ 251,224

Restricted Stock Units

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

In February 2022, 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, 2021	1,156,683	\$ 93.27	—	\$ —
RSUs granted	296,531	160.71	35,105	155.03
RSUs forfeited	(50,695)	127.27	—	—
RSUs vested	(282,326)	80.41	—	—
Balance, June 30, 2022	<u>1,120,193</u>	<u>112.83</u>	<u>35,105</u>	<u>155.03</u>

SHOCKWAVE MEDICAL, INC.
Notes to Condensed Consolidated Financial Statements

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 \$0.4 million and \$0.3 million of stock-based compensation expense related to the ESPP for the three months ended June 30, 2022 and 2021, respectively. The Company recorded \$0.8 million and \$0.6 million of stock-based compensation expense related to the ESPP for the six months ended June 30, 2022 and 2021, respectively. At June 30, 2022, a total of 1,212,769 shares were available for issuance under the ESPP.

9. Net Income (Loss) Per Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Numerator:				
Net income (loss)	\$ 25,561	\$ (425)	\$ 40,082	\$ (24,026)
Denominator:				
Basic:				
Weighted average number of common shares outstanding - basic	35,825,947	35,030,036	35,707,301	34,914,361
Diluted:				
Weighted average number of common shares outstanding - basic	35,825,947	35,030,036	35,707,301	34,914,361
Dilutive effect of outstanding common stock options	1,353,081	—	1,395,427	—
Dilutive effect of restricted stock units	511,046	—	587,097	—
Dilutive effect of common stock pursuant to employee stock purchase plan	20	—	495	—
Weighted average number of common shares outstanding - diluted	37,690,094	35,030,036	37,690,320	34,914,361
Net income (loss) per share:				
Basic	\$ 0.71	\$ (0.01)	\$ 1.12	\$ (0.69)
Diluted	\$ 0.68	\$ (0.01)	\$ 1.06	\$ (0.69)

SHOCKWAVE MEDICAL, INC.

Notes to Condensed Consolidated Financial Statements

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Common stock options issued and outstanding	—	1,765,933	—	1,765,933
Restricted stock units	56,283	1,137,189	67,452	1,137,189
Employee stock purchase plan	11,970	11,760	8,391	11,760
Total	68,253	2,914,882	75,843	2,914,882

10. Revenue

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands)		(in thousands)	
Coronary	\$ 87,828	\$ 36,702	\$ 158,165	\$ 52,010
Peripheral	31,886	18,793	54,738	34,934
Other	1,032	413	1,474	864
Product revenue	\$ 120,746	\$ 55,908	\$ 214,377	\$ 87,808

Coronary product revenue encompasses sales of the Company's C² catheters. Peripheral product revenue encompasses sales of the Company's M⁵, M⁵⁺ and S⁴ IVL catheters. Other product revenue encompasses sales of the Company's generators and related accessories.

The following table represents the Company's product revenue based on the location to which the product is shipped:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands)		(in thousands)	
United States	\$ 100,096	\$ 42,913	\$ 178,615	\$ 63,958
Europe	13,394	10,420	25,461	18,642
All other countries	7,256	2,575	10,301	5,208
Product revenue	\$ 120,746	\$ 55,908	\$ 214,377	\$ 87,808

11. Equity Method Investments

Genesis Shockwave Private Limited

On March 19, 2021, the Company entered into the Joint Venture Deed (or "JV Agreement") with Genesis MedTech International Private Limited ("Genesis") to establish a long-term strategic partnership to develop, manufacture and commercialize certain of the Company's interventional products in the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau (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.

SHOCKWAVE MEDICAL, INC.

Notes to Condensed Consolidated Financial Statements

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 paid upon signing and the remaining 50% was due within one year of signing, and (ii) 45,000 ordinary shares, which represents 45% of total equity, to the Company as consideration for the Shockwave License Agreement (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 Shockwave C², M⁵ and S⁴ IVL catheters in the PRC.

The Company has accounted for its investment in the JV under the equity method of accounting. As of June 30, 2022, the carrying value of the Company's investment in the JV was \$4.5 million and the Company owned a 45% interest in the entity. The Company recognizes product revenue on sales to the JV in the current period and eliminates 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 share in net loss of equity method investment.

For the three months ended June 30, 2022 and 2021, the Company recognized product revenue of \$3.0 million and nil, respectively, for products sold to the JV. For the six months ended June 30, 2022 and 2021, the Company recognized product revenue of \$3.0 million and nil, for products sold to the JV.

As of June 30, 2022, the Company eliminated \$0.7 million of intra-entity profit which was recorded as a reduction to equity method investment. There was no intra-entity profit deferral as of December 31, 2021. Accounts receivable from the JV was \$3.0 million and \$0.1 million as of June 30, 2022 and December 31, 2021, respectively.

For the three months ended June 30, 2022 and 2021, the Company's share in the losses incurred by the equity method investment was \$1.5 million and nil, respectively. For the six months ended June 30, 2022 and 2021, the Company's share in the losses incurred by the equity method investment was \$1.5 million and \$5.5 million, respectively. Included in the loss from equity for the three and six months ended June 30, 2022 is the intra-entity profit elimination of \$0.7 million.

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 June 30, 2022, 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.

12. 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 \$774,000 and \$73,000 for the three months ended June 30, 2022 and 2021, respectively. The Company recognized income tax expense of \$971,000 and \$117,000 for the six months ended June 30, 2022 and 2021, respectively. The income tax expense for the three and six

SHOCKWAVE MEDICAL, INC.
Notes to Condensed Consolidated Financial Statements

months ended June 30, 2022, reflects 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, 2021.

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.

While the Company has reported U.S. pre-tax income for the second quarter 2022, the Company has not yet been able to establish sufficient significant positive evidence to conclude that its U.S. deferred tax assets are more likely than not to be realized. Therefore, the Company continues to maintain a valuation allowance against all of its U.S. deferred tax assets. Once the Company establishes a sustained level of profitability and projects continued profitability, the Company may reverse a significant portion of its valuation allowance recorded against U.S. deferred tax assets, resulting in an income tax benefit.

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, 2021. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many important factors, including those set forth under “Special Note Regarding Forward-Looking Statements,” in the “Risk Factors” section of this Quarterly Report on Form 10-Q and in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2021, our actual results could differ materially from the results described in, or implied, by those forward-looking statements.

Overview

We are a medical device company focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. We aim to establish a new standard of care for medical device treatment of atherosclerotic cardiovascular disease through our differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which we refer to as intravascular lithotripsy (“IVL”). Our IVL system (our “IVL System”), which leverages our IVL technology (our “IVL Technology”), is a minimally invasive, easy-to-use, and safe way to significantly improve patient outcomes. We are currently selling the following products in a number of countries around the world where we have applicable regulatory approvals:

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

- Our Shockwave M⁵ IVL catheter (the “M⁵ catheter”) and M⁵⁺ IVL catheter (“M⁵⁺ catheter”) are five-emitter catheters for use in our IVL System in “medium” vessels for the treatment of above-the-knee PAD. The M⁵ catheter was CE-Marked in April 2018 and cleared by the U.S. Food and Drug Administration (“FDA”) in July 2018. The M⁵⁺ 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 M⁵ catheter in the People’s Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau (the “PRC”).
- Our Shockwave S⁴ IVL catheter (“S⁴ catheter”) is a four-emitter catheter for use in our IVL System in small vessels for the treatment of below-the-knee PAD. The second version of our S⁴ 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 S⁴ catheter in the PRC.

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

- Our Shockwave C² IVL catheter (“C² catheter”) is a two-emitter catheter for use in our IVL System for the treatment of CAD. The C² catheter was CE-Marked in June 2018. In August 2019, we received the Breakthrough Device Designation from the FDA for our C² catheters using our IVL System for the treatment of CAD. In August 2020, we submitted an application to the FDA for U.S. pre-market approval of our C² catheters, which was approved by the FDA in February 2021. In March 2021, we submitted DISRUPT CAD III and DISRUPT CAD IV data to support our Shonin submission in Japan for our C² Catheters and received approval in March 2022. In May 2022, we obtained regulatory approval, through our joint venture with Genesis, from the NMPA to sell our C² catheter in the PRC.

Our differentiated range of M⁵ and M⁵⁺ catheters, S⁴ catheters and C² catheters enables delivery of IVL therapy of 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 initial studies have consistently shown low rates of complications regardless of which vessel was being studied. In addition to gaining regulatory approvals or clearances, the data from our clinical studies strengthen our ability to drive adoption of IVL Technology across multiple therapies in existing and new market segments. Our past studies have

also guided optimal IVL procedure technique and informed the design of our IVL System and future products in development. In addition, we also have ongoing clinical programs across several products and indications, which, if successful, will allow us to expand commercialization of our products into new geographies and indications.

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

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

We market our products to hospitals whose interventional cardiologists, vascular surgeons, and interventional radiologists treat patients with PAD and CAD. We have dedicated meaningful resources to establish a direct sales capability in the United States, Germany, Austria, Switzerland, France, Ireland, and the United Kingdom, and we are working to build out our direct sales team in Japan in anticipation of the launch of our C² catheters, for which we received Japanese regulatory approval in March 2022. We have complemented our direct sales capability with distributors actively selling our products in over 50 countries in North and South America, Europe, the Middle East, Asia, Africa, and Australia/New Zealand. We are actively expanding our international field presence through new distributors, as well as additional sales and clinical personnel. In addition, we are continuing to add new U.S. sales territories.

For the three months ended June 30, 2022 and 2021, we generated product revenue of \$120.7 million and \$55.9 million, respectively, and income from operations of \$29.6 million and a loss from operations of \$0.2 million, respectively. For the three months ended June 30, 2022 and 2021, 17% and 23%, respectively, of our product revenue was generated from customers located outside of the United States.

For the six months ended June 30, 2022 and 2021, we generated product revenue of \$214.4 million and \$87.8 million, respectively, and income from operations of \$44.9 million and a loss from operations of \$17.7 million, respectively. For the six months ended June 30, 2022 and 2021, 17% and 27%, respectively, of our product revenue was generated from customers located outside of the United States.

Since inception, we have incurred significant net losses. Although we had positive net income for the quarter ended June 30, 2022, we had a net loss for the year ended December 31, 2021. We may continue to incur losses in the future, which may vary significantly from period to period. We expect to continue to incur significant expenses as we (i) expand our marketing efforts to increase adoption of our products, (ii) expand existing relationships with our customers, (iii) obtain regulatory clearances or approvals for our planned or future products, (iv) conduct clinical trials on our existing and planned or future products, and (v) develop new products or add new features to our existing products. We will need to continue to generate significant revenue in order to sustain profitability as we continue to grow our business. Even if we achieve profitability for any period, we cannot be sure that we will remain profitable for any substantial period of time.

To date, our principal sources of liquidity have been the net proceeds we received through the sale of our common stock in our public offerings, private sales of equity securities and payments received from customers using our products. As of June 30, 2022, we had \$224.9 million in cash, cash equivalents and short-term investments and an accumulated deficit of \$212.7 million.

Impact of the COVID-19 pandemic

The global COVID-19 pandemic presents significant risks to us and has had, and continues to have, impacts on our business, operations, and financial results and condition, directly and indirectly. Access to many hospitals and other customer sites may be or may periodically be, depending on the current COVID-19 infection rates in the applicable location, restricted to essential personnel, which negatively impacts our ability to promote the use of our products with physicians. Additionally, many hospitals and other therapeutic centers have in the past suspended, and may suspend or continue to suspend in the future, many elective procedures, resulting in a reduced volume of procedures using our products. Our customer behavior is impacted by the prevalence of COVID-19 and changes in the infection rates in the locations where our customers are located.

Quarantines, shelter-in-place and similar government orders have also impacted and may continue to impact, our third-party manufacturers and suppliers, and could in turn adversely impact the availability or cost of materials. We have recently seen some disruptions in the operations of certain of our third-party suppliers, resulting in increased lead-times, higher component costs and lower allocations for our purchase of some components. In certain cases, this has resulted in us being required to procure materials from alternate suppliers or incur higher logistical expenses. We are continuing to work closely with our manufacturing partners and suppliers to enable us to source key components and maintain appropriate inventory levels to meet customer demand. We, however, have not experienced material disruptions in our supply chain to date.

We have taken a variety of steps to address the impact of the COVID-19 pandemic, while attempting to minimize business disruption. In response to the COVID-19 pandemic, during 2020 and 2021 we limited access to our Santa Clara headquarters only to essential staff in manufacturing and limited support functions following appropriate hygiene and social distancing protocols. In the second quarter of 2021, certain other employees began to return to our headquarters, although we continue to review the impact of COVID-19 on employee safety. We continue to limit non-essential travel to protect the health and safety of our employees and customers.

We are continuing to monitor the impact of the COVID-19 pandemic on our employees and customers and on the markets in which we operate, and will take further actions that we consider prudent to address the COVID-19 pandemic, while ensuring that we can support our customers and continue to develop our products. The ultimate extent of the impact of the COVID-19 pandemic on us remains highly uncertain and will depend on future developments and factors that continue to evolve, including the ability of various regions to effectively manage COVID-19, the extent of the continuing resurgence of COVID-19, the efficacy and extent of distribution of vaccines, and the impact of mutations of COVID-19, and the ability of various economies and supply-chains to recover from the COVID-19 pandemic. Most of these developments and factors are outside of our control and could exist for an extended period of time even after the pandemic might end.

Components of Our Results of Operations

Product revenue

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

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

Cost of product revenue

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

Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, the cost of direct materials, product mix, geographic mix, discounting practices, manufacturing costs, product yields,

headcount and 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 (“R&D”) expenses consist of applicable personnel, consulting, materials, and clinical trial expenses. R&D 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 R&D and clinical activities;
- allocated overhead including facilities and information technology expenses; and
- cost of outside consultants who assist with technology development, regulatory affairs, clinical affairs and quality assurance.

R&D costs are expensed as incurred. In the future, we expect R&D expenses to increase in absolute dollars as we continue to develop new products, enhance existing products and technologies, and perform activities related to obtaining additional regulatory approvals.

Sales and marketing expenses

Sales and marketing expenses consist of personnel-related expenses, including salaries, benefits, sales commissions, travel, and stock-based compensation. Other sales and marketing expenses consist of marketing and promotional activities, including trade shows and market research. We expect to continue to grow our sales force and increase marketing efforts as we continue commercializing products based on our IVL Technology. As a result, we expect sales and marketing expenses to increase in absolute dollars over the long term.

General and administrative expenses

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

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 MedTech International Private Limited (“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 outstanding term loan, which matures in December 2023.

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.

Results of Operations

Comparison of the Three Months Ended June 30, 2022 and 2021

The following table shows our results of operations for the three months ended June 30, 2022 and 2021:

	Three Months Ended June 30,		Change \$	Change %
	2022	2021		
(in thousands, except percentages)				
Revenue:				
Product revenue	\$ 120,746	\$ 55,908	\$ 64,838	116%
Cost of revenue:				
Cost of product revenue	16,730	9,934	6,796	68%
Gross profit	104,016	45,974	58,042	126%
Operating expenses:				
Research and development	20,760	11,815	8,945	76%
Sales and marketing	40,515	25,713	14,802	58%
General and administrative	13,165	8,626	4,539	53%
Total operating expenses	74,440	46,154	28,286	61%
Income (loss) from operations	29,576	(180)	29,756	*
Loss from equity method investment	(1,464)	—	1,464	100%
Interest expense	(304)	(318)	(14)	(4)%
Other income (expense), net	(1,473)	146	(1,619)	*
Net income (loss) before taxes	26,335	(352)	26,687	*
Income tax provision	774	73	701	960%
Net income (loss)	\$ 25,561	\$ (425)	\$ 25,986	*

* Not meaningful.

Product revenue

Product revenue increased by \$64.8 million, or 116%, from \$55.9 million during the three months ended June 30, 2021 to \$120.7 million during the three months ended June 30, 2022.

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

	Three Months Ended June 30,		Change \$	Change %
	2022	2021		
(in thousands, except percentages)				
Coronary	\$ 87,828	\$ 36,702	\$ 51,126	139%
Peripheral	31,886	18,793	13,093	70%
Other	1,032	413	619	150%
Product revenue	\$ 120,746	\$ 55,908	\$ 64,838	116%

Coronary product revenue increased by \$51.1 million, or 139%, from \$36.7 million for the three months ended June 30, 2021 to \$87.8 million for the three months ended June 30, 2022. In February 2021, we received FDA approval for

our C² catheters. The increase in coronary product revenue was primarily due to the commencement of sales of our C² catheters in the United States, increased adoption of our products internationally, and continued recovery from the impact of the COVID-19 pandemic in the prior year.

Peripheral product revenue increased by \$13.1 million, or 70%, from \$18.8 million for the three months ended June 30, 2021 to \$31.9 million for the three months ended June 30, 2022. The change was due to an increase in purchase volume of our M⁵, M⁵⁺ and S⁴ IVL catheters within the United States and internationally driven by increased adoption of our products and recovery from the impact of the COVID-19 pandemic in the prior year.

We sold to a greater number of customers in the United States and to a greater number of distributors internationally for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021. Product revenue, classified by the major geographic areas in which our products are shipped, was \$100.1 million within the United States and \$20.7 million for all other countries in the three months ended June 30, 2022 compared to \$42.9 million within the United States and \$13.0 million for all other countries in three months ended June 30, 2021.

Cost of product revenue, gross profit and gross margin percentage

Cost of product revenue increased by \$6.8 million, or 68%, from \$9.9 million during the three months ended June 30, 2021 to \$16.7 million during the three months ended June 30, 2022. Gross margin percentage improved to 86% for the three months ended June 30, 2022, compared to 82% for the three months ended June 30, 2021. 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 operations and production.

Research and development expenses

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

	Three Months Ended June 30,		Change \$	Change %
	2022	2021		
	(in thousands)			
Compensation and personnel-related costs	\$ 11,659	\$ 6,940	\$ 4,719	68%
Materials and supplies	2,859	935	1,924	206%
Clinical-related costs	2,796	1,805	991	55%
Facilities and other allocated costs	2,277	1,326	951	72%
Outside consultants	752	554	198	36%
Other research and development costs	417	255	162	64%
Total research and development expenses	\$ 20,760	\$ 11,815	\$ 8,945	76%

R&D expenses increased by \$8.9 million, or 76%, from \$11.8 million during the three months ended June 30, 2021 to \$20.8 million during the three months ended June 30, 2022. The change was primarily due to a \$4.7 million increase in compensation and personnel-related costs due to an increase in headcount, a \$1.9 million increase in materials and supplies, an increase in clinical-related costs of \$1.0 million, a \$1.0 million increase in facilities and other allocated costs due to increased information technology, rent and building expenditures, a \$0.2 million increase in outside consultants, and a \$0.2 million increase in other R&D costs.

Sales and marketing expenses

Sales and marketing expenses increased by \$14.8 million, or 58%, from \$25.7 million during the three months ended June 30, 2021 to \$40.5 million during the three months ended June 30, 2022. The change was primarily due to a \$10.4 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 \$2.3 million increase in travel related costs, a \$1.1 million increase in facilities and other allocated costs, a \$0.7 million increase in marketing and promotional costs, a \$0.2 million increase in general corporate costs, and a \$0.1 million increase in professional services and consulting costs.

General and administrative expenses

General and administrative expenses increased by \$4.5 million, or 53%, from \$8.6 million during the three months ended June 30, 2021 to \$13.2 million during the three months ended June 30, 2022. The change was primarily due to a \$2.7 million increase in compensation and personnel-related costs, a \$0.7 million increase in professional services and consulting costs, a \$0.6 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 training and recruiting costs.

Loss from equity method investment

The increase in loss from equity method investment of \$1.5 million for the three months ended June 30, 2022 was due to increased JV activities to support commercialization of NMPA approved products in the PRC, and the elimination of intra-entity profit for goods sold by the Company to the JV but have not yet sold through by the JV to an end customer at the end of the reporting period.

Interest expense

Interest expense of \$0.3 million for the three months ended June 30, 2022 was related to our outstanding term loan which matures in December 2023. The term loan requires monthly repayments of principal starting in July 2022.

Other income (expense), net

Other income (expense), net decreased by \$1.6 million, from \$0.1 million in other income, net during the three months ended June 30, 2021 to \$1.5 million in other expense, net during the three months ended June 30, 2022. The decrease in other income (expense), net was primarily due to increased foreign exchange losses, partially offset by an increase in interest income due to the increased interest rate environment.

Comparison of the Six Months Ended June 30, 2022 and 2021

The following table shows our results of operations for the six months ended June 30, 2022 and 2021:

	Six Months Ended June 30,		Change \$	Change %
	2022	2021		
	(in thousands, except percentages)			
Revenue:				
Product revenue	\$ 214,377	\$ 87,808	\$ 126,569	144%
Cost of revenue:				
Cost of product revenue	29,620	17,826	11,794	66%
Gross profit	184,757	69,982	114,775	164%
Operating expenses:				
Research and development	37,779	22,092	15,687	71%
Sales and marketing	76,476	49,705	26,771	54%
General and administrative	25,554	15,852	9,702	61%
Total operating expenses	139,809	87,649	52,160	60%
Income (loss) from operations	44,948	(17,667)	62,615	354%
Loss from equity method investment	(1,511)	(5,523)	(4,012)	(73)%
Interest expense	(601)	(630)	(29)	(5)%
Other expense, net	(1,783)	(89)	1,694	*
Net income (loss) before taxes	41,053	(23,909)	64,962	272%
Income tax provision	971	117	854	730%
Net income (loss)	\$ 40,082	\$ (24,026)	\$ 64,108	267%

* Not meaningful.

Product revenue

Product revenue increased by \$126.6 million, or 144%, from \$87.8 million during the six months ended June 30, 2021 to \$214.4 million during the six months ended June 30, 2022.

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

	Six Months Ended June 30,		Change \$	Change %
	2022	2021		
	(in thousands, except percentages)			
Coronary	\$ 158,165	\$ 52,010	\$ 106,155	204%
Peripheral	54,738	34,934	19,804	57%
Other	1,474	864	610	71%
Product revenue	\$ 214,377	\$ 87,808	\$ 126,569	144%

Coronary product revenue increased by \$106.2 million, or 204%, from \$52.0 million for the six months ended June 30, 2021 to \$158.2 million for the six months ended June 30, 2022. In February 2021, we received FDA approval for our C² catheters. The increase in coronary product revenue was primarily due to the commencement of sales of our C² catheters in the United States, increased adoption of our products internationally, and continued recovery from the impact of the COVID-19 pandemic in the prior year.

Peripheral product revenue increased by \$19.8 million, or 57%, from \$34.9 million for the six months ended June 30, 2021 to \$54.7 million for the six months ended June 30, 2022. The change was due to an increase in purchase volume of our M⁵, M⁵⁺ and S⁴ IVL catheters within the United States and internationally driven by increased adoption of our products and recovery from the impact of the COVID-19 pandemic in the prior year.

We sold to a greater number of customers in the United States and to a greater number of distributors internationally for the six months ended June 30, 2022 as compared to the six months ended June 30, 2021. Product revenue, classified by the major geographic areas in which our products are shipped, was \$178.6 million within the United States and \$35.8 million for all other countries in the six months ended June 30, 2022, compared to \$64.0 million within the United States and \$23.8 million for all other countries in the six months ended June 30, 2021.

Cost of product revenue, gross profit and gross margin percentage

Cost of product revenue increased by \$11.8 million, or 66%, from \$17.8 million during the six months ended June 30, 2021 to \$29.6 million during the six months ended June 30, 2022. Gross margin percentage improved to 86% for the six months ended June 30, 2022, compared to 80% for the six months ended June 30, 2021. 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 operations and production.

Research and development expenses

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

	Six Months Ended June 30,		Change	Change
	2022	2021		
	(in thousands)			
Compensation and personnel-related costs	\$ 22,193	\$ 13,038	\$ 9,155	70%
Materials and supplies	3,914	962	2,952	307%
Facilities and other allocated costs	4,300	2,358	1,942	82%
Outside consultants	1,780	1,021	759	74%
Other research and development costs	890	389	501	129%
Clinical-related costs	4,702	4,324	378	9%
Total research and development expenses	\$ 37,779	\$ 22,092	\$ 15,687	71%

R&D expenses increased by \$15.7 million, or 71%, from \$22.1 million during the six months ended June 30, 2021 to \$37.8 million during the six months ended June 30, 2022. The change was primarily due to a \$9.2 million increase in compensation and personnel-related costs due to an increase in headcount, a \$3.0 million increase in materials and supplies, a \$1.9 million increase in facilities and other allocated costs due to increased information technology, rent and building expenditures, a \$0.8 million increase in outside consultants, a \$0.5 million increase in other R&D costs, and an increase in clinical-related costs of \$0.4 million.

Sales and marketing expenses

Sales and marketing expenses increased by \$26.8 million, or 54%, from \$49.7 million during the six months ended June 30, 2021 to \$76.5 million during the six months ended June 30, 2022. The change was primarily due to a \$17.2 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 \$5.2 million increase in travel related costs, a \$2.1 million increase in facilities and other allocated costs, a \$1.9 million increase in marketing and promotional costs, a \$0.4 million increase in professional services and consulting costs, a \$0.3 million increase in general corporate costs, and a \$0.1 million increase in recruiting and training costs. This was partially offset by a \$0.4 million decrease in materials and supplies.

General and administrative expenses

General and administrative expenses increased by \$9.7 million, or 61%, from \$15.9 million during the six months ended June 30, 2021 to \$25.6 million during the six months ended June 30, 2022. The change was primarily due to a \$5.0

million increase in compensation and personnel-related costs, a \$2.2 million increase in professional services and consulting costs, a \$1.3 million increase in general corporate costs, a \$0.7 million increase in facilities and other allocated costs, a \$0.4 million increase in travel related costs, and a \$0.1 million increase in recruiting and training costs.

Loss from equity method investment

The decrease in loss from equity method investment of \$4.0 million for the six months ended June 30, 2022 was due to in-process R&D costs expensed in the six months ended June 30, 2022, partially offset by increased JV activities to support commercialization of NMPA approved products in the PRC, and the elimination of intra-entity profit to the extent the goods sold by the Company to the JV have not yet sold through by the JV to an end customer at the end of the reporting period.

Interest expense

Interest expense of \$0.6 million for the six months ended June 30, 2022 was related to our outstanding term loan which matures in December 2023. The term loan requires monthly repayments of principal starting in July 2022.

Other expense, net

Other expense, net increased by \$1.7 million, from \$0.1 million during the six months ended June 30, 2021 to \$1.8 million during the six months ended June 30, 2022. The increase in other expense was primarily due to increased foreign exchange losses, partially offset by an increase in interest income due to the increased interest rate environment.

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 sales of our common stock in our public offerings, \$10.0 million of private sales of our equity securities, payments received from customers using our products and to a lesser extent proceeds from our debt financings.

We have a number of ongoing clinical trials and expect to continue to make substantial investments in these trials and in additional clinical trials that are designed to provide clinical evidence of the safety and efficacy of our products. We intend to continue to make significant investments in our sales and marketing organization by increasing the number of U.S. sales representatives and expanding our international marketing programs to help facilitate further adoption among existing hospital accounts and physicians as well as to broaden awareness of our products to new hospitals. We also expect to continue to make investments in R&D, regulatory affairs, and clinical studies to develop future generations of products based on our IVL Technology, support regulatory submissions, and demonstrate the clinical efficacy of our products. Moreover, we expect to continue to incur expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance, investor relations and other expenses. Because of these and other factors, although we had positive net income for the quarter ended June 30, 2022, we had a net loss for the year ended December 31, 2021 and we may incur net losses and have negative cash flows from operations in the future.

As of June 30, 2022, we had \$224.9 million in cash, cash equivalents and short-term investments and an accumulated deficit of \$212.7 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 and capital expenditure requirements. In the long term, our ability to support our working capital and capital expenditure requirements will depend on many factors, including but not limited to:

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost of our R&D 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, and rising interest rates;
- 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. If we are unable to raise additional capital when desired, our business, operating results, and financial condition could be adversely affected.

Manufacturing Purchase Obligations

We have engaged a contract manufacturer to produce and supply us with certain products. We have fixed commitments of approximately \$7.0 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. Our total operating lease commitments as of June 30, 2022 are approximately \$55.0 million, of which \$5.0 million is expected to be paid within the next twelve months.

There were no other material changes during the six months ended June 30, 2022 to our contractual obligations as compared to those disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2021.

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:

	Six Months Ended June 30,	
	2022	2021
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ 30,808	\$ (15,117)
Investing activities	(21,598)	54,300
Financing activities	3,020	(5,338)
Effect of exchange rate changes on cash and cash equivalents	(1,526)	—
Net increase in cash, cash equivalents and restricted cash	<u>\$ 10,704</u>	<u>\$ 33,845</u>

Operating activities

During the six months ended June 30, 2022, cash provided by operating activities was \$30.8 million, attributable to a net income of \$40.1 million, non-cash charges of \$27.8 million, partially offset by a net change in our net operating assets and liabilities of \$37.1 million. Non-cash charges of \$27.8 million primarily consisted of \$20.5 million in stock-based compensation, \$2.1 million in depreciation and amortization, and \$1.5 million in non-cash lease expense. The change in our net operating assets and liabilities of \$37.1 million was primarily due to a \$22.5 million increase in accounts receivable due to an increase in sales, a \$16.2 million increase in inventory driven by an increase in raw materials and finished goods

inventory. These changes were partially offset by a \$3.9 million increase in accrued and other current liabilities resulting from increased accrued asset purchases.

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

Investing activities

During the six months ended June 30, 2022, cash used in investing activities was \$21.6 million, attributable to purchases of available-for-sale investments of \$52.6 million and purchases of property and equipment of \$6.9 million, partially offset by proceeds from maturities of available-for-sale investments of \$37.9 million.

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

Financing activities

During the six months ended June 30, 2022, cash provided by financing activities was \$3.0 million, attributable to proceeds of \$2.1 million from the issuance of shares under our employee stock purchase plan and proceeds of \$0.9 million from stock option exercises.

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

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 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2021 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in internal control over financial reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Petitions for inter partes review (“IPR”) of U.S. Pat. Nos. 9,642,673, 8,956,371 and 8,728,091, which are three of our issued U.S. patents that relate to our current IVL technology, were 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 all three patents.

The PTAB held oral hearings on April 15-16, 2020. On July 8, 2020, the PTAB ruled that one claim (“Claim 5”) in U.S. Pat No. 8,956,371 (the “’371 patent”) is valid and ruled that all other claims in the ’371 patent are invalid and that all claims of U.S. Pat No. 8,728,091 (the “’091 patent”) are invalid. On July 20, 2020, the PTAB ruled that all claims of U.S. Pat. No. 9,642,673 (the “’673 patent”) are invalid. On August 27, 2020, further briefing by the parties was requested by the PTAB judge in the ’371 patent proceeding to assess whether recent guidance from the USPTO relating to “applicant admitted prior art” impacted the PTAB decision in the ’371 patent proceeding. In addition, the PTAB judge reset the time for commencement of an appeal in the ’371 patent proceeding pending the entry of a final decision after the requested briefing. On October 13, 2020, we submitted the last of the requested briefing, and the PTAB decision is pending. Subject to the final PTAB decision regarding the ’371 patent proceeding, we anticipate appealing this ruling to the U.S. Court of Appeals for the Federal Circuit (the “Federal Circuit”).

We appealed the rulings in the IPR proceedings for the ’091 patent and the ’673 patent to the Federal Circuit. On January 18, 2022, the Federal Circuit issued two short opinions affirming the decisions of the PTAB, finding that the claims of the ’091 patent and the ’673 patent are unpatentable (the “Rulings”). The Rulings conclude the IPR proceedings initiated by CSI for these two patents and resulted in the loss in scope of the ’091 patent and the ’673 patent, which may limit our ability to stop others from using or commercializing products and technology similar or identical to ours.

IPR proceedings relating to the ’371 patent remain pending before the PTAB on rehearing and have not yet been addressed by the Federal Circuit. Claim 5 of the ’371 patent was found to be valid, and all other claims remain valid and enforceable until a final decision is obtained from the PTAB, and any 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 Annual Report on Form 10-K for the year ended December 31, 2021, titled “Risk Factors—Risks Related to Our Intellectual Property.”

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

Item 1A. Risk Factors.

There have been no material changes from the risk factors disclosed in Part I, Item 1A. “Risk Factors” of our 2021 Annual Report on Form 10-K for the year ended December 31, 2021 (the “2021 Annual Report”), filed with the Securities and Exchange Commission on February 25, 2022. The risk factors described in our 2021 Annual Report, as well as other information set forth in this Quarterly Report on Form 10-Q, could materially adversely affect our business, financial condition, results of operations and prospects, and should be carefully considered. The risks and uncertainties that we face, however, are not limited to those described in the 2021 Annual Report. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business and the trading price of our securities, particularly in light of the fast-changing nature of the COVID-19 pandemic, containment measures and the related impacts to economic and operating conditions.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Number	Description	Form	File No.	Exhibit(s)	Filing Date
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 June 30, 2022 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.

**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: August 8, 2022

By: /s/ Douglas Godshall

Douglas Godshall

President and Chief Executive Officer
(Principal Executive Officer)

**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: August 8, 2022

By: /s/ Dan Puckett

Dan Puckett

Chief Financial Officer

(Principal Financial Officer)

**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 June 30, 2022 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: August 8, 2022

By: /s/ Douglas Godshall
Douglas Godshall
President and Chief Executive Officer
(Principal Executive Officer)

**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 June 30, 2022 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: August 8, 2022

By: /s/ Dan Puckett

Dan Puckett

Chief Financial Officer
(Principal Financial Officer)