
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 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: 001-40545
-

CVRx, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

41-1983744
(I.R.S. Employer
Identification No.)

9201 West Broadway Avenue
Suite 650
Minneapolis, MN 55445
(Address of Principal Executive Offices)
(763) 416-2840
(Registrant's telephone number)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.01 per share	CVRX	The 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of October 28, 2022, there were 20,584,163 shares of the registrant's common stock, par value \$0.01 per share outstanding.

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CVRx, Inc.
Quarterly Report on Form 10-Q
For the quarterly period ended September 30, 2022

Cautionary Note on Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements, including statements regarding our future results of operations and financial position, business strategy, the impact of the ongoing and global COVID-19 pandemic on our business, financial results and financial position, clinical trial results, prospective products, product approvals, research and development costs, timing and likelihood of success, and the plans and objectives of management for future operations.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of known and unknown risks, uncertainties and assumptions, including, but not limited to, the important factors discussed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, which are summarized below. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include, but are not limited to, the following:

- we have a history of significant losses, which we expect to continue, and we may not be able to achieve or sustain profitability;
- our principal stockholders, management and directors (four of whom are affiliated with our principal stockholders) own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval;
- we have a limited history operating as a commercial company and are highly dependent on a single product, Barostim, and the failure to obtain market acceptance in the U.S. for Barostim would negatively impact our business, liquidity and results of operations;

- we have limited commercial sales experience marketing and selling Barostim, and if we are unable to establish and maintain sales and marketing capabilities, we will be unable to successfully commercialize Barostim or generate sustained and increasing product revenue;
- we must demonstrate to physicians and patients the merits of Barostim;
- if third-party payors do not provide adequate coverage and reimbursement for the use of Barostim, our revenue will be negatively impacted;
- our industry is competitive; if our competitors, many of which are large, well-established companies with substantially greater resources than us and have a long history of competing in the heart failure market, are better able to develop and market products that are safer, more effective, less costly, easier to use or otherwise more attractive than Barostim, our business will be adversely impacted;
- if we fail to receive access to hospitals, our sales may decrease;
- we are dependent upon third-party manufacturers and suppliers, and in some cases a limited number of suppliers, making us vulnerable to supply shortages, loss or degradation in performance of the suppliers and price fluctuations, which could harm our business;
- manufacturing risks may adversely affect our ability to manufacture our product and could reduce our gross margin and profitability;
- a pandemic, epidemic or outbreak of an infectious disease in the U.S. or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect our business;
- we may face product liability claims that could be costly, divert management's attention and harm our reputation;
- we may in the future become involved in lawsuits to protect or enforce our intellectual property, which could be expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, thereby hindering our ability to effectively commercialize our existing or future products;
- if we fail to retain our key executives or recruit and hire new employees, our operations and financial results may be adversely affected while we attract other highly qualified personnel; and
- we will continue to obtain long-term clinical data regarding the safety and efficacy of our products, which could impact future adoption and regulatory approvals.

PART I —FINANCIAL INFORMATION**Item 1. Financial Statements**

CVRx, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 109,985	\$ 142,072
Accounts receivable, net	5,297	2,560
Inventory	6,064	3,880
Prepaid expenses and other current assets	3,066	2,585
Total current assets	124,412	151,097
Property and equipment, net	1,747	1,425
Operating lease right-of-use asset	391	—
Other non-current assets	26	26
Total assets	<u>\$ 126,576</u>	<u>\$ 152,548</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,276	\$ 510
Accrued expenses	6,120	5,398
Total current liabilities	7,396	5,908
Operating lease liability, non-current portion	175	—
Other long-term liabilities	761	681
Total liabilities	<u>8,332</u>	<u>6,589</u>
Commitments and contingencies (Notes 5 and 10)		
Stockholders' equity:		
Common stock, \$0.01 par value, 200,000,000 authorized as of September 30, 2022 and December 31, 2021; 20,578,963 and 20,399,337 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	206	204
Additional paid-in capital	543,903	540,707
Accumulated deficit	(425,646)	(394,754)
Accumulated other comprehensive loss	(219)	(198)
Total stockholders' equity	118,244	145,959
Total liabilities and stockholders' equity	<u>\$ 126,576</u>	<u>\$ 152,548</u>

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

CVRx, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Revenue	\$ 6,186	\$ 3,395	\$ 15,293	\$ 9,378
Cost of goods sold	1,340	876	3,490	2,656
Gross profit	4,846	2,519	11,803	6,722
Operating expenses:				
Research and development	2,293	1,699	6,906	5,704
Selling, general and administrative	12,679	8,111	35,945	18,198
Total operating expenses	14,972	9,810	42,851	23,902
Loss from operations	(10,126)	(7,291)	(31,048)	(17,180)
Interest expense	—	(614)	—	(1,823)
Other income (expense), net	328	1,795	237	(13,439)
Loss before income taxes	(9,798)	(6,110)	(30,811)	(32,442)
Provision for income taxes	(32)	(23)	(81)	(66)
Net loss	(9,830)	(6,133)	(30,892)	(32,508)
Cumulative translation adjustment	(8)	(3)	(21)	(8)
Comprehensive loss	\$ (9,838)	\$ (6,136)	\$ (30,913)	\$ (32,516)
Net loss per share, basic and diluted	\$ (0.48)	\$ (0.30)	\$ (1.51)	\$ (4.66)
Weighted-average common shares used to compute net loss per share, basic and diluted	20,576,838	20,126,672	20,512,254	6,975,386

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

CVRx, INC.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share data)
(Unaudited)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount				
Balances as of June 30, 2022	—	\$ —	20,576,149	\$ 206	\$ 542,967	\$ (415,816)	\$ (211)	\$ 127,146
Exercise of stock options	—	—	2,814	—	7	—	—	7
Employee stock compensation	—	—	—	—	929	—	—	929
Net loss for the three months ended September 30, 2022	—	—	—	—	—	(9,830)	—	(9,830)
Cumulative translation adjustment	—	—	—	—	—	—	(8)	(8)
Balances as of September 30, 2022	—	\$ —	20,578,963	\$ 206	\$ 543,903	\$ (425,646)	\$ (219)	\$ 118,244
Balances as of June 30, 2021	223,541,754	\$ 329,983	366,342	\$ 4	\$ 59,311	\$ (378,051)	\$ (195)	\$ (318,931)
Exercise of stock options	—	—	5,853	—	8	—	—	8
Employee stock compensation	—	—	—	—	474	—	—	474
Issuance of common stock, net of offering costs	—	—	8,050,000	81	133,080	—	—	133,161
Reverse stock split	—	—	—	—	(1)	—	—	(1)
Conversion of Series G preferred stock	(223,541,754)	(329,983)	11,929,584	119	347,069	—	—	347,188
Net loss for the three months ended September 30, 2021	—	—	—	—	—	(6,133)	—	(6,133)
Cumulative translation adjustment	—	—	—	—	—	—	(3)	(3)
Balances as of September 30, 2021	—	\$ —	20,351,779	\$ 204	\$ 539,941	\$ (384,184)	\$ (198)	\$ 155,763

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	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount				
Balances as of								
December 31, 2021	—	\$ —	20,399,337	\$ 204	\$ 540,707	\$ (394,754)	\$ (198)	\$ 145,959
Exercise of stock options	—	—	121,945	1	80	—	—	81
Proceeds from Employee Stock Purchase Plan	—	—	57,681	1	294	—	—	295
Employee stock compensation	—	—	—	—	2,822	—	—	2,822
Net loss for the nine months ended September 30, 2022	—	—	—	—	—	(30,892)	—	(30,892)
Cumulative translation adjustment	—	—	—	—	—	—	(21)	(21)
Balances as of September 30, 2022	—	\$ —	20,578,963	\$ 206	\$ 543,903	\$ (425,646)	\$ (219)	\$ 118,244
Balances as of								
December 31, 2020	223,541,754	\$ 329,983	360,412	\$ 4	\$ 58,624	\$ (351,676)	\$ (190)	\$ (293,238)
Exercise of stock options	—	—	11,783	—	10	—	—	10
Employee stock compensation	—	—	—	—	1,159	—	—	1,159
Issuance of common stock, net of offering costs	—	—	8,050,000	81	133,080	—	—	133,161
Reverse stock split	—	—	—	—	(1)	—	—	(1)
Conversion of Series G preferred stock	(223,541,754)	(329,983)	11,929,584	119	347,069	—	—	347,188
Net loss for the nine months ended September 30, 2021	—	—	—	—	—	(32,508)	—	(32,508)
Cumulative translation adjustment	—	—	—	—	—	—	(8)	(8)
Balances as of September 30, 2021	—	\$ —	20,351,779	\$ 204	\$ 539,941	\$ (384,184)	\$ (198)	\$ 155,763

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

CVRx, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine months ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (30,892)	\$ (32,508)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,822	1,159
Depreciation of property and equipment	284	112
Amortization of deferred financing costs and loan discount	—	206
Changes in fair value of convertible preferred stock warrants	—	13,294
Changes in operating assets and liabilities:		
Accounts receivable	(2,737)	(2,140)
Inventory	(2,184)	(97)
Prepaid expenses and other current assets	(479)	(2,359)
Accounts payable	766	58
Accrued expenses	584	1,558
Net cash used in operating activities	<u>(31,836)</u>	<u>(20,717)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(606)	(645)
Net cash used in investing activities	<u>(606)</u>	<u>(645)</u>
Cash flows from financing activities:		
Proceeds from the exercise of common stock options	81	10
Proceeds from Employee Stock Purchase Plan	295	—
Payments related to reverse stock split	—	(1)
Proceeds from the issuance of common stock, net of offering costs	—	133,161
Net cash provided by financing activities	<u>376</u>	<u>133,170</u>
Effect of currency exchange on cash and cash equivalents	(21)	(7)
Net change in cash and cash equivalents	<u>(32,087)</u>	<u>111,801</u>
Cash and cash equivalents at beginning of period	142,072	59,112
Cash and cash equivalents at end of period	<u>\$ 109,985</u>	<u>\$ 170,913</u>
Supplemental Information:		
Cash paid for interest	\$ —	\$ 1,522
Cash paid for income taxes	4	1

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

CVRx, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Business organization

CVRx, Inc. (the “Company”) was incorporated in Delaware and is headquartered in Minneapolis, Minnesota. The Company has developed and is marketing a medical device, Barostim, for heart failure (“HF”) and resistant hypertension. The Company is focused on the sale of its product in the U.S. and Europe.

Management expects that operating losses and negative cash flows from operations could continue in the foreseeable future. There is no assurance that the Company will generate sufficient product sales to produce positive earnings or cash flows.

2. Summary of significant accounting policies

Statement presentation and basis of consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and with the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”) applicable to interim financial statements. In the Company’s opinion, the accompanying unaudited condensed consolidated financial statements reflect all adjustments necessary for a fair presentation of the Company’s statements of financial position, results of operations and cash flows for the periods presented. The results of operations for the interim periods are not necessarily indicative of results that may be expected for the fiscal year as a whole or any other future period.

The condensed consolidated financial statements include the accounts of CVRx, Inc., its wholly owned subsidiary, CVRx Switzerland LLC, and its sales branch in Italy. All intercompany balances and transactions have been eliminated in consolidation.

JOBS Act accounting election

The Company is an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). As a result, the Company has elected to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies.

Use of estimates

Preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and the accompanying notes. Actual results could differ from those estimates.

Cash and cash equivalents

Cash and cash equivalents include highly liquid investments with an original maturity of three months or less. As of September 30, 2022 and December 31, 2021, cash equivalents consisted of money market funds, which are stated at cost and approximate fair value.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. Customer credit terms are established prior to shipment with the standard generally being net 30 days. We do not record an allowance on our trade accounts receivable but monitor the collectability of individual customer accounts on an ongoing basis.

Inventory

Inventory is stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. The Company regularly reviews inventory quantities in consideration of actual loss experiences, projected future demand and remaining shelf life to record a provision for excess and obsolete inventory when appropriate.

Leases

Operating leases are included in operating lease right-of-use ("ROU") asset, accrued expenses, and operating lease liability – non-current portion in our balance sheets. ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. We used the incremental borrowing rate based on information readily available at the time of recognition to determine the present value of the lease payments. The determination of our incremental borrowing rate requires management judgement based on information available at lease commencement.

Revenue recognition

The Company sells its products primarily through a direct sales force and to a lesser extent through a combination of sales agents and independent distributors. The Company's revenue consists primarily of the sale of its Barostim, which consists of two implantable components: a pulse generator and a stimulation lead.

Under Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. The Company recognizes net revenue on product sales when the customer obtains control of the Company's product, which generally occurs at a point in time upon delivery based on the contractual shipping terms of a contract.

Stock-Based Compensation

We recognize equity-based compensation expense for awards of equity instruments to employees and non-employees based on the grant date fair value of those awards in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires all equity-based compensation awards to employees and non-employee directors, including grants of restricted shares and stock options, to be recognized as expense in the statements of operations and comprehensive loss based on their grant date fair values. We estimate the grant date fair value of stock options using the Black-Scholes option pricing model. We use an estimate of the value of our common stock, with the assistance of an independent appraiser, to determine the fair value of options. We account for forfeitures as they occur. We expense the fair value of our equity-based compensation awards

granted to employees on a straight-line basis over the associated service period, which is generally the period in which the related services are received.

Recent accounting pronouncements

On January 1, 2022, the Company adopted Accounting Standards Codification Topic 842, *Leases* (“ASC 842”), utilizing the alternative modified retrospective transition approach. Under the alternative modified retrospective transition approach, the reported results for 2022 reflect the application of Topic 842 guidance, whereas comparative periods and their respective disclosures prior to the adoption of Topic 842 are presented using the legacy guidance of ASC 840. As a result of adopting the new standard, the Company recognized ROU assets of \$579,000 and lease liabilities of \$561,000 as of January 1, 2022. The lease liabilities represent the present value of the remaining lease payments, discounted using the Company’s incremental borrowing rate as of January 1, 2022. The corresponding ROU assets are recorded based on the lease liabilities and the cumulative difference between rent expense and the amounts paid under the lease. The Company did not elect any practical expedients.

3. Selected balance sheet information

Inventory consists of the following at:

<i>(in thousands)</i>	September 30, 2022	December 31, 2021
Raw material	\$ 2,139	\$ 1,593
Work-in-process	917	482
Finished goods	3,008	1,805
	<u>\$ 6,064</u>	<u>\$ 3,880</u>

Property and equipment, net consists of the following at:

<i>(in thousands)</i>	September 30, 2022	December 31, 2021
Office furniture and equipment	\$ 350	\$ 271
Lab equipment	2,632	1,565
Computer equipment and software	610	556
Leasehold improvements	95	88
Capital equipment in process	212	813
	<u>3,899</u>	<u>3,293</u>
Less: Accumulated depreciation and amortization	<u>2,152</u>	<u>1,868</u>
	<u>\$ 1,747</u>	<u>\$ 1,425</u>

Depreciation expense was \$127,000 and \$42,000 for the three months ended September 30, 2022 and 2021, respectively, and \$284,000 and \$112,000 for the nine months ended September 30, 2022 and 2021, respectively.

Accrued expenses consist of the following at:

<i>(in thousands)</i>	September 30, 2022	December 31, 2021
Bonuses	\$ 2,048	\$ 2,028
Clinical trial and other professional fees	1,808	1,607
Paid time off	853	699
Customer rebates	370	380
Operating lease liability, current portion	218	—
Other	823	684
	<u>\$ 6,120</u>	<u>\$ 5,398</u>

4. Fair value measurements

Fair value is defined as the price that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

- Level 1 — Inputs are quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, and inputs (other than quoted prices) that are observable for the asset or liability, either directly or indirectly.
- Level 3 — Inputs are unobservable for the asset or liability.

There was no convertible preferred stock warranty liability as of the periods ended September 30, 2022 and December 31, 2021.

The Company's recurring fair value measurements using significant unobservable inputs (Level 3) related solely to the Company's convertible preferred stock warrant liability. The convertible preferred stock warrant liability was remeasured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. In connection with the closing of the initial public offering ("IPO"), all of the outstanding convertible preferred stock warrants were converted to common stock warrants. The related liability was remeasured at the time of the IPO and reclassified to additional paid-in capital.

The following table sets forth a summary of changes in the estimated fair value of the Company's convertible preferred stock warrants during the nine months ended:

<i>(in thousands)</i>	September 30,	
	2022	2021
Beginning of the period	\$ —	\$ 3,911
Change in fair value	—	13,294
Conversion to common stock warrants	—	(17,205)
End of the period	\$ —	\$ —

There were no transfers in or out of Level 1, Level 2 or Level 3 fair value measurements during the periods ended September 30, 2022 and 2021.

5. Leases

We lease 23,890 square feet of office space in Minneapolis, Minnesota, which houses our principal executive offices and our manufacturing facility. We lease this space under an operating lease agreement that commenced December 1, 2008 and expires July 31, 2024. We intend to add new facilities as we grow, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations. Our operating lease agreement includes an option to renew for one additional period of five years. The exercise of the lease renewal option is at our sole discretion and was not included in the lease term for the calculation of the ROU asset and lease liability upon adoption of ASC 842 on January 1, 2022, as it is not reasonably certain of exercise.

In addition to base rent, we will also pay our proportionate share of operating expenses, as defined in the lease. These payments will be made monthly and will be adjusted annually to reflect actual charges incurred for operating expenses, such as common area maintenance, taxes and insurance.

The following table presents the lease balances within the condensed consolidated balance sheets:

<i>(in thousands)</i>	September 30, 2022
Right-of-use assets:	
Operating lease right-of-use asset	\$ 391
Operating lease liabilities:	
Accrued expenses	218
Operating lease liability, non-current portion	175
Total operating lease liabilities	<u>\$ 393</u>

Maturities of our lease liability for our operating lease are as follows as of September 30, 2022:

<i>(in thousands)</i>	September 30, 2022
2022	\$ 58
2023	234
2024	119
Total undiscounted lease payments	411
Less: imputed interest	(18)
Present value of lease liability	<u>\$ 393</u>

As of September 30, 2022, the remaining lease term was 1.8 years and the discount rate was 5.0%. The operating cash outflows from our operating lease were \$0.3 million for the nine months ended September 30, 2022.

6. Stockholders' equity

Initial Public Offering

On July 2, 2021, the Company closed its IPO of 8,050,000 shares of its common stock at a public offering price of \$18.00 per share, which included 1,050,000 shares of common stock issued upon the exercise in full by the underwriters of their option to purchase additional shares, for net proceeds from the IPO, after deducting the underwriting discount and other offering expenses payable by the Company totaling \$1.6 million, of \$133.2 million.

Upon the closing of the IPO, all shares of convertible preferred stock were automatically converted into common stock. Series G convertible preferred stock was converted into common stock on a 15.819-for-1 basis, and all other shares of convertible preferred stock were automatically converted into common stock on a 39.548-for-1 basis. The conversion of the outstanding preferred stock resulted in an aggregate of 11,929,584 shares of common stock.

Reverse Stock Split

In connection with the IPO, the Company's Board of Directors and stockholders approved a 1-for-39.548 reverse stock split of the Company's common stock. The reverse stock split became effective on June 22, 2021. The par value of the common stock was not adjusted as a result of the reverse stock split. Adjustments corresponding to the reverse stock split were made to the ratio at which the convertible preferred stock

converted into common stock in connection with the closing of the IPO. Accordingly, all share and per-share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse stock split and the adjustment of the conversion ratio of the convertible preferred stock.

Common Stock Warrants

In connection with the IPO, the warrants to purchase shares of convertible preferred stock automatically converted into warrants to purchase common stock, resulting in the reclassification of the related convertible preferred stock warrant liability to additional paid-in capital. Upon the closing of the IPO, these warrants to purchase convertible preferred stock became exercisable for 716,131 shares of common stock upon conversion at a weighted average exercise price of \$2.39 per share.

7. Stock-Based compensation

Summary of plans and activity

In June 2001, the Company's Board of Directors and stockholders established the 2001 Stock Incentive Award Plan ("2001 Plan"). Under the 2001 Plan, as amended, 2,674,749 shares of common stock had been reserved for the issuance of incentive stock options granted to employees, non-employee directors, consultants or independent contractors. Options granted under the 2001 Plan have vesting terms that range from the date of grant to four years and expire within a maximum term of 10 years from the grant date.

In connection with the IPO in 2021, the Company's Board of Directors and stockholders established the 2021 Equity Incentive Plan ("2021 Plan"). The number of shares of common stock initially reserved for issuance under the 2021 Plan was 1,854,490 newly reserved shares in addition to the 600,737 shares that remained available for issuance under the 2001 Plan. The shares available for issuance under the 2021 Plan will automatically increase on the first day of each year, commencing January 1, 2022, and ending on (and including) January 1, 2031, in an amount equal to 5% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of each automatic increase, or such lesser number of shares as determined by the Board of Directors. The annual increase resulted in an additional 1,019,967 shares being reserved for issuance under the 2021 Plan as of January 1, 2022. The 2021 Plan provides for the issuance of stock options, stock appreciation rights, restricted stock awards, stock unit awards and other stock-based awards and cash incentive awards to employees, consultants and non-employee directors of the Company and its subsidiaries. Awards granted under the 2021 Plan will have such vesting schedules and other terms as determined by the Compensation Committee and stock options and stock appreciation rights have a maximum term of 10 years from the grant date. No further awards can be made under the 2001 Plan following the adoption of the 2021 Plan. As of September 30, 2022, there were 1,576,113 shares available for future issuance under the 2021 Plan.

Options are granted at exercise prices not less than the fair market value (as determined by the Board of Directors) of the Company's common stock on the date of grant.

During the years 2008 through September 30, 2022, the Board of Directors authorized the grant of stock options for the purchase of shares of common stock to the employers of certain non-employee directors. The options were not granted under the 2001 Plan or the 2021 Plan, but terms are substantially the same as the Company's standard form of option agreement for non-employee directors as they have an exercise price not less than the fair market value on the grant date and vest over 48 months from the date of grant.

The following is a summary of stock option activity:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value <i>(in thousands)</i>
Balance as of December 31, 2021	2,749,441	\$ 7.93	
Granted	1,406,783	7.87	
Cancelled / Forfeited	(310,780)	7.56	
Exercised	(121,945)	0.67	
Balance as of September 30, 2022	<u>3,723,499</u>	<u>\$ 8.17</u>	<u>\$ 10,623</u>
Options exercisable as of September 30, 2022	1,547,838	\$ 5.96	\$ 7,581

As of September 30, 2022, stock options outstanding included 8,796 options that were not granted under the 2001 Plan or the 2021 Plan. For options outstanding as of September 30, 2022, the weighted average remaining contractual life was 8.0 years. For options exercisable as of September 30, 2022, the weighted average remaining contractual life was 6.7 years.

In connection with the IPO, the Company's Board of Directors and stockholders also established an Employee Stock Purchase Plan (the "ESPP"). The number of shares of common stock initially reserved for issuance under the ESPP was 278,170. The shares available for issuance under the ESPP will automatically increase on the first day of each year, commencing January 1, 2022, and ending on (and including) January 1, 2031, in an amount equal to 1% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of each automatic increase, or such lesser number of shares as determined by the Board of Directors. The annual increase resulted in an additional 203,993 shares being reserved for issuance under the ESPP as of January 1, 2022. The ESPP will permit certain of the Company's U.S. employees to purchase shares of the Company's common stock at a price per share not less than 85% of the lower of (i) the closing market price per share of the Company's common stock on the first day of the applicable purchase period or (ii) the closing market price per share of the Company's common stock on the purchase date at the end of the applicable six-month purchase period. The first purchase date under the ESPP was June 30, 2022. Accordingly, as of September 30, 2022, 57,681 shares of common stock have been purchased under the ESPP for \$0.3 million of employee contributions. As of September 30, 2022, there were 424,482 shares available for issuance under the ESPP.

Stock-based compensation expense

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options and ESPP purchase rights on the grant date. The Company measures stock-based compensation expense based on the grant date fair value of the award and recognizes compensation expense over the requisite service period, which is generally the vesting period for stock options and the offering period for ESPP purchase rights. The amount of stock-based compensation expense recognized for stock option awards during a period is based on the portion of the awards that are ultimately expected to vest. The amount of stock-based

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compensation expense recognized for ESPP purchase rights during a period is based on the estimated purchase rights as of the grant date. The Company accounts for forfeitures as they occur.

The following table provides the weighted average fair value of options granted to employees and the related assumptions used in the Black-Scholes option pricing model for the nine months ended September 30, 2022 and 2021:

	September 30,	
	2022	2021
Weighted average fair value of options granted	\$ 4.56	\$ 5.25
Expected term (in years) — non-officer employees	5.5 to 6.1	2.7 to 6.1
Expected term (in years) — officer employees	3.2 to 6.1	3.0
Expected volatility	56.3% to 58.6 %	56.1% to 63.4 %
Expected dividend yield	— %	— %
Risk-free interest rate	1.75% to 3.97 %	0.17% to 0.47 %

The following table provides the weighted average fair value of ESPP purchase rights and the related assumptions used in the Black-Scholes option pricing model for the nine months ended September 30, 2022:

	September 30,
	2022
Weighted average fair value per ESPP purchase right	\$ 2.85
Expected term (in years)	0.5
Expected volatility	51.3% to 62.9 %
Expected dividend yield	— %
Risk-free interest rate	0.22% to 2.52 %

There were no ESPP purchase rights for the nine months ended September 30, 2021.

The Company reviews these assumptions on a periodic basis and adjusts them, as necessary. The expected term of a stock option award was determined based on the Company's analysis of historical exercise behavior while taking into consideration various participant demographics and option characteristics. The expected term of an ESPP purchase right is based on the offering period. We utilize the simplified method to develop the estimate of the expected term. The expected volatility is based upon observed volatility of comparable public companies. The expected dividend yield is assumed to be zero, as the Company has never paid dividends and has no current plans to do so. The risk-free interest rate is based on the yield on U.S. Treasury securities for a period approximating the expected term of the options being valued.

The following table presents the components and classification of stock-based compensation expense for the periods indicated:

<i>(in thousands)</i>	Three Months Ended		Nine months ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Stock options	\$ 866	\$ 474	\$ 2,657	\$ 1,159
Employee Stock Purchase Plan	63	—	165	—
Total stock-based compensation expense	<u>\$ 929</u>	<u>\$ 474</u>	<u>\$ 2,822</u>	<u>\$ 1,159</u>
Selling, general & administrative	\$ 785	\$ 353	\$ 2,402	\$ 830
Research & development	132	115	367	319
Cost of goods sold	12	6	53	10
	<u>\$ 929</u>	<u>\$ 474</u>	<u>\$ 2,822</u>	<u>\$ 1,159</u>

As of September 30, 2022, unrecognized compensation expense related to unvested stock-based compensation arrangements was \$9.2 million. As of September 30, 2022, the related weighted average period over which the expense is expected to be recognized is approximately 2.7 years.

Early exercise of stock options

Under the 2001 Plan, the Company has issued options to certain executive officers with early-exercise provisions. The options may be exercised by the holder any time after they are granted. The Company has the right to repurchase, at the original option exercise price, shares issued pursuant to such early-exercise provisions, upon the termination of employment or death of the stockholder. This repurchase right expires based upon the original option vesting schedule. As of September 30, 2022 and 2021, there have been no early exercises and therefore there is no liability recorded for the early exercise of stock options.

8. Income taxes

As of September 30, 2022 and December 31, 2021, a valuation allowance was recorded against all deferred tax assets due to the Company's cumulative net loss position. Provision for income taxes for the three months ended September 30, 2022 and 2021 was \$32,000 and \$23,000, respectively. Provision for income taxes for the nine months ended September 30, 2022 and 2021 was \$81,000 and \$66,000, respectively.

As of December 31, 2021, the Company had federal and state net operating loss carryforwards ("NOLs") of approximately \$324.8 million and \$6.5 million, respectively. The federal NOLs began expiring in 2021 and the state NOLs began expiring in 2020. As of December 31, 2021, the Company had federal and state tax credit carryforwards of approximately \$8.9 million and \$1.6 million, respectively. The federal tax credit carryforwards began expiring in 2021 and the state tax credit carryforwards will begin expiring in 2028.

Utilization of NOLs may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986 and similar state provisions. The Company has not performed a detailed analysis to determine whether an ownership change has occurred. Such a change of ownership would limit the Company's utilization of the NOLs and could be triggered by subsequent sales of securities by the Company or its stockholders.

9. (Loss) Earnings Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated for the periods indicated (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net loss	\$ (9,830)	\$ (6,133)	\$ (30,892)	\$ (32,508)
Denominator:				
Weighted average common shares outstanding — basic and diluted	20,576,838	20,126,672	20,512,254	6,975,386
Net loss per share attributable to common stockholders — basic and diluted	\$ (0.48)	\$ (0.30)	\$ (1.51)	\$ (4.66)

The Company's potentially dilutive securities, which include stock options, shares of convertible preferred stock, warrants to purchase shares of convertible preferred stock and warrants to purchase shares of common stock, have been excluded from the computation of diluted net loss per share attributable to common stockholders, as the effect would be to reduce the net loss per share attributable to common stockholders. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period

end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Nine months ended September 30,	
	2022	2021
Options to purchase common stock	3,723,499	2,657,333
Warrants to purchase common stock	716,131	716,131
	<u>4,439,630</u>	<u>3,373,464</u>

10. Commitments and contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual or disclosure as of September 30, 2022 or December 31, 2021.

11. Employee benefit plans

The Company sponsors a voluntary defined-contribution employee retirement plan (the “401(k) plan”) for its U.S. employees. The 401(k) plan provides that each participant may contribute pre-tax or post-tax compensation up to the statutory limit allowable. Under the 401(k) plan, each participant is fully vested in his or her deferred salary contributions when contributed. The Company does not provide matching contributions to employees.

12. Segment, geographic information and revenue disaggregation

The chief operating decision maker for the Company is the Chief Executive Officer. The Chief Executive Officer reviews financial information presented on a consolidated basis, accompanied by information about revenue by geographic region, for purposes of allocating resources and evaluating financial performance. The Company has one business activity and there are no segment managers who are held accountable for operations, operating results or plans for levels or components below the consolidated unit level. Accordingly, the Company has determined that it has a single reportable and operating segment structure. The Company and its Chief Executive Officer evaluate performance based primarily on revenue in the geographic locations in which the Company operates.

The Company derives all its revenues from sales to customers in Europe and the U.S. The following table provides revenue by country for each location accounting for more than 10% of the total revenue for the periods indicated (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
U.S.	\$ 5,039	\$ 2,572	\$ 12,035	\$ 6,289
Germany	933	682	2,744	2,589
Other countries	214	141	514	500
	<u>\$ 6,186</u>	<u>\$ 3,395</u>	<u>\$ 15,293</u>	<u>\$ 9,378</u>

As of September 30, 2022 and December 31, 2021, long-lived assets were located primarily in the U.S.

13. Subsequent events

On October 31, 2022, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Fund I, LP, as the collateral agent and a lender, under which the Company may borrow, subject to the Company's achievement of certain milestones, up to a total of \$50.0 million in a series of term loans. On the closing date, the Company borrowed the minimum amount of \$7.5 million under the Loan Agreement. The terms loans advanced pursuant to the Loan Agreement (collectively, the "Term Loans") will bear interest at a floating rate per annum equal to the sum of (a) the greater of (i) the prime rate and (ii) 5.50% plus (b) 2.65%. The Term Loans mature on January 31, 2028 and require interest-only payments until November 1, 2027. The Term Loans are secured by substantially all of the personal property of the Company. The remaining amount of the facility will be available to be drawn in three separate tranches prior to December 2024.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

We are a commercial-stage medical device company focused on developing, manufacturing and commercializing innovative and minimally invasive neuromodulation solutions for patients with cardiovascular disease. Our proprietary platform technology, Barostim, is designed to leverage the power of the brain and nervous system to address the imbalance of the Autonomic Nervous System, which causes HF with reduced Ejection Fraction ("HFrEF") and other cardiovascular diseases. Our second-generation product, Barostim, is the first and only commercially available neuromodulation device indicated to improve symptoms for patients with HFrEF. Barostim provides Baroreflex Activation Therapy by sending imperceptible and persistent electrical pulses to baroreceptors located in the wall of the carotid artery to signal the brain to modulate cardiovascular function. Barostim is currently approved by the U.S. Food and Drug Administration (the "FDA") to improve the symptoms of patients with HFrEF and is CE Marked for HFrEF and resistant hypertension.

Since our inception we have generated minimal revenue, as our activities have consisted primarily of developing Barostim Therapy, conducting our BeAT-HF pre-market and post-market pivotal studies in the U.S. and filing for regulatory approvals. Our ability to generate revenue from product sales and become profitable will depend on our ability to successfully commercialize Barostim and any product enhancements we may advance in the future. We expect to derive future revenue by expanding our own dedicated salesforce and increasing awareness of Barostim among payors, physicians and patients.

Our sales and marketing efforts are directed at electrophysiologists, HF specialists, general cardiologists and vascular surgeons because they are the primary users of our technology. However, we consider hospitals, where the procedures are performed primarily in an outpatient setting, to be our customers, as they are the purchasing entities of Barostim in the U.S. We intend to continue making significant investments building our U.S. commercial infrastructure by expanding and training our U.S. sales force. We have dedicated significant resources to educate physicians who treat HFrEF about the advantages of Barostim and train them on the implant procedure.

The costs for the device and implantation procedure are reimbursed through various third-party payors, such as government agencies and commercial payors. In the U.S., we estimate that 67% of our target patient population is Medicare-eligible based on the age demographic of the HFrEF patient population indicated for Barostim. As a result, we have prioritized coverage by the Centers for Medicare and Medicaid Services ("CMS") while simultaneously developing processes to engage commercial payors. All Medicare Administrative Contractors have retired automatic coverage denial policies for our Current Procedural Terminology codes, thereby allowing hospitals to be paid for the Barostim procedure. Our reimbursement strategy involves continuing to broaden our current coverage and build our in-house market access team to assist patients and physicians in obtaining appropriate prior authorization approvals in advance of treatment

on a case-by-case basis where positive coverage policies currently do not exist. Outside the U.S., reimbursement levels vary by country and within some countries by region. Barostim is eligible for reimbursement in certain countries in the European Union (“EU”), such as Germany, where annual healthcare budgets for the hospital generally determine the number of patients to be treated and the prices to be paid for the related devices that may be purchased.

We manage all aspects of manufacturing operations and product supply of Barostim, which include final assembly, testing and packaging of our implantable pulse generator (“IPG”) and stimulation lead, at our headquarters in Minneapolis, Minnesota. We utilize components or various subassemblies manufactured by third-party suppliers, some of which have significant lead times. Many of these components are from a limited number of suppliers. We believe that our component manufacturers are recognized in their field for their competency to manufacture the respective portions of Barostim and have quality systems established that meet FDA requirements. We seek to maintain higher levels of inventory to protect ourselves from supply interruptions and continue to seek to broaden and strengthen our supply chain through additional sourcing channels.

From our inception until the IPO, we financed our operations primarily through preferred stock financings, and additionally, from sales of our Barostim products and amounts borrowed under our past credit facilities. We have devoted substantially all of our resources to research and development activities related to Barostim Therapy, including clinical and regulatory initiatives to obtain marketing approval and sales and marketing activities.

We intend to use a portion of the IPO proceeds to continue funding the expansion of our direct sales force and commercial organization related to Barostim in the U.S. We also intend to continue investing in research and development in the near term to improve clinical outcomes, optimize patient adoption and comfort, increase patient access and enhance the physician and patient experience. Longer term, we plan to explore Barostim’s potential to expand its indications for use to other cardiovascular diseases. On October 31, 2022, we entered into a loan and security agreement under which we may borrow, subject to our achievement of certain milestones, up to a total of \$50.0 million in a series of term loans described in Note 13 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q and we borrowed \$7.5 million of such total on that date to fund our commercial and investment efforts. As a result of these investments and our commercialization efforts, we expect to continue to incur net losses for the next several years, which may require additional funding and could include future equity and debt financings.

Recent developments

Since it was reported to have surfaced in December 2019, a novel strain of coronavirus (“COVID-19”) has spread across the world and has been declared a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have been significant and governments around the world, including in the U.S., have implemented severe travel restrictions, social distancing requirements, quarantines, stay-at-home orders and other significant restrictions. As a result, the current COVID-19 pandemic has presented a substantial public health and economic challenge and is affecting hospitals, physicians, patients, communities and business operations, as well as contributing to significant volatility and negative pressure on the U.S. and world economy and in financial markets.

The COVID-19 pandemic has negatively impacted our business, financial condition and results of operations by decreasing and delaying procedures performed to implant Barostim, and we expect the pandemic will continue to negatively impact our business, financial condition and results of operations. Beginning in March 2020, our revenue was negatively impacted by COVID-19 as healthcare facilities and clinics began restricting in-person access to their clinicians, reducing patient consultations and treatments or temporarily closing their facilities. As a result, substantially all of our then-scheduled procedures were postponed, and numerous other cases could not be scheduled. During May 2020, the widespread shutdown resulted in key physician-society conferences being moved to a virtual setting, which directly impacted our planned commercial launch in the U.S.

In response to the COVID-19 pandemic, we have implemented a variety of measures intended to help us manage its impact while maintaining business continuity to support our customers and patients. These measures include:

- Establishing safety protocols, facility enhancements and work-from-home strategies to protect our employees;
- Ensuring that our manufacturing and supply chain operations remain intact and operational;
- Keeping our workforce intact, including our experienced and specialized U.S. sales and clinical support team;
- Implementing virtual physician education programs to support opening new accounts with minimal in person interaction; and
- Increasing our capital resources through the completion of the IPO, which resulted in net proceeds of \$133.2 million.

Our hospital customers in the U.S. and Europe began to gradually perform elective procedures again during the fourth quarter of 2020. As the pandemic eased throughout 2021, we experienced the following positive trends:

- Strong physician participation in our virtual educational events;
- Expansion into new accounts; and
- Hospitals accepting patients for elective procedures at closer to pre-pandemic levels in the U.S.

However, procedure volumes were again negatively impacted by the Delta and Omicron variants of COVID-19 in the third and fourth quarters of 2021 and continuing into the first quarter of 2022. By March 2022, and continuing into the second and third quarters of 2022, implant centers resumed procedures at more normal levels. We believe the challenges resulting from COVID-19 will likely continue for the duration of the pandemic. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity and spread of COVID-19 and its variants and the actions to contain the spread of COVID-19 and its variants or treat its impact.

Factors affecting our performance

We believe there are several important factors that have impacted and that we expect will continue to impact our business and results of operations. These factors include:

- Growing and supporting our U.S. commercial organization;
- Promoting awareness among physicians, hospitals and patients to accelerate adoption of Barostim;
- Raising awareness among payors to build upon reimbursement for Barostim;
- Investing in research and development to foster innovation and further simplify the Barostim procedure; and
- Leveraging our manufacturing capacity to further improve our gross margins.

Components of results of operations

Revenue

Our U.S. sales have increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement changes in 2020. We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients and payors and by the expansion of our U.S. sales force. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.

We derive a portion of our revenue from the sale of Barostim to hospitals in Germany and other select countries in Europe. Revenue from sales of Barostim in Europe fluctuates based on the average selling price of Barostim as determined by location of sale and channel mix, each of which may vary significantly from country to country. Our revenue from international sales can also be significantly impacted by fluctuations in foreign currency exchange rates.

Cost of goods sold and gross margin

Cost of goods sold consists primarily of acquisition costs of the components and subassemblies of Barostim, allocated manufacturing overhead and scrap and inventory obsolescence, as well as distribution-related expenses such as logistics and shipping costs. We expect cost of goods sold to increase in absolute dollars primarily as, and to the extent, our revenue grows. Gross margin may also vary based on regional differences in rebates and incentives negotiated with certain customers.

We calculate gross margin as revenue less cost of goods sold divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, but is primarily driven by the average sale price of our product, the percentage of products sold that include a full system (i.e., an IPG and a stimulation lead), as compared to individual IPG sales, and the allocated manufacturing overhead. Although we sell the majority of our devices directly to hospitals, the impact of the average selling price on gross margin is driven by the percentage of products we sold to distributors as compared to those sold directly to hospitals, as our average selling price is typically higher on products we sell directly. The full system sales typically have a lower gross margin as they include the cost of an IPG and a stimulation lead whereas individual IPG sales only include the cost of an IPG. The manufacturing overhead costs of Barostim are directly aligned to our production volume and therefore the cost per product is reduced if production levels increase. While we expect our gross margin to be positively affected over time to the extent we are successful in selling more product through our direct sales force and by increasing our production volumes, it will likely fluctuate from period to period 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 primarily of personnel costs, including salaries, bonuses, employee benefits and stock-based compensation expenses for our R&D employees. R&D expenses also include costs associated with product design efforts, development prototypes, testing, clinical trial programs and regulatory activities, contractors and consultants, equipment and software to support our development, facilities and information technology. We expense R&D costs as they are incurred. We expect R&D expenses to increase in absolute dollars as we continue to develop enhancements to Barostim. Our R&D expenses may fluctuate from period to period due to the timing and extent of our product development and clinical trial expenses related to Barostim in HFrEF.

Selling, general and administrative expenses

Selling, general and administrative (“SG&A”) expenses consist primarily of personnel costs, including base salaries, bonuses, employee benefits and stock-based compensation expense for our sales and marketing personnel, including sales commissions, and for administrative personnel that support our general operations

such as executive management, financial accounting, information technology and human resources personnel. SG&A expenses also include costs attributable to marketing, as well as travel, legal fees, financial audit fees, insurance, fees for other consulting services, depreciation and facilities. We expense commissions at the time of the sale.

We expect SG&A expenses to increase in absolute dollars as we continue to expand our direct sales force and commercial organization in the U.S. In addition, we will continue to increase our international presence and to develop and assist our channel partners. However, we expect our SG&A expenses to decrease as a percentage of revenue as our revenue grows.

Interest expense

Interest expense consists of interest on our debt and amortization of associated debt discount.

Other income (expense), net

Other income (expense), net consists primarily of the fair value adjustments related to our formerly outstanding convertible preferred stock warrants, which were accounted for as a liability and marked-to-market at each reporting period. The final fair value adjustment of the warrant liability was recorded upon the closing of the IPO in connection with the conversion of the warrants to common stock warrants. Other items include losses on the extinguishment of debt, interest income earned on our cash and cash equivalents and the effect of exchange rates on our foreign currency-denominated asset and liability balances.

Provision for income taxes

Provision for income taxes consists primarily of income taxes in foreign jurisdictions in which we conduct business. We maintain a full valuation allowance for deferred tax assets including NOL carryforwards, R&D credits and other tax credits.

Results of operations

Consolidated results of operations for the three months ended September 30, 2022, compared to the three months ended September 30, 2021

<i>(unaudited and in thousands)</i>	Three months ended September 30,		Change	
	2022	2021	\$	%
Revenue	\$ 6,186	\$ 3,395	\$ 2,791	82 %
Cost of goods sold	1,340	876	464	53 %
Gross profit	4,846	2,519	2,327	92 %
Gross margin	78 %	74 %		
Operating expenses:				
Research and development	2,293	1,699	594	35 %
Selling, general and administrative	12,679	8,111	4,568	56 %
Total operating expenses	14,972	9,810	5,162	53 %
Loss from operations	(10,126)	(7,291)	(2,835)	39 %
Interest expense	—	(614)	614	NM
Other income, net	328	1,795	(1,467)	NM
Loss before income taxes	(9,798)	(6,110)	(3,688)	60 %
Provision for income taxes	(32)	(23)	(9)	39 %
Net loss	\$ (9,830)	\$ (6,133)	\$ (3,697)	60 %

NM – Not meaningful

The following table provides revenue by geography:

<i>(unaudited and in thousands)</i>	Three months ended September 30,		Change	
	2022	2021	\$	%
United States	\$ 5,039	\$ 2,572	\$ 2,467	96 %
Europe	1,147	823	324	39 %
Total Revenue	\$ 6,186	\$ 3,395	\$ 2,791	82 %

Revenue was \$6.2 million for the three months ended September 30, 2022, an increase of \$2.8 million, or 82%, over the three months ended September 30, 2021.

Revenue generated in the U.S. was \$5.0 million for the three months ended September 30, 2022, an increase of \$2.5 million, or 96%, over the three months ended September 30, 2021. Total HF revenue units in the U.S. totaled 167 and 84 for the three months ended September 30, 2022 and 2021, respectively.

HF revenue in the U.S. totaled \$4.9 million for the three months ended September 30, 2022, an increase of \$2.4 million, or 99%, over the three months ended September 30, 2021. The increase was primarily driven by continued growth as a result of the expansion into new sales territories and new accounts, as well as increased physician and patient awareness of Barostim.

As of September 30, 2022, we had a total of 91 active implanting centers as compared to 38 as of September 30, 2021. Active implanting centers are customers that have completed at least one commercial HF implant in the last 12 months. As of September 30, 2022, the Company had a total of 23 sales territories as compared to 11 as of September 30, 2021.

Revenue generated in Europe was \$1.1 million for the three months ended September 30, 2022, an increase of \$0.3 million, or 39%, over the three months ended September 30, 2021. Total revenue units in Europe were 61 for the three months ended September 30, 2022 as compared to 38 in the prior year period. The revenue increase was primarily due to the lessening impact of the COVID-19 pandemic in Europe, partially

offset by an unfavorable currency impact on net sales. As of September 30, 2022, we had a total of six sales territories in Europe.

Cost of goods sold and gross margin

Cost of goods sold increased \$0.5 million, or 53%, to \$1.3 million for the three months ended September 30, 2022, compared to the three months ended September 30, 2021. This increase was primarily due to higher sales of Barostim.

Gross profit was \$4.8 million for the three months ended September 30, 2022, an increase of \$2.3 million, or 92%, over the three months ended September 30, 2021. Gross margin increased to 78% for the three months ended September 30, 2022, compared to 74% for the three months ended September 30, 2021. Gross margin for the three months ended September 30, 2022 was higher due to a decrease in the cost per unit. This was partially offset by a decrease in the average selling price and a larger percentage of our revenue units coming from full systems versus battery replacements. New patients receive a full system that includes an IPG and a stimulation lead, which has a lower gross margin than a stand-alone IPG used for a battery replacement.

Research and development expenses

R&D expenses increased \$0.6 million, or 35%, to \$2.3 million for the three months ended September 30, 2022, compared to the three months ended September 30, 2021. This change was primarily driven by a \$0.5 million increase in compensation expenses, mainly as a result of increased headcount, and a \$0.1 million increase in non-cash stock-based compensation expense, partially offset by a \$0.1 million decrease in clinical study expenses.

Selling, general and administrative expenses

SG&A expenses increased \$4.6 million, or 56%, to \$12.7 million for the three months ended September 30, 2022, compared to the three months ended September 30, 2021. This was primarily driven by a \$3.2 million increase in compensation expenses, mainly as a result of increased headcount, a \$0.5 million increase in travel expenses, a \$0.4 million increase in non-cash stock-based compensation expense, a \$0.3 million increase in marketing and advertising expenses associated with the commercialization of Barostim in the U.S. and a \$0.2 million increase in professional fees.

Interest expense

Interest expense decreased \$0.6 million for the three months ended September 30, 2022, compared to the three months ended September 30, 2021. This decrease was driven by the repayment of the outstanding debt under the loan agreement with Horizon Technology Finance Corporation (the "Horizon loan agreement") in November 2021.

Other income, net

Other income, net was \$0.3 million for the three months ended September 30, 2022, compared to \$1.8 million for the three months ended September 30, 2021. The income in the third quarter of 2021 reflects \$1.5 million of income related to the change in the fair value of our convertible preferred stock warrants from June 30, 2021 to July 2, 2021, which is the date the warrants converted to common stock warrants. As these preferred stock warrants converted to common stock warrants upon the IPO, there is no longer a change in fair value recorded in other income, net.

Provision for income taxes

Provision for income taxes was nominal for each of the three months ended September 30, 2022, and September 30, 2021.

Consolidated results of operations for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021

<i>(unaudited and in thousands)</i>	Nine months ended September 30,		Change	
	2022	2021	\$	%
Revenue	\$ 15,293	\$ 9,378	\$ 5,915	63 %
Cost of goods sold	3,490	2,656	834	31 %
Gross profit	11,803	6,722	5,081	76 %
Gross margin	77 %	72 %		
Operating expenses:				
Research and development	6,906	5,704	1,202	21 %
Selling, general and administrative	35,945	18,198	17,747	98 %
Total operating expenses	42,851	23,902	18,949	79 %
Loss from operations	(31,048)	(17,180)	(13,868)	81 %
Interest expense	—	(1,823)	1,823	NM
Other income (expense), net	237	(13,439)	13,676	NM
Loss before income taxes	(30,811)	(32,442)	1,631	(5)%
Provision for income taxes	(81)	(66)	(15)	23 %
Net loss	\$ (30,892)	\$ (32,508)	\$ 1,616	(5)%

NM – Not meaningful

The following table provides revenue by geography:

<i>(unaudited and in thousands)</i>	Nine months ended September 30,		Change	
	2022	2021	\$	%
United States	\$ 12,035	\$ 6,289	\$ 5,746	91 %
Europe	3,258	3,089	169	5 %
Total Revenue	\$ 15,293	\$ 9,378	\$ 5,915	63 %

Revenue was \$15.3 million for the nine months ended September 30, 2022, an increase of \$5.9 million, or 63%, over the nine months ended September 30, 2021.

Revenue generated in the U.S. was \$12.0 million for the nine months ended September 30, 2022, an increase of \$5.7 million, or 91%, over the nine months ended September 30, 2021. Total HF revenue units in the U.S. totaled 394 and 195 for the nine months ended September 30, 2022 and 2021, respectively.

HF revenue in the U.S. totaled \$11.6 million for the nine months ended September 30, 2022, an increase of \$5.9 million, or 103%, over the nine months ended September 30, 2021. The increase was primarily driven by continued growth as a result of the expansion into new sales territories, new accounts and increased physician and patient awareness of Barostim.

Revenue generated in Europe was \$3.3 million for the nine months ended September 30, 2022, an increase of \$0.2 million, or 5%, over the nine months ended September 30, 2021. Total revenue units in Europe were 163 for the nine months ended September 30, 2022, as compared to 137 in the prior year period. The slight revenue increase was primarily due to the lessening impact of the COVID-19 pandemic in Europe, partially offset by an unfavorable currency impact on net sales. As of September 30, 2022, the Company had a total of six sales territories in Europe.

Cost of goods sold and gross margin

Cost of goods sold increased \$0.8 million, or 31%, to \$3.5 million for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021. This increase was primarily due to higher sales of Barostim.

Gross profit was \$11.8 million for the nine months ended September 30, 2022, an increase of \$5.1 million, or 76%, over the nine months ended September 30, 2021. Gross margin increased to 77% for the nine months ended September 30, 2022, compared to 72% for the nine months ended September 30, 2021. Gross margin for the nine months ended September 30, 2022 was higher due to a decrease in the cost per unit and an increase in the average selling price. This was partially offset by a larger percentage of our revenue units coming from full systems versus battery replacements.

Research and development expenses

R&D expenses increased \$1.2 million, or 21%, to \$6.9 million for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021. This change was primarily driven by a \$1.3 million increase in compensation expenses, mainly as a result of increased headcount, partially offset by a \$0.1 million decrease in clinical study expenses.

Selling, general and administrative expenses

SG&A expenses increased \$17.7 million, or 98%, to \$35.9 million for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021. This was primarily driven by a \$9.9 million increase in compensation expenses, mainly as a result of increased headcount, a \$1.8 million increase in travel expenses, a \$1.6 million increase in non-cash stock-based compensation expense, a \$1.5 million increase in marketing and advertising expenses associated with the commercialization of Barostim in the U.S., a \$1.3 million increase in public company costs, and a \$1.2 million increase in consulting fees.

Interest expense

Interest expense decreased \$1.8 million for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021. This decrease was driven by the repayment of the outstanding debt under the Horizon loan agreement in November 2021.

Other income (expense), net

Other income, net was \$0.2 million for the nine months ended September 30, 2022, compared to other expense, net of \$13.4 million for the nine months ended September 30, 2021. The expense for the nine months ended September 30, 2021 was primarily driven by the increase in fair value of the convertible preferred stock warrant liability from December 31, 2020 to July 2, 2021, which is the date the warrants converted to common stock warrants. As these preferred stock warrants converted to common stock warrants upon the IPO, there is no longer a change in fair value recorded in other income (expense), net.

Provision for income taxes

Provision for income taxes was nominal for each of the nine months ended September 30, 2022 and September 30, 2021.

Liquidity, capital resources and plan of operations

We have incurred significant operating losses and negative cash flows from operations since our inception, and we anticipate that we will incur significant losses for at least the next several years. As of September 30, 2022 and December 31, 2021, we had cash and cash equivalents of \$110.0 million and \$142.1 million, respectively. For the three months ended September 30, 2022 and 2021, our net losses were \$9.8 million and \$6.1 million, respectively. For the nine months ended September 30, 2022 and 2021, our net losses were \$30.9 million and \$32.5 million, respectively. Our net cash used in operating activities for the nine months ended September 30, 2022 and 2021 was \$31.8 million and \$20.7 million, respectively.

Prior to the IPO, our operations were financed primarily by aggregate net proceeds from the sale of our convertible preferred stock of \$383.1 million, as well as debt financings. In September 2019, we entered into

the Horizon loan agreement to borrow \$20.0 million, which was fully repaid on November 3, 2021. In July 2020, we completed an equity financing pursuant to which we issued 62,500,000 shares of Series G convertible preferred stock at a price of \$0.80 per share, for net proceeds of \$49.8 million after deducting offering expenses. On July 2, 2021, we closed our IPO for net proceeds from the offering, after deducting the underwriting discount and other offering expenses payable by us, of \$133.2 million. On October 31, 2022, we entered into a loan and security agreement under which we may borrow, subject to our achievement of certain milestones, up to a total of \$50.0 million in a series of term loans described in Note 13 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q and we borrowed \$7.5 million of such total on that date to fund our commercial and investment efforts.

Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our investment in our U.S. commercial infrastructure and sales forces;
- the degree and rate of market acceptance of Barostim and the ability for our customers to obtain appropriate levels of reimbursement;
- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution;
- our R&D activities for product enhancements and to expand our indications;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our need to implement additional infrastructure and internal systems;
- our ability to hire additional personnel to support our operations as a public company; and
- the emergence of competing technologies or other adverse market developments.

We believe that our existing cash resources and term loan facility together with revenue will be sufficient to meet our forecasted requirements for operating liquidity, capital expenditures and debt services for at least the next three years. If these sources are insufficient to satisfy our liquidity requirements, however, we may seek to sell additional equity or enter into an additional loan agreement. If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Additional debt financing, if available, may involve covenants further restricting our operations or our ability to incur additional debt. Any such debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

Additional financing may not be available at all or may only be available in amounts or on terms that we do not deem to be favorable. If we are unable to obtain additional financing when needed to satisfy our liquidity requirements, we may be required to delay the commercialization and marketing of Barostim.

Cash flows

The following table sets forth the primary sources and uses of cash for each of the periods indicated below:

<i>(in thousands)</i>	Nine months ended September 30 <i>(unaudited)</i>	
	2022	2021
Net cash (used in) provided by:		
Operating activities	\$ (31,836)	\$ (20,717)
Investing activities	(606)	(645)
Financing activities	376	133,170
Effect of exchange rate changes on cash and cash equivalents	(21)	(7)
Net change in cash and cash equivalents	<u>\$ (32,087)</u>	<u>\$ 111,801</u>

Cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2022, was \$31.8 million and consisted primarily of a net loss of \$30.9 million and a decrease in net operating assets of \$4.1 million, partially offset by a non-cash charge of \$2.8 million related to stock-based compensation expense. Net operating assets consisted primarily of inventory, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses to support the growth of our operations.

Net cash used in operating activities for the nine months ended September 30, 2021 was \$20.7 million and consisted primarily of a net loss of \$32.5 million and a decrease in net operating assets of \$3.0 million, partially offset by non-cash charges of \$13.3 million related to the fair value adjustment to our convertible preferred stock warrants and \$1.2 million from non-cash stock-based compensation expense. Net operating assets consisted primarily of inventory, accounts receivable and accrued expenses to support the growth of our operations.

Cash used in investing activities:

Cash used in investing activities was \$0.6 million for each of the nine months ended September 30, 2022 and 2021, and consisted of purchases of property and equipment.

Cash provided by financing activities:

Net cash provided by financing activities for the nine months ended September 30, 2022, was \$0.4 million and consisted of \$0.3 million related to proceeds from the ESPP and \$0.1 million related to proceeds from the exercise of common stock options.

Net cash provided by financing activities for the nine months ended September 30, 2021 was \$133.2 million and consisted primarily of proceeds from the issuance of common stock of \$133.2 million.

Contractual obligations and commitments

There have been no material changes to our contractual obligations as of September 30, 2022, as compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021.

Critical accounting policies and estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires our management to make estimates and judgments that affect the amounts reported in our condensed consolidated financial statements and accompanying notes included elsewhere in this Quarterly Report on Form 10-Q. We base our estimates on historical experience and on various other assumptions that we

believe to be reasonable and supportable under the circumstances. The results of this evaluation then form the basis for making judgments about the carrying values 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 such differences may be material to our condensed consolidated financial statements.

While our significant accounting policies are more fully described in Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to the portrayal of our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Stock-based compensation

We maintain an equity incentive plan that was adopted in 2001 to provide long-term incentives for employees, consultants, and members of the Board of Directors. The plan allows for the issuance of non-statutory and incentive stock options to employees and non-statutory stock options to consultants and non-employee directors. In connection with the IPO, we adopted the 2021 Plan under which we may grant equity incentive awards to eligible employees (including our named executive officers), non-employee directors and consultants in order to enable us to obtain and retain services of these individuals, which we deem as essential to our long-term success.

We recognize equity-based compensation expense for awards of equity instruments to employees and non-employees based on the grant date fair value of those awards in accordance with ASC 718. ASC 718 requires all equity-based compensation awards to employees and non-employee directors, including grants of restricted shares and stock options, to be recognized as expense in the condensed consolidated statements of operations and comprehensive loss based on their grant date fair values. We estimate the grant date fair value of stock options using the Black-Scholes option pricing model. We use an estimate of the value of our common stock, with the assistance of an independent appraiser, to determine the fair value of options.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (i) the fair value of common stock, (ii) the expected share price volatility, (iii) the expected term of the award, (iv) the risk-free interest rate and (v) the expected dividend yield.

- Fair value of common stock — Given the absence of a public trading market for our common stock prior to the IPO, the fair value of our common stock was determined by our Board of Directors with the assistance of an unrelated third-party valuation firm. The valuation was determined in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held Company Equity Securities Issued as Compensation. For the valuation as of the date of pricing of the IPO, the fair value of our common stock was determined by our Board of Directors to be the public offering price of the shares of common stock issued in the IPO. For valuations after the completion of the IPO, our Board of Directors determines the fair value of each share of common stock based on the closing price of our common stock as reported on the date of grant. Future expense amounts for any particular period could be affected by changes in our assumptions or market conditions.
- Expected share price volatility — Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar (guideline) companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The group of guideline companies have characteristics similar to us, including stage of product development and focus on the life science industry.
- Expected term of an award — Determined based on our analysis of historical exercise behavior while taking into consideration various participant demographics and option characteristics. We utilize the simplified method to develop the estimate of the expected term.

- Risk-free interest rate — Based on a treasury instrument whose term is consistent with the expected term of the stock options.
- Expected dividend yield — We assume an expected dividend yield of zero, as we have never paid dividends and have no current plans to pay any dividends on our common stock.

We account for forfeitures as they occur. We expense the fair value of our equity-based compensation awards granted to employees on a straight-line basis over the associated service period, which is generally the period in which the related services are received.

JOBS Act accounting election

The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

Recent accounting pronouncements

A discussion of recent accounting pronouncements is included in Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents, which are carried at quoted market prices. We do not currently use or plan to use financial derivatives in our investment portfolio.

Foreign currency exchange rate risk

Portions of our revenue and operating expenses that are incurred outside the U.S. are thus denominated in foreign currencies and subject to fluctuations due to changes in foreign currency exchange rates, particularly changes in the Euro. Additionally, fluctuations in foreign currency exchange rates may cause us to recognize transaction gains and losses in our condensed consolidated statements of operations and comprehensive loss. To date, foreign currency transaction realized gains and losses have not been material to our condensed consolidated financial statements, and we have not engaged in any foreign currency hedging transactions. As our international operations grow, we will continue to reassess our approach to managing the risks relating to fluctuations in currency rates.

Inflation risk

Inflationary factors, such as increases in our cost of goods sold and operating expenses, may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, a high rate of inflation in the future may have an adverse effect on our ability to maintain and increase our gross margin and selling and marketing and operating expenses as a percentage of our revenue if the selling prices of our products do not increase as much as or more than these increased costs.

Credit risk

As of September 30, 2022 and December 31, 2021, our cash and cash equivalents were maintained with one financial institution in the U.S., and our current deposits are likely in excess of insured limits. We believe this institution has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and other procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures 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 our chief financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this Quarterly Report on Form 10-Q.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended September 30, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors

For a discussion of our potential risks and uncertainties, see the information in Part I, Item IA. “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021. There have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021.

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

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of CVRx, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 7, 2021)
3.2	Amended and Restated By-Laws of CVRx, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on July 7, 2021)
31.1†	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2†	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1†	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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- 32.2† [Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002](#)
- 101.INS† Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
- 101.SCH† Inline XBRL Taxonomy Extension Schema Document
- 101.CAL† Inline XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF† Inline XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB† Inline XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE† Inline XBRL Taxonomy Extension Presentation Linkbase Document
- 104† Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

† Filed herewith.

SIGNATURES

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

Date: November 4, 2022

CVRX, INC.

By: /s/ Nadim Yared
Name: Nadim Yared
Title: President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Jared Oasheim
Name: Jared Oasheim
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Nadim Yared, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CVRx, 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 controls 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: November 04, 2022

By: /s/ Nadim Yared

Name: Nadim Yared

Title: President and Chief Executive Officer

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Jared Oasheim, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CVRx, 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 controls 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: November 04, 2022

By: /s/ Jared Oasheim
Name: Jared Oasheim
Title: Chief Financial Officer

Certification of CEO 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 CVRx, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2022 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, the undersigned, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 04, 2022

By: /s/ Nadim Yared

Name: Nadim Yared

Title: President and Chief Executive Officer

Certification of CFO 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 CVRx, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2022 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, the undersigned, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 04, 2022

By: /s/ Jared Oasheim

Name: Jared Oasheim

Title: Chief Financial Officer
