Table of Contents

**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, 2023**

**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** | **41-1983744** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(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 24, 2023, there were 20,815,635 shares of the registrant's common stock, par value $0.01 per share outstanding.

## TABLE OF CONTENTS

**CVRx, Inc.**
**Quarterly Report on Form 10-Q**
**For the quarterly period ended September 30, 2023**

***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 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, 2022, which are summarized below, as updated in Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q. 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, 2022, as updated in Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q. 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 (three of whom are affiliated with our principal stockholders) own a significant percentage of our stock and will be 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 increase 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 continue to maintain and grow sales and marketing capabilities, we will be unable to 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 highly 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, price fluctuations and ongoing supply chain disruptions, 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 or defend ourselves against intellectual property disputes, which could be expensive, 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, 2023 | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 82,993 | $ 106,194 |
| Accounts receivable, net of allowances of $506 and $679, respectively | 6,372 | 5,504 |
| Inventory | 10,887 | 6,957 |
| Prepaid expenses and other current assets | 3,345 | 4,223 |
| Total current assets | 103,597 | 122,878 |
| Property and equipment, net | 1,723 | 1,698 |
| Operating lease right-of-use asset | 1,058 | 334 |
| Other non-current assets | 26 | 27 |
| Total assets | $ 106,404 | $ 124,937 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,133 | $ 1,719 |
| Accrued expenses | 6,274 | 6,369 |
| Total current liabilities | 7,407 | 8,088 |
| Long-term debt | 14,294 | 6,747 |
| Operating lease liability, non-current portion | 916 | 117 |
| Other long-term liabilities | 960 | 805 |
| Total liabilities | 23,577 | 15,757 |
| Commitments and contingencies (Note 10) | | |
| Stockholders' equity: | | |
| Common stock, $0.01 par value, 200,000,000 authorized as of September 30, 2023 and December 31, 2022; 20,813,612 and 20,663,736 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively | 208 | 207 |
| Additional paid-in capital | 551,045 | 545,362 |
| Accumulated deficit | (468,218) | (436,182) |
| Accumulated other comprehensive loss | (208) | (207) |
| Total stockholders' equity | 82,827 | 109,180 |
| Total liabilities and stockholders' equity | $ 106,404 | $ 124,937 |

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, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Revenue | $ 10,511 | $ 6,186 | $ 27,990 | $ 15,293 |
| Cost of goods sold | 1,691 | 1,340 | 4,536 | 3,490 |
| Gross profit | 8,820 | 4,846 | 23,454 | 11,803 |
| Operating expenses: | | | | |
| Research and development | 2,696 | 2,293 | 9,392 | 6,906 |
| Selling, general and administrative | 15,652 | 12,679 | 47,504 | 35,945 |
| Total operating expenses | 18,348 | 14,972 | 56,896 | 42,851 |
| Loss from operations | (9,528) | (10,126) | (33,442) | (31,048) |
| Interest expense | (499) | — | (1,220) | — |
| Other income, net | 1,056 | 328 | 2,734 | 237 |
| Loss before income taxes | (8,971) | (9,798) | (31,928) | (30,811) |
| Provision for income taxes | (40) | (32) | (108) | (81) |
| Net loss | (9,011) | (9,830) | (32,036) | (30,892) |
| Cumulative translation adjustment | (21) | (8) | (1) | (21) |
| Comprehensive loss | $ (9,032) | $ (9,838) | $ (32,037) | $ (30,913) |
| Net loss per share, basic and diluted | $ (0.43) | $ (0.48) | $ (1.55) | $ (1.51) |
| Weighted-average common shares used to compute net loss per share, basic and diluted | 20,801,350 | 20,576,838 | 20,730,024 | 20,512,254 |

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

**CVRx, INC.**
**Condensed Consolidated Statements of Stockholders' Equity**
**(In thousands, except share data)**
**(Unaudited)**

| | Common stock | | Additional paid-in capital | Accumulated deficit | Accumulated other comprehensive loss | Total stockholders' equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| Balances as of June 30, 2023 | 20,750,910 | $ 208 | $ 549,150 | $ (459,207) | $ (187) | $ 89,964 |
| Exercise of stock options | 62,702 | — | 363 | — | — | 363 |
| Employee stock compensation | — | — | 1,532 | — | — | 1,532 |
| Net loss for the three months ended September 30, 2023 | — | — | — | (9,011) | — | (9,011) |
| Cumulative translation adjustment | — | — | — | — | (21) | (21) |
| **Balances as of September 30, 2023** | **20,813,612** | **$ 208** | **$ 551,045** | **$ (468,218)** | **$ (208)** | **$ 82,827** |
| | | | | | | |
| 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** |

| | Common stock | | Additional paid-in capital | Accumulated deficit | Accumulated other comprehensive loss | Total stockholders' equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| Balances as of December 31, 2022 | 20,663,736 | $ 207 | $ 545,362 | $ (436,182) | $ (207) | $ 109,180 |
| Exercise of stock options | 115,455 | 1 | 518 | — | — | 519 |
| Proceeds from Employee Stock Purchase Plan | 34,421 | — | 452 | — | — | 452 |
| Employee stock compensation | — | — | 4,713 | — | — | 4,713 |
| Net loss for the nine months ended September 30, 2023 | — | — | — | (32,036) | — | (32,036) |
| Cumulative translation adjustment | — | — | — | — | (1) | (1) |
| **Balances as of September 30, 2023** | **20,813,612** | **$ 208** | **$ 551,045** | **$ (468,218)** | **$ (208)** | **$ 82,827** |
| | | | | | | |
| 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** |

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, | |
|---|---|---|
| | **2023** | **2022** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (32,036) | $ (30,892) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 4,713 | 2,822 |
| Depreciation of property and equipment | 393 | 284 |
| Loss on disposal of equipment | 4 | — |
| Amortization of deferred financing costs and loan discount | 114 | — |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (868) | (2,737) |
| Inventory | (3,930) | (2,184) |
| Prepaid expenses and other current assets | 902 | (479) |
| Accounts payable | (586) | 766 |
| Accrued expenses | 112 | 584 |
| Net cash used in operating activities | (31,182) | (31,836) |
| **Cash flows from investing activities:** | | |
| Purchase of property and equipment | (422) | (606) |
| Net cash used in investing activities | (422) | (606) |
| **Cash flows from financing activities:** | | |
| Proceeds from the exercise of common stock options | 519 | 81 |
| Proceeds from Employee Stock Purchase Plan | 452 | 295 |
| Proceeds from debt financing | 7,500 | — |
| Debt financing costs | (67) | — |
| Net cash provided by financing activities | 8,404 | 376 |
| Effect of currency exchange on cash and cash equivalents | (1) | (21) |
| **Net change in cash and cash equivalents** | (23,201) | (32,087) |
| Cash and cash equivalents at beginning of period | 106,194 | 142,072 |
| **Cash and cash equivalents at end of period** | $ 82,993 | $ 109,985 |
| **Supplemental Information:** | | |
| Cash paid for interest | $ 979 | $ — |
| Cash paid for income taxes | $ 4 | $ 4 |

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, 2023 and December 31, 2022, cash equivalents consisted of money market funds, which are stated at cost and approximate fair value. Additionally, as of September 30, 2023 and December 31, 2022, a majority of our cash and cash equivalents were maintained with two financial institutions in the U.S., and our current deposits are likely in excess of insured limits.

**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 evaluate the collectability of our accounts receivable based on known collection risks and historical experience. In circumstances where we are aware of a specific customer's inability to meet its financial obligations to us, we record a specific allowance for bad debts against amounts due to reduce the carrying amount of accounts receivable to the amount we reasonably believe will be collected.

**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 (“ASC”) 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 ASC 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 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.

## 3. Selected balance sheet information

Inventory consists of the following at:

| *(in thousands)* | September 30, 2023 | December 31, 2022 |
|---|---|---|
| Raw material | $ 4,875 | $ 2,390 |
| Work-in-process | 1,173 | 1,033 |
| Finished goods | 4,839 | 3,534 |
| | $ 10,887 | $ 6,957 |

Property and equipment, net consists of the following at:

| *(in thousands)* | September 30, 2023 | December 31, 2022 |
|---|---|---|
| Office furniture and equipment | $ 402 | $ 350 |
| Lab equipment | 2,685 | 2,684 |
| Computer equipment and software | 772 | 618 |
| Leasehold improvements | 98 | 95 |
| Capital equipment in process | 425 | 231 |
| | 4,382 | 3,978 |
| Less: Accumulated depreciation and amortization | 2,659 | 2,280 |
| | $ 1,723 | $ 1,698 |

Depreciation is determined using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the term of the lease. Depreciation expense was $137,000 and $127,000 for the three months ended September 30, 2023 and 2022, respectively, and $393,000 and $284,000 for the nine months ended September 30, 2023 and 2022, respectively.

Accrued expenses consist of the following at:

| *(in thousands)* | September 30, 2023 | December 31, 2022 |
|---|---|---|
| Bonuses | $ 2,366 | $ 2,303 |
| Paid time off | 1,212 | 960 |
| Clinical trial and other professional fees | 892 | 1,733 |
| Customer rebates | 382 | 256 |
| Employee Stock Purchase Plan | 280 | — |
| Operating lease liability, current portion | 170 | 222 |
| Taxes | 103 | 120 |
| Other | 869 | 775 |
| | $ 6,274 | $ 6,369 |

## 4. Debt

**Innovatus Loan Agreement**

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. On March 10, 2023, the Company borrowed the $7.5 million remaining under the first tranche of the Loan Agreement, with $4.0 million received on March 13, 2023, and $3.5 million received on March 15, 2023. The Loan Agreement initially requires interest only payments through November 2027, followed by three monthly principal and interest payments. A final payment of $0.7 million, equal to 4.5% of the original borrowed principal, is due in January 2028. The term loans advanced pursuant to the Loan Agreement (collectively, the "Term Loans") 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 are secured by substantially all of the personal property of the Company. The Company has the option to draw down (i) up to $30.0 million less the amount funded from the first tranche between September 1, 2023 and December 15, 2023 if the Company achieves trailing three months revenue of $5.75 million prior to June 30, 2023 (which was achieved), and (ii) up to $20.0 million between September 1, 2024 and December 15, 2024 if the Company achieves trailing three months revenue of $9.0 million prior to June 30, 2024. A performance covenant takes effect at the earlier of September 30, 2025 or the third tranche funding, requiring that the Company achieve 50% of the trailing twelve months revenue target set in the Board-approved revenue plan in effect for such period. The Loan Agreement requires the payment of certain penalties if the Term Loans are paid off prior to maturity for any reason, including pursuant to an acceleration clause, and includes various restrictive covenants, including a restriction on the payment of dividends or making other distributions or payments on the Company's capital stock, subject to limited exceptions. The Company was in compliance with these covenants as of September 30, 2023.

In connection with the Loan Agreement, the Company recorded $0.8 million of debt issuance costs and discounts as a reduction of long-term debt.

The annual principal maturities of debt under the Loan Agreement are as follows:

| *(in thousands)* | September 30, 2023 |
|---|---|
| 2023 | $ — |
| 2024 | — |
| 2025 | — |
| 2026 | — |
| 2027 | 10,000 |
| 2028 | 5,000 |
| | 15,000 |
| Less: Unamortized debt costs and discounts | (706) |
| Long-term debt | $ 14,294 |

## 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 was scheduled to expire August 31, 2024. On April 21, 2023, we extended the operating lease for our office space in Minneapolis, Minnesota for an additional 49 consecutive months through August 31, 2028. 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 three

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, as it is not reasonably certain of exercise.

In addition to base rent, we also pay our proportionate share of operating expenses, as defined in the lease. These payments are made monthly and are 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:

| *(in thousands)* | September 30, 2023 | December 31, 2022 |
|---|---|---|
| **Right-of-use assets:** | | |
| Operating lease right-of-use asset | $ 1,058 | $ 334 |
| **Operating lease liabilities:** | | |
| Accrued expenses | 170 | 222 |
| Operating lease liability, non-current portion | 916 | 117 |
| Total operating lease liabilities | $ 1,086 | $ 339 |

Maturities of our lease liability for our operating lease are as follows as of September 30, 2023:

| *(in thousands)* | September 30, 2023 |
|---|---|
| 2023, remainder | $ 59 |
| 2024 | 223 |
| 2025 | 255 |
| 2026 | 262 |
| 2027 | 270 |
| 2028 | 161 |
| Total undiscounted lease payments | 1,230 |
| Less: imputed interest | (144) |
| Present value of lease liability | $ 1,086 |

As of September 30, 2023, the remaining lease term was 4.9 years and the discount rate was 5.0%. The operating cash outflows from our operating lease were $0.3 million for each of the nine months ended September 30, 2023 and 2022.

## 6. Stockholders' equity

### Common Stock Warrants

The Company has common stock warrants 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 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 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 1,033,186 shares being reserved for issuance under the 2021 Plan as of January 1, 2023. 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, 2023, there were 1,724,683 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 the initial public offering (the "IPO"), 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 |
|---|---|---|---|
| | | | *(in thousands)* |
| Balance as of December 31, 2022 | 3,756,835 | $ 8.28 | $ 36,616 |
| Granted | 1,086,876 | 14.06 | |
| Cancelled / Forfeited | (264,160) | 10.42 | |
| Exercised | (115,455) | 4.50 | |
| Balance as of September 30, 2023 | 4,464,096 | $ 9.66 | $ 37,331 |
| Options exercisable as of September 30, 2023 | 2,311,211 | $ 7.05 | $ 25,374 |

As of September 30, 2023, 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, 2023, the weighted average remaining contractual life was 7.5 years. For options exercisable as of September 30, 2023, the weighted average remaining contractual life was 6.4 years.

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 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 206,637 shares being reserved for issuance under the ESPP as of January 1, 2023. The ESPP permits 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 September 30, 2022. For the nine months ended September 30, 2023, 34,421 shares of common stock were purchased under the ESPP for $0.5 million of employee contributions. As of September 30, 2023, there were 540,489 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 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, 2023 and 2022:

| | September 30, | |
|---|---|---|
| | 2023 | 2022 |
| Weighted average fair value of options granted | $ 10.59 | $ 4.56 |
| Expected term (in years) — non-officer employees | 5.5 to 6.1 | 5.5 to 6.1 |
| Expected term (in years) — officer employees | 2.5 to 6.1 | 3.2 to 6.1 |
| Expected volatility | 77.2% to 79.6 % | 56.3% to 58.6 % |
| Expected dividend yield | — % | — % |
| Risk-free interest rate | 3.40% to 4.61 % | 1.75% to 3.97 % |

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, 2023 and 2022:

| | September 30, | |
|---|---|---|
| | 2023 | 2022 |
| Weighted average fair value per ESPP purchase right | $ 9.01 | $ 2.85 |
| Expected term (in years) | 0.5 | 0.5 |
| Expected volatility | 76.2% to 84.6 % | 51.3% to 62.9 % |
| Expected dividend yield | — % | — % |
| Risk-free interest rate | 4.77% to 5.53 % | 0.22% to 2.52 % |

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:

| *(in thousands)* | Three Months Ended September 30, 2023 | Three Months Ended September 30, 2022 | Nine months ended September 30, 2023 | Nine months ended September 30, 2022 |
|---|---|---|---|---|
| Stock options | $ 1,419 | $ 866 | $ 4,403 | $ 2,657 |
| Employee Stock Purchase Plan | 113 | 63 | 310 | 165 |
| Total stock-based compensation expense | $ 1,532 | $ 929 | $ 4,713 | $ 2,822 |
| | | | | |
| Selling, general & administrative | $ 1,290 | $ 785 | $ 3,728 | $ 2,402 |
| Research & development | 221 | 132 | 927 | 367 |
| Cost of goods sold | 21 | 12 | 58 | 53 |
| | $ 1,532 | $ 929 | $ 4,713 | $ 2,822 |

As of September 30, 2023, unrecognized compensation expense related to unvested stock-based compensation arrangements was $14.1 million. As of September 30, 2023, the related weighted average period over which the expense is expected to be recognized is approximately 2.5 years.

## 8. Income taxes

As of September 30, 2023 and December 31, 2022, 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, 2023 and 2022 was $40,000 and $32,000, respectively. Provision for income taxes for the nine months ended September 30, 2023 and 2022 was $108,000 and $81,000, respectively.

As of December 31, 2022, the Company had federal and state net operating loss carryforwards ("NOLs") of approximately $361.0 million and $6.2 million, respectively. The federal NOLs began expiring in 2021 and the state NOLs began expiring in 2020. As of December 31, 2022, the Company had federal and state tax credit carryforwards of approximately $9.3 million and $1.8 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 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, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| **Numerator:** | | | | |
| Net loss | $ (9,011) | $ (9,830) | $ (32,036) | $ (30,892) |
| **Denominator:** | | | | |
| Weighted average common shares outstanding — basic and diluted | 20,801,350 | 20,576,838 | 20,730,024 | 20,512,254 |
| Net loss per share attributable to common stockholders — basic and diluted | $ (0.43) | $ (0.48) | $ (1.55) | $ (1.51) |

The Company's potentially dilutive securities, which include stock options 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, | |
|---|---|---|
| | 2023 | 2022 |
| Options to purchase common stock | 4,464,096 | 3,723,499 |
| Warrants to purchase common stock | 716,131 | 716,131 |
| | 5,180,227 | 4,439,630 |

## 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, 2023 or December 31, 2022.

## 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, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| U.S. | $ 9,579 | $ 5,039 | $ 24,818 | $ 12,035 |
| Germany | 802 | 933 | 2,819 | 2,744 |
| Other countries | 130 | 214 | 353 | 514 |
| | $ 10,511 | $ 6,186 | $ 27,990 | $ 15,293 |

As of September 30, 2023 and December 31, 2022, long-lived assets were located primarily in the U.S.

## 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 ("FDA") to improve the symptoms of patients with HFrEF and is CE Marked for HFrEF and resistant hypertension.

Since our inception, 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 significant revenue from product sales and become profitable will depend on our ability to continue to successfully commercialize Barostim and any product enhancements we may advance in the future. We expect to derive future revenue by continuing to both expand our own dedicated salesforce and increase awareness of Barostim among payors, physicians, and patients.

Our sales and marketing efforts are directed at electrophysiologists, HF specialists, interventional and 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 while simultaneously developing processes to engage commercial payors. All Medicare Administrative Contractors have retired their official automatic coverage denial policies for our Current Procedural Terminology codes, thereby allowing hospitals to submit payment requests for the Barostim procedure to be reviewed on a claim-

by-claim basis. Our reimbursement strategy involves continuing to broaden our current coverage and build our in-house market access team to obtain 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 Economic Area ("EEA"), 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 credit facilities. We then 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 used 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 have continued investing in research and development 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 4 to our condensed 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. On March 10, 2023, we borrowed the $7.5 million remaining under the first tranche of the Loan Agreement, with $4.0 million received on March 13, 2023, and $3.5 million received on March 15, 2023. Following this draw, we have $15.0 million in outstanding Term Loans under the Loan Agreement. The Loan Agreement provides for up to two additional tranches of loans totaling up to an additional $35.0 million based on timing, the achievement of certain trailing three months revenue targets and other conditions set forth in the Loan Agreement. 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 financing.

## Recent developments

In February 2023, we were unblinded to the morbidity and mortality data from the BeAT-HF pivotal trial. The totality of the evidence from the trial shows long-term benefits for patients with HF. While the trial did not reach statistical significance on the primary endpoint, it did contain additional clinically meaningful prespecified analyses favoring Barostim. We filed a regulatory submission to the FDA for expanded labeling in early June 2023. If successful, this label expansion could expand our addressable patient population.

In August 2023, we delivered a presentation before the Centers for Medicare & Medicaid Services ("CMS") Advisory Panel on Hospital Outpatient Payment, resulting in a unanimous non-binding vote in favor of mapping Barostim to the higher paying code, New Technology APC1580, which would offer an average reimbursement of $45,000 to hospitals in 2024. If CMS instead decides to map Barostim to APC5465 without the transitional passthrough payment for 2024, which is the basis for our plans, then the average

reimbursement to hospitals will be approximately $30,000. The final outpatient payment rule is expected to be published in late November.

## 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;
- Seeking expanded labeling for Barostim and 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 steadily increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement changes. 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 well as by seeking expanded labeling for Barostim. 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.

***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 financing costs.

***Other income, net***

Other income, net consists primarily of interest income on our interest-bearing accounts, partially offset by 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, 2023, compared to the three months ended September 30, 2022***

| *(unaudited and in thousands)* | Three months ended September 30, 2023 | 2022 | Change $ | Change % |
|---|---|---|---|---|
| Revenue | $ 10,511 | $ 6,186 | $ 4,325 | 70 % |
| Cost of goods sold | 1,691 | 1,340 | 351 | 26 % |
| Gross profit | 8,820 | 4,846 | 3,974 | 82 % |
| Gross margin | 84 % | 78 % | | |
| Operating expenses: | | | | |
| Research and development | 2,696 | 2,293 | 403 | 18 % |
| Selling, general and administrative | 15,652 | 12,679 | 2,973 | 23 % |
| Total operating expenses | 18,348 | 14,972 | 3,376 | 23 % |
| Loss from operations | (9,528) | (10,126) | 598 | (6)% |
| Interest expense | (499) | — | (499) | NM |
| Other income, net | 1,056 | 328 | 728 | 222 % |
| Loss before income taxes | (8,971) | (9,798) | 827 | (8)% |
| Provision for income taxes | (40) | (32) | (8) | 25 % |
| Net loss | $ (9,011) | $ (9,830) | $ 819 | (8)% |

NM – Not meaningful

***The following table provides revenue by geography:***

| *(unaudited and in thousands)* | Three months ended September 30, 2023 | 2022 | Change $ | Change % |
|---|---|---|---|---|
| United States | $ 9,579 | $ 5,039 | $ 4,540 | 90 % |
| Europe | 932 | 1,147 | (215) | (19)% |
| Total Revenue | $ 10,511 | $ 6,186 | $ 4,325 | 70 % |

Revenue was $10.5 million for the three months ended September 30, 2023, an increase of $4.3 million, or 70%, over the three months ended September 30, 2022.

Revenue generated in the U.S. was $9.6 million for the three months ended September 30, 2023, an increase of $4.5 million, or 90%, over the three months ended September 30, 2022. HF revenue units in the U.S. totaled 303 and 167 for the three months ended September 30, 2023 and 2022, respectively. HF revenue in the U.S. totaled $9.4 million and $4.9 million for the three months ended September 30, 2023 and 2022, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

As of September 30, 2023, we had a total of 159 active implanting centers, as compared to 91 as of September 30, 2022. Active implanting centers are customers that have completed at least one commercial HF implant in the last 12 months. As of September 30, 2023, we had a total of 35 sales territories as compared to 23 as of September 30, 2022.

Revenue generated in Europe was $0.9 million for the three months ended September 30, 2023, a decrease of $0.2 million, or 19%, over the three months ended September 30, 2022. Total revenue units in Europe decreased to 47 for the three months ended September 30, 2023, as compared to 61 in the prior year period. As of both September 30, 2023 and 2022, we had six sales territories in Europe.

*Cost of goods sold and gross margin*

Cost of goods sold increased $0.4 million, or 26%, to $1.7 million for the three months ended September 30, 2023, compared to the three months ended September 30, 2022. This increase was primarily due to higher sales of Barostim.

Gross profit was $8.8 million for the three months ended September 30, 2023, an increase of $4.0 million, or 82%, over the three months ended September 30, 2022. Gross margin increased to 84% for the three months ended September 30, 2023, compared to 78% for the three months ended September 30, 2022. This increase was due primarily to a decrease in the cost per unit driven by an increase in the production volume.

*Research and development expenses*

R&D expenses increased $0.4 million, or 18%, to $2.7 million for the three months ended September 30, 2023, compared to the three months ended September 30, 2022. This change was driven by a $0.3 million increase in compensation expenses as a result of increased headcount and a $0.1 million increase in non-cash stock-based compensation expense.

*Selling, general and administrative expenses*

SG&A expenses increased $3.0 million, or 23%, to $15.7 million for the three months ended September 30, 2023, compared to the three months ended September 30, 2022. This change was primarily driven by a $1.9 million increase in compensation expenses, mainly as a result of increased headcount, a $0.5 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 $0.1 million increase in travel expenses.

*Interest expense*

Interest expense increased $0.5 million for the three months ended September 30, 2023, compared to the three months ended September 30, 2022. This increase was driven by the interest expense on borrowings under the Loan Agreement entered into on October 31, 2022.

*Other income, net*

Other income, net increased $0.7 million for the three months ended September 30, 2023, compared to the three months ended September 30, 2022. This increase was primarily driven by higher interest rates on interest-bearing accounts partially offset by a lower cash balance.

*Provision for income taxes*

Provision for income taxes was nominal for each of the three months ended September 30, 2023 and September 30, 2022.

***Consolidated results of operations for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022***

| | Nine months ended September 30, | | Change | |
|---|---|---|---|---|
| *(unaudited and in thousands)* | 2023 | 2022 | $ | % |
| Revenue | $ 27,990 | $ 15,293 | $ 12,697 | 83 % |
| Cost of goods sold | 4,536 | 3,490 | 1,046 | 30 % |
| Gross profit | 23,454 | 11,803 | 11,651 | 99 % |
| Gross margin | 84 % | 77 % | | |
| Operating expenses: | | | | |
| Research and development | 9,392 | 6,906 | 2,486 | 36 % |
| Selling, general and administrative | 47,504 | 35,945 | 11,559 | 32 % |
| Total operating expenses | 56,896 | 42,851 | 14,045 | 33 % |
| Loss from operations | (33,442) | (31,048) | (2,394) | 8 % |
| Interest expense | (1,220) | — | (1,220) | NM |
| Other income, net | 2,734 | 237 | 2,497 | NM |
| Loss before income taxes | (31,928) | (30,811) | (1,117) | 4 % |
| Provision for income taxes | (108) | (81) | (27) | 33 % |
| Net loss | $ (32,036) | $ (30,892) | $ (1,144) | 4 % |

NM – Not meaningful

***The following table provides revenue by geography:***

| | Nine months ended September 30, | | Change | |
|---|---|---|---|---|
| *(unaudited and in thousands)* | 2023 | 2022 | $ | % |
| United States | $ 24,818 | $ 12,035 | $ 12,783 | 106 % |
| Europe | 3,172 | 3,258 | (86) | (3)% |
| Total Revenue | $ 27,990 | $ 15,293 | $ 12,697 | 83 % |

Revenue was $28.0 million for the nine months ended September 30, 2023, an increase of $12.7 million, or 83%, over the nine months ended September 30, 2022.

Revenue generated in the U.S. was $24.8 million for the nine months ended September 30, 2023, an increase of $12.8 million, or 106%, over the nine months ended September 30, 2022. HF revenue units in the U.S. totaled 793 and 394 for the nine months ended September 30, 2023 and 2022, respectively. HF revenue in the U.S. totaled $24.5 million and $11.6 million for the nine months ended September 30, 2023 and 2022, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

As of September 30, 2023, we had a total of 159 active implanting centers, as compared to 91 as of September 30, 2022. Active implanting centers are customers that have completed at least one commercial HF implant in the last 12 months. As of September 30, 2023, we had a total of 35 sales territories as compared to 23 as of September 30, 2022.

Revenue generated in Europe was $3.2 million for the nine months ended September 30, 2023, a decrease of $0.1 million, or 3%, over the nine months ended September 30, 2022. Total revenue units in Europe decreased to 155 for the nine months ended September 30, 2023, as compared to 163 in the prior year period. As of both September 30, 2023 and 2022, we had six sales territories in Europe.

*Cost of goods sold and gross margin*

Cost of goods sold increased $1.0 million, or 30%, to $4.5 million for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. This increase was primarily due to higher sales of Barostim.

Gross profit was $23.5 million for the nine months ended September 30, 2023, an increase of $11.7 million, or 99%, over the nine months ended September 30, 2022. Gross margin increased to 84% for the nine months ended September 30, 2023, compared to 77% for the nine months ended September 30, 2022. This increase was due primarily to a decrease in the cost per unit driven by an increase in the production volume.

*Research and development expenses*

R&D expenses increased $2.5 million, or 36%, to $9.4 million for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. This change was driven by a $1.4 million increase in compensation expenses as a result of increased headcount, a $0.6 million increase in non-cash stock-based compensation expense and a $0.4 million increase in consulting fees.

*Selling, general and administrative expenses*

SG&A expenses increased $11.6 million, or 32%, to $47.5 million for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. This change was primarily driven by a $6.9 million increase in compensation expenses, mainly as a result of increased headcount, a $1.6 million increase in marketing and advertising expenses associated with the commercialization of Barostim in the U.S, a $1.3 million increase in travel expenses, a $1.3 million increase in non-cash stock-based compensation expense and a $0.6 million increase in consulting fees.

*Interest expense*

Interest expense increased $1.2 million for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. This increase was driven by the interest expense on borrowings under the Loan Agreement entered into on October 31, 2022.

*Other income, net*

Other income, net increased $2.5 million for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. This increase was primarily driven by higher interest rates on interest-bearing accounts partially offset by a lower cash balance.

*Provision for income taxes*

Provision for income taxes was nominal for each of the nine months ended September 30, 2023 and September 30, 2022.

## 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, 2023 and December 31, 2022, we had cash and cash equivalents of $83.0 million and $106.2 million, respectively. For the three months ended September 30, 2023 and 2022, our net losses were $9.0 million and $9.8 million, respectively. For the nine months ended September 30, 2023 and 2022, our net losses were $32.0 million and $30.9 million, respectively. Our net cash used in operating activities for the nine months ended September 30, 2023 and 2022 was $31.2 million and $31.8 million, respectively.

On October 31, 2022, we entered into the Loan 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 4 to our condensed 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. On March 10, 2023, we borrowed the $7.5 million remaining under the first tranche of the Loan Agreement, with $4.0 million received on March 13, 2023, and $3.5 million received on March 15, 2023. Following this draw, we have $15.0 million in outstanding Term Loans under the Loan Agreement. The Loan Agreement provides for up to two additional tranches of loans totaling up to an additional $35.0 million, based on timing, the achievement of certain trailing three months revenue targets and other conditions set forth in the Loan Agreement.

On November 4, 2022, we entered into an Equity Distribution Agreement with Piper Sandler & Co., as agent, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50.0 million in an “at-the-market” or ATM offering, to or through the agent. As of September 30, 2023, no shares have been sold.

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 Loan Agreement for Term Loans 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 or provide funding to execute or accelerate our growth strategies, however, we may seek to sell additional equity or enter into an additional loan agreement. If we were to 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:

| *(in thousands)* | Nine months ended September 30, *(unaudited)* 2023 | 2022 |
|---|---|---|
| Net cash (used in) provided by: | | |
| Operating activities | $ (31,182) | $ (31,836) |
| Investing activities | (422) | (606) |
| Financing activities | 8,404 | 376 |
| Effect of exchange rate changes on cash and cash equivalents | (1) | (21) |
| Net change in cash and cash equivalents | $ (23,201) | $ (32,087) |

*Cash used in operating activities*

Net cash used in operating activities for the nine months ended September 30, 2023 was $31.2 million and consisted primarily of a net loss of $32.0 million and a change in net operating assets of $4.4 million, partially offset by a non-cash charge of $4.7 million related to stock-based compensation expense. Net operating assets consisted primarily of accounts receivable, inventory, 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, 2022 was $31.8 million and consisted primarily of a net loss of $30.9 million and a change 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.

*Cash used in investing activities:*

Cash used in investing activities was $0.4 million and $0.6 million for each of the nine months ended September 30, 2023 and 2022, respectively, 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, 2023 was $8.4 million and consisted of $7.5 million related to proceeds under the Loan Agreement, $0.5 million related to proceeds from the ESPP and $0.5 million related to proceeds from the exercise of common stock options, partially offset by $0.1 million related to debt financing costs.

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.

## Contractual obligations and commitments

There have been no material changes to our contractual obligations as of September 30, 2023, as compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022.

## Critical accounting policies and estimates

For a discussion of our potential risks and uncertainties, see the information in Part II, Item 7. “Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical accounting policies and estimates" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022. We have

reviewed and determined that those critical accounting policies and estimates remain our critical accounting policies and estimates as of and for the nine months ended September 30, 2023.

## 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 and debt issued under the Loan Agreement, which are carried at quoted market prices and the prime rate, respectively. 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 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, 2023 and December 31, 2022, our cash and cash equivalents were maintained with financial institutions which we believe have sufficient assets and liquidity to conduct their operations in the ordinary course of business with little or no credit risk to us; however, our cash balances were in excess of insured limits.

## 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, 2023, 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, 2022. Other than the risk factors set forth below, there have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K.

***If third-party payors do not provide adequate coverage and reimbursement for the use of Barostim, our revenue will be negatively impacted.***

Medicare reimbursement levels are important to increasing adoption of Barostim because nearly two-thirds of the target patient population for Barostim is over the age of 65. Effective January 2021, CMS awarded Barostim a TPT payment for outpatient procedures that adds the device cost as a pass-through payment to the calculated procedure payment, which will remain in place through 2023. The calculated procedure payment depends on many factors, including the location of the hospitals and their billing practices, and may not adequately cover hospital costs associated with the procedure. CMS recently released the proposed Outpatient Prospective Payment System (or “OPPS”), for 2024, which did not address our March 2023 submission requesting assignment to one of the New Technology APC payment codes for 2024. We submitted formal comments on the proposed OPPS package to advocate for inclusion in the 2024 final rule to be released later this year. In August 2023, we delivered a presentation before the CMS Advisory Panel on Hospital Outpatient Payment, resulting in a unanimous non-binding vote in favor of mapping Barostim to the higher paying code, New Technology APC1580, which would offer an average reimbursement of $45,000 to hospitals in 2024. If CMS instead decides to map Barostim to APC5465 without the transitional passthrough payment for 2024, which is the basis for our plans, then the average reimbursement to hospitals will be approximately $30,000. The final outpatient payment rule is expected to be published in late November. There can be no assurance that our efforts to request the higher paying code or the CMS Advisory Panel’s vote will be successful in securing the higher paying code. Any future decline in the amount Medicare is willing to reimburse our customers for procedures using Barostim could make it difficult for new customers to adopt Barostim and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business. From time to time, physicians and hospitals have in the past experienced, and others may experience, delays in Medicare reimbursement, which have delayed or may delay their willingness to schedule additional Barostim procedures.

***If clinical studies for future indications do not produce results necessary to support regulatory clearance or approval in the U.S. or elsewhere, we will be unable to commercialize our products for these indications.***

We will likely need to conduct additional clinical studies in the future to support approval for new indications. For example, in February of 2023, we were unblinded to the morbidity and mortality data from the BeAT-HF pivotal trial that began in 2016. While the trial did not reach statistical significance on the primary endpoint, it did contain additional clinically meaningful prespecified analyses favoring Barostim. We filed a regulatory submission to the FDA for expanded labeling in early June 2023; however, the timing and scope of any such expansion is currently uncertain.

More generally, clinical testing takes many years, is expensive and carries uncertain outcomes. The initiation and completion of studies may be prevented, delayed, or halted for numerous reasons, including, but not limited to, the following:

- the FDA, institutional review boards ("IRBs"), ethics committees, European Union ("EU") competent authorities or other regulatory authorities do not approve a clinical study protocol, force us to modify a previously approved protocol, or place a clinical study on hold;
- patients do not enroll in, or enroll at a lower rate than we expect, or do not complete a clinical study;
- patients or investigators do not comply with study protocols;
- patients do not return for post-treatment follow-up at the expected rate;
- patients experience serious or unexpected adverse side effects for a variety of reasons that may or may not be related to our products, such as the advanced stage of co-morbidities that may exist at the time of treatment, causing a clinical study to be put on hold;
- sites participating in an ongoing clinical study withdraw, requiring us to engage new sites;
- difficulties or delays associated with establishing additional clinical sites;
- third-party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule, or perform in a manner inconsistent with the investigator agreement, clinical study protocol, good clinical practices, other FDA, IRB or ethics committee requirements and EEA member state or other foreign regulations governing clinical trials;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical studies or manufacturing facilities require us to undertake corrective action or suspend or terminate our clinical studies;
- changes in federal, state, or foreign governmental statutes, regulations or policies;
- interim results are inconclusive or unfavorable as to immediate and long-term safety or efficacy;
- the study design is inadequate to demonstrate safety and efficacy; or
- the statistical endpoints are not met.

Clinical trials can fail at any stage. Our clinical studies may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional clinical or non-clinical studies in addition to those we have planned. The impacts of the COVID-19 pandemic, which may have affected certain participants in the post-market pivotal trial, are being analyzed, and they may exacerbate certain risks described above. In addition, if the FDA determines for any reason, including safety or their risk-benefit analysis, that the results of a trial are negative, the FDA may decide to modify or revoke our existing approval, or such data may impact the adoption of Barostim. Moreover, a negative perception of clinical results for one indication for use could impact the use of Barostim for other FDA approved and clinically supported indications for use.

We could also encounter delays if the FDA concludes that our financial relationships with investigators result in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized.

Even if our products are approved in the U.S. and the EEA, comparable regulatory authorities of additional foreign countries must also approve the manufacturing and marketing of our products in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review

periods different from, and greater than, those in the U.S. or the EEA, including additional preclinical studies or clinical trials. Any of these occurrences may harm our business, financial condition, and prospects significantly.

***Barostim is also subject to extensive governmental regulation in foreign jurisdictions, such as Europe, and our failure to comply with applicable requirements could cause our business to suffer.***

In the EEA, Barostim was required to comply with the Essential Requirements laid down in Annex I to the EU Active Implantable Medical Devices Directive. Compliance with these requirements was a prerequisite to affixing the CE mark to Barostim. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE Mark to Barostim, we underwent a conformity assessment procedure, which varied according to the type of medical device and its classification. Except for low-risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer could issue an EU Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure required the intervention of a Notified Body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body would audit the Quality Management System and examine the Technical File for the manufacture, design, and final inspection of our devices. The Notified Body would issue a CE Certificate of Conformity following successful completion of this conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate would entitle the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EU Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the Essential Requirements must be based on, among other things, the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. With respect to active implantable medical devices or Class III devices, the manufacturer must conduct clinical studies to obtain the required clinical data, unless reliance on existing clinical data from equivalent devices can be justified. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming.

In order to continue to sell Barostim in Europe, we must comply with the Medical Devices Regulation (Regulation (EU) 2017/745 — "MDR") and its evolving transition requirements. We have submitted our application for Barostim to comply with the general safety and performance requirements of the EU MDR (which are similar to the Essential Requirements of the Active Implantable Medical Device Directive ("AIMDD")), and it is currently under review. Additionally, the EU did approve an amendment to the MDR which allows qualifying AIMDD CE certificates to be accepted through December of 2027. We have already met the qualifications identified within this amendment to allow continued distribution of Barostim through this time. Failing to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the EEA countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our Notified Body (the National Standards Authority of Ireland, or NSAI), which could impair our ability to market products in the EEA in the future.

## Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

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 |
| 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: October 31, 2023

**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)

**Exhibit 31.1**

**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: October 31, 2023

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

**Exhibit 31.2**

**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: October 31, 2023

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

**Exhibit 32.1**

**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, 2023 (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: October 31, 2023

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

**Exhibit 32.2**

**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, 2023 (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: October 31, 2023

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