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

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**FORM 10-Q**

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(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended June 30, 2025

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

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**CVRx, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<b>Common stock, par value \$0.01 per share</b>	<b>CVRX</b>	<b>The Nasdaq Global Select Market</b>

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 July 29, 2025, there were 26,151,724 shares of the registrant's common stock, par value \$0.01 per share outstanding.

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**CVRx, Inc.**  
**Quarterly Report on Form 10-Q**  
**For the quarterly period ended June 30, 2025**

***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, 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, 2024, 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, 2024, 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 (one of whom is affiliated with one of 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 continue to demonstrate to physicians and patients the merits of Barostim;
- if third-party payers 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 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 effectiveness 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)**

	June 30, 2025	December 31, 2024
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 95,025	\$ 105,933
Accounts receivable, net of allowances of \$871 and \$780, respectively	7,153	9,268
Inventory	11,720	12,107
Prepaid expenses and other current assets	2,247	2,505
Total current assets	116,145	129,813
Property and equipment, net	2,345	2,505
Operating lease right-of-use asset	1,048	1,069
Other non-current assets	26	27
Total assets	<u>\$ 119,564</u>	<u>\$ 133,414</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,032	\$ 2,582
Accrued expenses	6,657	8,180
Total current liabilities	9,689	10,762
Long-term debt	49,392	49,273
Operating lease liability, non-current portion	819	877
Other long-term liabilities	1,730	1,447
Total liabilities	<u>61,630</u>	<u>62,359</u>
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, \$0.01 par value, 200,000,000 authorized as of June 30, 2025 and December 31, 2024; 26,145,951 and 25,324,684 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	261	253
Additional paid-in capital	623,724	608,354
Accumulated deficit	(565,848)	(537,346)
Accumulated other comprehensive loss	(203)	(206)
Total stockholders' equity	<u>57,934</u>	<u>71,055</u>
Total liabilities and stockholders' equity	<u>\$ 119,564</u>	<u>\$ 133,414</u>

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

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

	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Revenue	\$ 13,589	\$ 11,807	\$ 25,937	\$ 22,577
Cost of goods sold	2,139	1,900	4,175	3,515
Gross profit	11,450	9,907	21,762	19,062
Operating expenses:				
Research and development	2,469	2,765	4,986	5,822
Selling, general and administrative	23,357	21,115	44,589	49,445
Total operating expenses	25,826	23,880	49,575	55,267
Loss from operations	(14,376)	(13,973)	(27,813)	(36,205)
Interest expense	(1,473)	(959)	(2,930)	(1,919)
Other income, net	1,110	944	2,233	1,988
Loss before income taxes	(14,739)	(13,988)	(28,510)	(36,136)
Benefit (provision) for income taxes	3	(41)	8	(79)
Net loss	(14,736)	(14,029)	(28,502)	(36,215)
Cumulative translation adjustment	3	—	3	(3)
Comprehensive loss	\$ (14,733)	\$ (14,029)	\$ (28,499)	\$ (36,218)
Net loss per share, basic and diluted	\$ (0.57)	\$ (0.65)	\$ (1.10)	\$ (1.69)
Weighted-average common shares used to compute net loss per share, basic and diluted	26,071,316	21,628,542	25,974,229	21,430,276

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 March 31, 2024	26,051,992	\$ 261	\$ 620,416	\$ (551,112)	\$ (205)	\$ 71,055
Exercise of stock options	22,017	—	32	—	—	32
Proceeds from Employee Stock Purchase Plan	71,942	—	360	—	—	360
Employee stock compensation	—	—	2,916	—	—	2,916
Net loss for the three months ended June 30, 2025	—	—	—	(14,736)	—	(14,736)
Cumulative translation adjustment	—	—	—	—	2	2
<b>Balances as of June 30, 2025</b>	<b>26,145,951</b>	<b>\$ 261</b>	<b>\$ 623,724</b>	<b>\$ (565,848)</b>	<b>\$ (203)</b>	<b>\$ 57,934</b>
Balances as of March 31, 2023	21,593,173	\$ 216	\$ 565,822	\$ (499,567)	\$ (210)	\$ 66,261
Exercise of stock options	79,377	1	66	—	—	67
Proceeds from Employee Stock Purchase Plan	39,807	—	406	—	—	406
Employee stock compensation	—	—	2,544	—	—	2,544
Issuance of common stock	—	—	(1)	—	—	(1)
Net loss for the three months ended June 30, 2024	—	—	—	(14,029)	—	(14,029)
<b>Balances as of June 30, 2024</b>	<b>21,712,357</b>	<b>\$ 217</b>	<b>\$ 568,837</b>	<b>\$ (513,596)</b>	<b>\$ (210)</b>	<b>\$ 55,248</b>

	Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity
	Shares	Amount				
Balances as of December 31, 2024	25,324,684	\$ 253	\$ 608,354	\$ (537,346)	\$ (206)	\$ 71,055
Exercise of stock options	205,863	2	447	—	—	449
Proceeds from Employee Stock Purchase Plan	71,942	—	360	—	—	360
Employee stock compensation	—	—	5,371	—	—	5,371
Issuance of common stock	543,462	6	9,192	—	—	9,198
Net loss for the six months ended June 30, 2025	—	—	—	(28,502)	—	(28,502)
Cumulative translation adjustment	—	—	—	—	3	3
<b>Balances as of June 30, 2025</b>	<b>26,145,951</b>	<b>\$ 261</b>	<b>\$ 623,724</b>	<b>\$ (565,848)</b>	<b>\$ (203)</b>	<b>\$ 57,934</b>
Balances as of December 31, 2023	20,879,199	\$ 209	\$ 553,326	\$ (477,381)	\$ (207)	\$ 75,947
Exercise of stock options	165,987	2	880	—	—	882
Proceeds from Employee Stock Purchase Plan	39,807	—	406	—	—	406
Employee stock compensation	—	—	13,685	—	—	13,685
Issuance of common stock	23,364	—	546	—	—	546
Issuance of common stock upon net exercise of common warrants	604,000	6	(6)	—	—	—
Net loss for the six months ended June 30, 2024	—	—	—	(36,215)	—	(36,215)
Cumulative translation adjustment	—	—	—	—	(3)	(3)
<b>Balances as of June 30, 2024</b>	<b>21,712,357</b>	<b>\$ 217</b>	<b>\$ 568,837</b>	<b>\$ (513,596)</b>	<b>\$ (210)</b>	<b>\$ 55,248</b>

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

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

	Six months ended June 30,	
	2025	2024
<b>Cash flows from operating activities:</b>		
Net loss	\$ (28,502)	\$ (36,215)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,371	13,685
Depreciation of property and equipment	377	272
Amortization of deferred financing costs and loan discount	119	97
Changes in operating assets and liabilities:		
Accounts receivable	2,115	(1,055)
Inventory	387	(241)
Prepaid expenses and other current assets	271	1,253
Accounts payable	450	1,632
Accrued expenses	(1,291)	(154)
Net cash used in operating activities	<u>(20,703)</u>	<u>(20,726)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(217)	(1,272)
Net cash used in investing activities	<u>(217)</u>	<u>(1,272)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from the exercise of common stock options	449	882
Proceeds from Employee Stock Purchase Plan	360	406
Proceeds from the issuance of common stock	9,198	546
Net cash provided by financing activities	<u>10,007</u>	<u>1,834</u>
Effect of currency exchange on cash and cash equivalents	5	(5)
<b>Net change in cash and cash equivalents</b>	<u>(10,908)</u>	<u>(20,169)</u>
Cash and cash equivalents at beginning of period	105,933	90,569
<b>Cash and cash equivalents at end of period</b>	<u>\$ 95,025</u>	<u>\$ 70,400</u>
<b>Supplemental Information:</b>		
Cash paid for interest	\$ 2,537	\$ 1,613
Cash paid for income taxes	\$ —	\$ —

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. and its wholly owned subsidiary, CVRx Switzerland LLC. All intercompany balances and transactions have been eliminated in consolidation.

### **JOBS Act accounting election**

We are an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). As a result, we have 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 June 30, 2025 and December 31, 2024, cash equivalents consisted of money market funds, which are stated at cost and approximate fair value. Additionally, as of June 30, 2025 and December 31, 2024, 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. We regularly review inventory quantities based on 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**

We sell our products primarily through a direct sales force and to a lesser extent through a combination of sales agents and independent distributors. Our revenue consists primarily of the sale of our 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, we perform 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. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services it transfers to the customer. We recognize net revenue on product sales, adjusted for any applicable estimates of variable consideration, when the customer obtains control of our product, which generally occurs at a point in time upon delivery based on the contractual shipping terms of a contract. Our contracts have a single performance obligation, and our payment terms with customers are generally between 30 and 90 days. Variable consideration related to certain customer rebates is estimated based on the amounts expected to be paid under the agreement with the customer.

## 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 (“FASB”) Accounting Standards Codification Topic 718, *Compensation—Stock Compensation* (“ASC 718”). ASC 718 requires all equity-based compensation awards to employees and non-employee directors, including grants of restricted shares and stock options, to be recognized as expense in the statements of operations and comprehensive loss based on their grant date fair values. We estimate the grant date fair value of stock options using the Black-Scholes option pricing model, and the fair value of restricted stock units (“RSUs”) is equal to the closing price of our common stock on the grant date. We account for forfeitures as they occur. We expense the fair value of our equity-based compensation awards granted to employees on a straight-line basis over the associated service period, which is generally the period in which the related services are received.

## Recent accounting pronouncements

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures* (“ASU 2023-09”), which requires public business entities to disclose specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. ASU 2023-09 is effective for annual periods beginning after December 15, 2024. This ASU will be effective for our annual period ending December 31, 2025. We are evaluating the impact of this new guidance on our income tax disclosures.

## 3. Selected balance sheet information

Inventory consists of the following at:

<i>(in thousands)</i>	June 30, 2025	December 31, 2024
Raw material	\$ 7,698	\$ 6,857
Work-in-process	230	353
Finished goods	3,792	4,897
	<u>\$ 11,720</u>	<u>\$ 12,107</u>

Property and equipment, net consists of the following at:

<i>(in thousands)</i>	June 30, 2025	December 31, 2024
Office furniture and equipment	\$ 512	\$ 512
Lab equipment	3,620	3,144
Computer equipment and software	1,133	994
Leasehold improvements	548	542
Capital equipment in process	316	720
	<u>6,129</u>	<u>5,912</u>
Less: Accumulated depreciation and amortization	<u>3,784</u>	<u>3,407</u>
	<u>\$ 2,345</u>	<u>\$ 2,505</u>

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 \$193,000 and \$141,000 for the three months ended June 30, 2025 and 2024, respectively, and \$377,000 and \$272,000 for the six months ended June 30, 2025 and 2024, respectively.

Accrued expenses consist of the following at:

<i>(in thousands)</i>	June 30, 2025	December 31, 2024
Bonuses	\$ 2,515	\$ 3,621
Paid time off	1,254	947
401(k) match	637	1,106
Accrued interest payable	417	437
Operating lease liability, current portion	333	282
Customer rebates	300	592
Clinical trial and other professional fees	124	182
Taxes	46	135
Other	1,031	878
	<u>\$ 6,657</u>	<u>\$ 8,180</u>

#### 4. Debt

##### Innovatus Loan Agreement

On October 31, 2022, we entered into a Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Fund I, LP, as the collateral agent and a lender, allowing us to borrow, subject to our achievement of certain milestones, up to a total of \$50.0 million in a series of term loans (collectively, the "Term Loans"). We had \$50.0 million in outstanding Term Loans under the Loan Agreement as of June 30, 2025. The Loan Agreement initially requires interest only payments through November 2027, followed by three monthly principal and interest payments, of which a principal payment of \$16.7 million is due in December 2027 and two principal payments of \$16.7 million each are due in January 2028. A final payment of \$2.3 million, equal to 4.5% of the funded amount, is due in January 2028. 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 our personal property. A performance covenant took effect upon the third tranche funding, requiring that we 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 our capital stock, subject to limited exceptions. We were in compliance with these covenants as of June 30, 2025.

In connection with the Loan Agreement, we recorded \$1.1 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:

<i>(in thousands)</i>	June 30, 2025
2025	\$ —
2026	—
2027	16,667
2028	33,333
	<u>50,000</u>
Less: Unamortized debt costs and discounts	(608)
Long-term debt	<u>\$ 49,392</u>

## 5. Leases

We lease 35,183 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, which has been amended to expand the leased space and extend the term of the lease, which expires August 31, 2028. Most recently, on May 20, 2025, we expanded our existing office space with an additional 3,678 square feet of property adjacent to our principal executive offices and our manufacturing facility. The term on this expanded property is for 39 consecutive months and runs concurrently with the term on the existing lease. 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:

<i>(in thousands)</i>	June 30, 2025	December 31, 2024
<b>Right-of-use assets:</b>		
Operating lease right-of-use asset	\$ 1,048	\$ 1,069
<b>Operating lease liabilities:</b>		
Accrued expenses	333	282
Operating lease liability, non-current portion	819	877
Total operating lease liabilities	<u>\$ 1,152</u>	<u>\$ 1,159</u>

Maturities of our lease liability for our operating lease are as follows as of June 30, 2025:

<i>(in thousands)</i>	June 30, 2025
2025	201
2026	410
2027	424
2028	253
Total undiscounted lease payments	1,288
Less: imputed interest	(136)
Present value of lease liability	<u>\$ 1,152</u>

As of June 30, 2025, the remaining lease term was 3.2 years, and the weighted average discount rate was 7.1%. The operating cash outflows from our operating lease were \$0.3 million for each of the six months ended June 30, 2025 and 2024.

## 6. Stockholders' equity

### Common Stock Warrants

We had common stock warrants exercisable for 103,349 shares of common stock upon conversion at a weighted average exercise price of \$12.92 per share outstanding at June 30, 2025 and December 31, 2024. Johnson & Johnson Innovation – JJDC, Inc. had common stock warrants exercisable for 607,725 shares of our common stock with an exercise price of \$0.16 per share that were all exercised through a net exercise transaction for 604,000 shares of common stock during the six months ended June 30, 2024.

## **At-the-Market (“ATM”) Offering**

In January 2024, we commenced an ATM offering, which allows us to issue and sell shares of our common stock having an aggregate offering price of up to \$50.0 million. We issued 543,462 shares of common stock for gross proceeds of \$9.5 million under the ATM offering during the six months ended June 30, 2025. We have remaining capacity to issue and sell up to approximately \$6.7 million of additional shares of common stock under this ATM offering.

## **7. Stock-based compensation**

### **Summary of plans and activity**

In June 2001, our 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, our 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 our 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 1,266,234 shares being reserved for issuance under the 2021 Plan as of January 1, 2025. 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 June 30, 2025, there were 1,392,926 shares available for future issuance under the 2021 Plan.

### **Stock Options**

Options are granted at exercise prices not less than the fair market value (as determined by the Board of Directors) of our 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 our standard form of option agreement for non-employee directors as they have an exercise price not less than the fair market value on the grant date and vest over 48 months from the date of grant.

The following is a summary of stock option activity:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
			<i>(in thousands)</i>
Balance as of December 31, 2024	5,550,419	\$ 11.81	\$ 18,771
Granted	926,572	12.03	
Cancelled / Forfeited	(246,004)	14.75	
Exercised	(205,863)	2.18	
Balance as of June 30, 2025	<u>6,025,124</u>	\$ 12.06	<u>\$ 1,535</u>
Options exercisable as of June 30, 2025	3,397,633	\$ 11.00	\$ 1,535

As of June 30, 2025, stock options outstanding included 4,402 options that were not granted under the 2001 Plan or the 2021 Plan. For options outstanding as of June 30, 2025, the weighted average remaining contractual life was 7.0 years. For options exercisable as of June 30, 2025, the weighted average remaining contractual life was 5.6 years. As of June 30, 2025, unrecognized compensation expense related to unvested stock-based compensation arrangements for stock options was \$23.2 million. As of June 30, 2025, the related weighted average period over which the expense is expected to be recognized is approximately 2.7 years.

### Restricted Stock Units

RSUs are share awards that entitle the holder to receive freely tradable shares of our common stock upon vesting. The RSUs cannot be transferred and the awards are subject to forfeiture if the holder's service terminates prior to vesting other than for death, disability, or other qualifying terminations.

The following is a summary of RSU activity:

	Number of RSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
			<i>(in thousands)</i>
Unvested Balance as of December 31, 2024	—	\$ —	\$ —
Granted	340,078	12.85	
Vested	—	—	
Cancelled / Forfeited	(4,420)	12.96	
Unvested Balance as of June 30, 2025	<u>335,658</u>	\$ 12.85	<u>\$ 1,974</u>

The aggregate intrinsic value of unvested RSUs is based on our closing stock price on the last trading day of the period. No RSUs were vested as of June 30, 2025. As of June 30, 2025, the unrecognized compensation expense related to unvested stock-based compensation arrangements for RSUs was \$4.0 million. As of June 30, 2025, the related weighted average period over which the expense is expected to be recognized is approximately 3.7 years.

### Employee Stock Purchase Plan

Our 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 our 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 253,246 shares being reserved for issuance under the ESPP as of January 1, 2025. The ESPP permits certain of our U.S. employees to purchase shares of our common stock at a price per share not less than 85% of the lower of (i) the closing market price per share of our common stock on the first day of the applicable purchase period or (ii) the closing market price per share of our common stock on the purchase date at the end of the applicable six-month purchase period. For the six months ended June 30, 2025, 71,942 shares of common stock were purchased under the ESPP for \$0.4 million of employee contributions. As of June 30, 2025, there were 814,111 shares available for issuance under the ESPP.

### Stock-based compensation expense

We use the Black-Scholes option pricing model to determine the fair value of stock options and ESPP purchase rights on the grant date. The fair value of RSUs is determined based on the closing stock price of our common stock on the grant date. We measure stock-based compensation expense based on the grant date fair value of the award and recognize compensation expense over the requisite service period, which is generally the vesting period for stock options and RSUs, and the offering period for ESPP purchase rights. The amount of stock-based compensation expense recognized for stock option and RSU 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. We account 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 six months ended June 30, 2025 and 2024:

	June 30,	
	2025	2024
Weighted average fair value of options granted	\$ 9.52	\$ 10.81
Expected term (in years) — non-officer employees	5.5 to 6.1	5.0 to 6.1
Expected term (in years) — officer employees	6.1	2.5 to 6.1
Expected volatility	95.0% to 103.1 %	87.7% to 94.6 %
Expected dividend yield	— %	— %
Risk-free interest rate	3.93% to 4.47 %	3.95% to 4.71 %

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 six months ended June 30, 2025 and 2024:

	June 30,	
	2025	2024
Weighted average fair value per ESPP purchase right	\$ 2.83	\$ 4.31
Expected term (in years)	0.5	0.5
Expected volatility	112.3 %	74.0 %
Expected dividend yield	— %	— %
Risk-free interest rate	4.25 %	5.24 %

We review these assumptions on a periodic basis and adjust them, as necessary. We utilize the simplified method to develop the estimate of the expected term for stock option awards and ESPP purchase rights. The expected volatility is based upon our historical stock price. The expected dividend yield is assumed to be zero, as we have never paid dividends and have no current plans to do so. The risk-free interest rate is based

on the yield on U.S. Treasury securities for a period approximating the expected term of the options being valued.

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

<i>(in thousands)</i>	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Options	\$ 2,596	\$ 2,485	\$ 4,810	\$ 13,513
RSUs	265	—	357	—
Employee Stock Purchase Plan	55	59	204	172
Total stock-based compensation expense	<u>\$ 2,916</u>	<u>\$ 2,544</u>	<u>\$ 5,371</u>	<u>\$ 13,685</u>
Selling, general & administrative	\$ 2,610	\$ 2,208	\$ 4,865	\$ 13,033
Research & development	270	303	435	588
Cost of goods sold	36	33	71	64
	<u>\$ 2,916</u>	<u>\$ 2,544</u>	<u>\$ 5,371</u>	<u>\$ 13,685</u>

On January 30, 2024, we amended the terms and conditions of certain stock option award agreements granted under the 2001 Plan and 2021 Plan between us and our former Chief Executive Officer in connection with his retirement, which occurred on February 11, 2024. The option agreements were amended to provide that, if not already vested at the time of termination of his employment due to retirement, the options will continue to vest on the previously scheduled vesting dates following his retirement, subject to his compliance with certain covenants. Additionally, the option agreements were modified so that the options may be exercised, to the extent vested, by our former Chief Executive Officer until the earlier of (a) five years following his retirement date, or (b) the applicable option expiration date. The modification of these option awards resulted in an additional \$8.4 million of non-cash stock-based compensation expense recognized during the six months ended June 30, 2024.

## 8. Income taxes

As of June 30, 2025 and December 31, 2024, a valuation allowance was recorded against all deferred tax assets due to our cumulative net loss position. Benefit for income taxes for the three months ended June 30, 2025 was \$3,000 and provision for income taxes for the three months ended June 30, 2024 was \$41,000. Benefit for income taxes for the six months ended June 30, 2025 was \$8,000 and provision for income taxes for the six months ended June 30, 2024 was \$79,000.

As of December 31, 2024, we had federal and state net operating loss carryforwards (“NOLs”) of approximately \$429.7 million and \$8.1 million, respectively. The federal NOLs began expiring in 2021 and the state NOLs began expiring in 2020. As of December 31, 2024, we had federal and state tax credit carryforwards of approximately \$10.2 million and \$1.7 million, respectively. The federal tax credit carryforwards began expiring in 2021 and the state tax credits 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, as amended, and similar state provisions. We have not performed a detailed analysis to determine whether an ownership change has occurred. Such a change of ownership would limit our utilization of the NOLs and could be triggered by subsequent sales of securities by us or our stockholders.

On July 4, 2025, the One Big Beautiful Bill Act (“OBCCA”) was enacted in the U.S. The OBCCA includes significant tax-related provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework, and the restoration of favorable tax treatment for certain business provisions, including the capitalization of certain R&D costs. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. We

are currently evaluating the potential impact of the OBBBA on our consolidated financial statements and related disclosures.

## 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 June 30,		Six months ended June 30,	
	2025	2024	2025	2024
<b>Numerator:</b>				
Net loss	\$ (14,736)	\$ (14,029)	\$ (28,502)	\$ (36,215)
<b>Denominator:</b>				
Weighted average common shares outstanding — basic and diluted	26,071,316	21,628,542	25,974,229	21,430,276
Net loss per share attributable to common stockholders — basic and diluted	<u>\$ (0.57)</u>	<u>\$ (0.65)</u>	<u>\$ (1.10)</u>	<u>\$ (1.69)</u>

Our potentially dilutive securities, which include stock options, RSUs, 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. We 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:

	Six months ended June 30,	
	2025	2024
Options	6,025,124	5,748,130
RSUs	335,658	—
Warrants	103,349	108,406
	<u>6,464,131</u>	<u>5,856,536</u>

## 10. Commitments and contingencies

From time to time, we may have certain contingent liabilities that arise in the ordinary course of business. We accrue 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 June 30, 2025 or December 31, 2024.

## 11. Employee benefit plans

We sponsor a voluntary defined-contribution employee retirement plan (the “401(k) plan”) for our 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. Beginning January 1, 2024, we adopted a policy to match a portion of employee contributions for all qualified employees participating in the 401(k) plan. We recorded an expense for matching contributions of \$0.3 million for each of the three months ended June 30, 2025 and 2024. We recorded an expense for matching contributions of \$0.6 million for each of the six months ended June 30, 2025 and 2024.

## 12. Segment, geographic information, and revenue disaggregation

We have determined that we have a single reportable and operating segment structure. We have 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. Our chief operating decision maker is our Chief Executive Officer. Our Chief Executive Officer evaluates performance based primarily on revenue in the geographic locations in which the Company operates and consolidated net loss. The Chief Executive Officer reviews financial information presented on a consolidated basis, including consolidated net loss, accompanied by information about revenue by geographic region, for purposes of allocating resources and evaluating financial performance. Further, the financial information on expenses provided to the Chief Executive Officer is presented on a consolidated basis, as reported in the condensed consolidated statements of operations and comprehensive loss in this Quarterly Report on Form 10-Q.

We derive all our 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 June 30,		Six months ended June 30,	
	2025	2024	2025	2024
U.S.	\$ 12,243	\$ 10,673	\$ 23,444	\$ 20,508
Other countries	1,346	1,134	2,493	2,069
	<u>\$ 13,589</u>	<u>\$ 11,807</u>	<u>\$ 25,937</u>	<u>\$ 22,577</u>

As of June 30, 2025 and December 31, 2024, substantially all our long-lived assets were located 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 indicated by the U.S. Food and Drug Administration ("FDA") for patients who are NYHA Class III or II (who had a recent history of Class III) despite treatment with guideline-directed medical therapies (medications and devices), have a LVEF  $\leq$  35% and a NT-proBNP < 1600 pg/ml 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 payers, 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 and advanced practice providers 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 payers, such as government agencies and commercial payers. 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 payers. 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 adjudicated 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, 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.

On October 31, 2022, we entered into the Loan Agreement allowing borrowing, 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. We had \$50.0 million in outstanding Term Loans under the Loan Agreement as of June 30, 2025.

As a result of the planned investments to fund 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 July 2025, the Centers for Medicare & Medicaid Services (“CMS”) released the 2026 Proposed Medicare Physician Fee Schedule (“MPFS”). This proposed rule includes the new Category I CPT codes for the Barostim implant and follow-up services. The proposal establishes national pricing for the code series used to report procedures associated with Barostim, supporting continued access for Medicare beneficiaries. We expect the transition to Category I will eliminate the automatic denials regularly seen with Category III codes and improve prior authorization predictability to fairly pay physicians for the procedure. The final rule is expected to be issued in the November and take effect January 1, 2026.

Also in July 2025, CMS, as part of the proposed rule for the 2026 Outpatient Prospective Payment System (“OPPS”), proposed to retain the Barostim implant procedure under New Technology Ambulatory Payment Classification (“APC”) 1580, with an associated outpatient payment rate of approximately \$45,000. CMS continues to solicit comments on the need for a Level 6 Neurostimulator APC, and we will continue to work with CMS in an effort to create this new classification. The final rule is expected to be issued in November and take effect January 1, 2026.

## **Factors affecting our performance**

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

- Growing and supporting our U.S. commercial organization;
- Promoting awareness among physicians, hospitals, and patients to accelerate adoption of Barostim;
- Continuing to develop and disseminate clinical evidence supporting the benefits of Barostim;
- Raising awareness among payers to build upon reimbursement for Barostim;
- Investing in research and development to foster innovation; 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 payers, 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 or modified 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.

***Benefit (provision) for income taxes***

Benefit (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 June 30, 2025, compared to the three months ended June 30, 2024

<i>(unaudited and in thousands)</i>	Three months ended June 30,		Change	
	2025	2024	\$	%
Revenue	\$ 13,589	\$ 11,807	\$ 1,782	15 %
Cost of goods sold	2,139	1,900	239	13 %
Gross profit	11,450	9,907	1,543	16 %
Gross margin	84 %	84 %		
Operating expenses:				
Research and development	2,469	2,765	(296)	(11)%
Selling, general and administrative	23,357	21,115	2,242	11 %
Total operating expenses	25,826	23,880	1,946	8 %
Loss from operations	(14,376)	(13,973)	(403)	3 %
Interest expense	(1,473)	(959)	(514)	54 %
Other income, net	1,110	944	166	18 %
Loss before income taxes	(14,739)	(13,988)	(751)	5 %
Benefit (provision) for income taxes	3	(41)	44	(107)%
Net loss	\$ (14,736)	\$ (14,029)	\$ (707)	5 %

### The following table provides revenue by geography:

<i>(unaudited and in thousands)</i>	Three months ended June 30,		Change	
	2025	2024	\$	%
United States	\$ 12,243	\$ 10,673	\$ 1,570	15 %
Europe	1,346	1,134	212	19 %
Total Revenue	\$ 13,589	\$ 11,807	\$ 1,782	15 %

Revenue was \$13.6 million for the three months ended June 30, 2025, an increase of \$1.8 million, or 15%, over the three months ended June 30, 2024.

Revenue generated in the U.S. was \$12.2 million for the three months ended June 30, 2025, an increase of \$1.6 million, or 15%, over the three months ended June 30, 2024. HF revenue in the U.S. totaled \$12.1 million and \$10.5 million for the three months ended June 30, 2025 and 2024, respectively. HF revenue units in the U.S. totaled 387 and 339 for the three months ended June 30, 2025 and 2024, 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 June 30, 2025, we had a total of 240 active implanting centers in the U.S., as compared to 189 as of June 30, 2024. Active implanting centers are customers that have completed at least one commercial HF implant in the last 12 months. As of June 30, 2025, we had a total of 47 sales territories in the U.S. as compared to 42 sales territories as of June 30, 2024.

Revenue generated in Europe was \$1.3 million for the three months ended June 30, 2025, a \$0.2 million increase, or 19%, compared to the three months ended June 30, 2024. Total revenue units in Europe decreased to 61 for the three months ended June 30, 2025, as compared to 63 in the prior year period. As of June 30, 2025 we had five sales territories in Europe as compared to six sales territories as of June 30, 2024.

*Cost of goods sold and gross margin*

Cost of goods sold increased \$0.2 million, or 13%, to \$2.1 million for the three months ended June 30, 2025, compared to the three months ended June 30, 2024. This increase was driven by higher sales of Barostim.

Gross profit was \$11.5 million for the three months ended June 30, 2025, an increase of \$1.5 million, or 16%, over the three months ended June 30, 2024. Gross margin was 84% for each of the three months ended June 30, 2025 and 2024.

*Research and development expenses*

R&D expenses decreased \$0.3 million, or 11%, to \$2.5 million for the three months ended June 30, 2025, compared to the three months ended June 30, 2024. This change was driven by a \$0.3 million decrease in compensation expenses.

*Selling, general and administrative expenses*

SG&A expenses increased \$2.2 million, or 11%, to \$23.4 million for the three months ended June 30, 2025, compared to the three months ended June 30, 2024. This change was primarily driven by a \$1.4 million increase in compensation expenses, a \$0.8 million increase in travel expenses, and a \$0.4 million increase in non-cash stock-based compensation expense, partially offset by a \$0.5 million decrease in advertising expenses.

*Interest expense*

Interest expense increased \$0.5 million for the three months ended June 30, 2025, compared to the three months ended June 30, 2024. This increase was driven by the interest expense on higher levels of borrowings under the Loan Agreement.

*Other income, net*

Other income, net increased \$0.2 million for the three months ended June 30, 2025, compared to the three months ended June 30, 2024. This increase was primarily driven by more interest income on our interest-bearing accounts.

*Benefit (provision) for income taxes*

Benefit (provision) for income taxes was nominal for each of the three months ended June 30, 2025 and 2024.

**Consolidated results of operations for the six months ended June 30, 2025, compared to the six months ended June 30, 2024**

<i>(unaudited and in thousands)</i>	Six months ended June 30,		Change	
	2025	2024	\$	%
Revenue	\$ 25,937	\$ 22,577	\$ 3,360	15 %
Cost of goods sold	4,175	3,515	660	19 %
Gross profit	21,762	19,062	2,700	14 %
Gross margin	84 %	84 %		
Operating expenses:				
Research and development	4,986	5,822	(836)	(14)%
Selling, general and administrative	44,589	49,445	(4,856)	(10)%
Total operating expenses	49,575	55,267	(5,692)	(10)%
Loss from operations	(27,813)	(36,205)	8,392	(23)%
Interest expense	(2,930)	(1,919)	(1,011)	53 %
Other income, net	2,233	1,988	245	12 %
Loss before income taxes	(28,510)	(36,136)	7,626	(21)%
Benefit (provision) for income taxes	8	(79)	87	(110)%
Net loss	\$ (28,502)	\$ (36,215)	\$ 7,713	(21)%

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

<i>(unaudited and in thousands)</i>	Six months ended June 30,		Change	
	2025	2024	\$	%
United States	\$ 23,444	\$ 20,508	\$ 2,936	14 %
Europe	2,493	2,069	424	20 %
Total Revenue	\$ 25,937	\$ 22,577	\$ 3,360	15 %

Revenue was \$25.9 million for the six months ended June 30, 2025, an increase of \$3.4 million, or 15%, over the six months ended June 30, 2024.

Revenue generated in the U.S. was \$23.4 million for the six months ended June 30, 2025, an increase of \$2.9 million, or 14%, over the six months ended June 30, 2024. HF revenue in the U.S. totaled \$23.2 million and \$20.3 million for the six months ended June 30, 2025 and 2024, respectively. HF revenue units in the U.S. totaled 740 and 658 for the six months ended June 30, 2025 and 2024, 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.

Revenue generated in Europe was \$2.5 million for the six months ended June 30, 2025, a \$0.4 million increase, or 20%, compared to the six months ended June 30, 2024. Total revenue units in Europe increased to 120 for the six months ended June 30, 2025, as compared to 107 in the prior year period.

**Cost of goods sold and gross margin**

Cost of goods sold increased \$0.7 million, or 19%, to \$4.2 million for the six months ended June 30, 2025, compared to the six months ended June 30, 2024. This increase was driven by higher sales of Barostim.

Gross profit was \$21.8 million for the six months ended June 30, 2025, an increase of \$2.7 million, or 14%, over the six months ended June 30, 2024. Gross margin was 84% for each of the six months ended June 30, 2025 and 2024.

*Research and development expenses*

R&D expenses decreased \$0.8 million, or 14%, to \$5.0 million for the six months ended June 30, 2025, compared to the six months ended June 30, 2024. This change was driven by a \$0.4 million decrease in compensation expenses and a \$0.3 million decrease in clinical trial expenses.

*Selling, general and administrative expenses*

SG&A expenses decreased \$4.9 million, or 10%, to \$44.6 million for the six months ended June 30, 2025, compared to the six months ended June 30, 2024. This change was primarily driven by an \$8.2 million decrease in non-cash stock-based compensation expense and a \$0.5 million decrease in advertising expenses, partially offset by a \$2.9 million increase in compensation expenses and a \$1.1 million increase in travel expenses. The modification of stock options held by our former Chief Executive Officer in connection with his retirement in the first quarter of 2024 described in Note 7 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q contributed approximately \$8.4 million to the decrease in non-cash stock-based compensation expense.

*Interest expense*

Interest expense increased \$1.0 million for the six months ended June 30, 2025, compared to the six months ended June 30, 2024. This increase was driven by the interest expense on higher levels of borrowings under the Loan Agreement.

*Other income, net*

Other income, net increased \$0.2 million for the six months ended June 30, 2025, compared to the six months ended June 30, 2024. This increase was primarily driven by increased interest income on our interest-bearing accounts.

*Benefit (provision) for income taxes*

Benefit (provision) for income taxes was nominal for each of the six months ended June 30, 2025 and 2024.

**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 June 30, 2025 and December 31, 2024, we had cash and cash equivalents of \$95.0 million and \$105.9 million, respectively. For the three months ended June 30, 2025 and 2024, our net losses were \$14.7 million and \$14.0 million, respectively. For the six months ended June 30, 2025 and 2024, our net losses were \$28.5 million and \$36.2 million, respectively. Our net cash used in operating activities was \$20.7 million for each of the six months ended June 30, 2025 and 2024.

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. We had \$50.0 million in outstanding Term Loans under the Loan Agreement as of June 30, 2025.

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” (“ATM”) offering, to or through the agent. In January 2024, we commenced this ATM offering and, during the six months ended June 30, 2025, we issued 543,462 shares of common stock under the program for gross proceeds of \$9.5 million. We have remaining capacity to issue and sell up to \$6.7 million of additional shares of common stock under this ATM offering.

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 together with cash from operations 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 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 presented below:

<i>(in thousands)</i>	Six months ended June 30, <i>(unaudited)</i>	
	2025	2024
Net cash (used in) provided by:		
Operating activities	\$ (20,703)	\$ (20,726)
Investing activities	(217)	(1,272)
Financing activities	10,007	1,834
Effect of currency exchange on cash and cash equivalents	5	(5)
Net change in cash and cash equivalents	<u>\$ (10,908)</u>	<u>\$ (20,169)</u>

### **Cash used in operating activities**

Net cash used in operating activities for the six months ended June 30, 2025 was \$20.7 million and consisted primarily of a net loss of \$28.5 million, partially offset by a non-cash charge of \$5.4 million related to stock-based compensation expense, and a change in net operating assets of \$1.9 million. Net operating assets

consisted primarily of accounts receivable, accrued expenses, accounts payable, inventory and prepaid expenses and other current assets to support the growth of our operations.

Net cash used in operating activities for the six months ended June 30, 2024 was \$20.7 million and consisted primarily of a net loss of \$36.2 million, partially offset by a non-cash charge of \$13.7 million related to stock-based compensation expense and an increase in net operating assets of \$1.4 million. 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.

*Cash used in investing activities:*

Cash used in investing activities was \$0.2 million and \$1.3 million for the six months ended June 30, 2025 and 2024, respectively, and consisted of purchases of property and equipment.

*Cash provided by financing activities:*

Net cash provided by financing activities for the six months ended June 30, 2025 was \$10.0 million and consisted of \$9.2 million related to net proceeds from the issuance of common stock through the ATM offering, \$0.4 million related to proceeds from the exercise of common stock options and \$0.4 million related to proceeds from the ESPP.

Net cash provided by financing activities for the six months ended June 30, 2024 was \$1.8 million and consisted of \$0.9 million related to net proceeds from the exercise of common stock options, \$0.5 million related to proceeds from the issuance of common stock through the ATM offering, and \$0.4 million related to proceeds from the ESPP.

## **Contractual obligations and commitments**

There have been no material changes to our contractual obligations as of June 30, 2025, as compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2024.

## **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, 2024. We have reviewed and determined that those critical accounting policies and estimates remain our critical accounting policies and estimates as of and for the six months ended June 30, 2025.

## **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 June 30, 2025 and December 31, 2024, 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 June 30, 2025, 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, 2024. Other than the risk factor set forth below, there have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K.

***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 European Economic Area (“EEA”), Barostim was required to comply with the Essential Requirements laid down in Annex I to the European Union (“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.

Regulations in the EU were updated to require compliance to Regulation (EU) 2017/745 on Medical Devices ("MDR"). Additional amendments to the regulation have delayed required implementation dates to December 31, 2027. Compliance with the new regulation required extensive updates to the quality system and device technical file documentation to new requirements. Updates were made and annual Notified Body inspections assessing compliance of the quality system to the MDR have been ongoing since 2020. An application was made for Barostim to comply with the general safety and performance requirements of the EU MDR. Final approval and certificates of compliance for both the technical file and quality system were issued on April 9, 2025. We are required to continue to submit updates for any substantial changes to the design, manufacturing or quality system for assessment against the MDR requirements. Annual audits by the Notified Body are required to verify that we continue to meet the MDR requirements. The current integrated platform technology, Barostim is approved under the MDR. Barostim Legacy is not approved under MDR, but can still be sold under the Active Implantable Medical Device Directive ("AIMDD") approval through 2027. 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), which could impair our ability to market products in the EEA in the future.

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

None.

## **Item 3. Defaults Upon Senior Securities**

None.

## **Item 4. Mine Safety Disclosures**

Not applicable.

## **Item 5. Other Information**

### **Adoption, Modification or Termination of Rule 10b5-1 Plans and Certain Other Trading Arrangements**

During the three months ended June 30, 2025, none of our directors or officers adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

## Item 6. Exhibits

### EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Description</b>
3.1	<a href="#">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 June 7, 2024)</a>
3.2	<a href="#">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)</a>
10.1†	<a href="#">Seventh Amendment to Lease, dated May 20, 2025, by and between the Company and TCI TT, LLC</a>
31.1†	<a href="#">Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
31.2†	<a href="#">Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
32.1†	<a href="#">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</a>
32.2†	<a href="#">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</a>
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: August 5, 2025

### **CVRX, INC.**

By: /s/ Kevin Hykes  
Name: Kevin Hykes  
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)

## SEVENTH AMENDMENT TO LEASE

THIS SEVENTH AMENDMENT TO LEASE (“Amendment”) is dated May 20<sup>th</sup>, 2025 (“Effective Date”), by and between TCI TT, LLC, a Delaware limited liability company (“Landlord”), and CVRx, Inc., a Delaware corporation (“Tenant”).

A. Landlord, as successor in interest to Duke Realty Limited Partnership, and Tenant are the current parties to that certain Lease dated October 13, 2008 (“Original Lease”), as amended by that certain First Lease Amendment dated November 30, 2010 (“First Amendment”), as further amended by that certain Second Lease Amendment dated October 22, 2012 (“Second Amendment”), as further amended by that certain Lease Amending Agreement No. 3 dated May 20, 2016 (“Third Amendment”), as further amended by that certain Lease Amending Agreement No. 4 dated May 18, 2020 (“Fourth Amendment”), as further amended by that certain Fifth Amendment to Lease dated April 21, 2023 (“Fifth Amendment”), and as further amended by that certain Sixth Amendment to Lease dated November 7, 2023 (“Sixth Amendment”) (the Original Lease, First Amendment, Second Amendment, Third Amendment, Fourth Amendment, Fifth Amendment and Sixth Amendment are hereinafter collectively referred to as the “Lease”), for the lease by Tenant of Suites 615 and 660 located at 9201 West Broadway, Brooklyn Park, Minnesota 55445, consisting of approximately 31,505 rentable square feet, as more particularly described in the Lease (“Current Premises”).

B. Landlord and Tenant desire to amend the Lease to provide for an expansion of the Current Premises, and to make certain other specific modifications to the Lease, upon the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants hereinafter contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Capitalized Terms. All capitalized terms in this Amendment have the same meaning defined in the Lease, except where expressly defined to the contrary in this Amendment.
2. Confirmation. Tenant acknowledges and agrees that: (a) Tenant is in sole possession of the Current Premises demised under the Lease; (b) all work, improvements and furnishings required by Landlord under the Lease for the Current Premises have been completed and accepted by Tenant; (c) Tenant has no offset, claim, recoupment, or defense against the payment of rent or other sums and the performance of all obligations of Tenant under the Lease; (d) the Lease is binding on Tenant and is in full force and effect, and Tenant has no defenses to the enforcement of the Lease; (e) Tenant has not assigned the Lease, or sublet the Current Premises; and (f) Tenant is not in default of the Lease and Tenant acknowledges that Landlord is not in default of the Lease.
3. Expansion of Premises. Commencing on June 1, 2025 (“Expansion Date”), Landlord leases to Tenant and Tenant takes from Landlord the addition of approximately 3,678 rentable square feet of space, which is depicted in purple on **Exhibit A** attached hereto (“Expansion Premises”). If, for any reason, Landlord is unable to deliver possession of the Expansion Premises on the Expansion Date, Landlord shall not be liable for any damage caused thereby, nor shall this Amendment be void or voidable, but, rather, the Expansion Premises Term shall commence upon,

and the Expansion Date shall be, the date that possession of the Expansion Premises is so tendered to Tenant. From and after the Expansion Date, the total leased space shall consist of both the Current Premises and the Expansion Premises, which totals approximately 35,183 rentable square feet. Commencing as of the Expansion Date, the Current Premises and the Expansion Premises shall be referred to as the “Premises” for all purposes under the Lease and this Amendment, subject to the terms hereof.

4. Term. The current term of the Lease for the Current Premises is set to expire on August 31, 2028. It is agreed and understood that the Term of the Lease for the Expansion Premises will commence on the Expansion Date, and run concurrently with the Term for the Current Premises, expiring on August 31, 2028 (“Expansion Premises Term”).

5. Monthly Rental Installments. Tenant shall continue to pay the Monthly Rental Installments for the Current Premises in accordance with the Lease. The Monthly Rental Installments for the Expansion Premises after the Expansion Date shall be paid in accordance with the Lease in the following amounts:

<u>Time Period</u>	<u>S.F.</u>	<u>Rate (PSF)</u>	<u>Monthly Rental Installments</u>
6/1/2025 – 11/30/2025	3,678	\$12.50	\$3,831.25
12/1/2025 – 11/30/2026	3,678	\$13.00	\$3,984.50
12/1/2026 – 11/30/2027	3,678	\$13.52	\$4,143.88
12/1/2027 – 8/31/2028	3,678	\$14.06	\$4,309.39

6. Condition of Premises. Tenant shall accept the Current Premises in its as-is condition as of the date of this Amendment and as of the date of the commencement of the Expansion Premises Term, and Landlord shall have no obligation to make or pay for any alterations, additions, improvements or renovations in or to the Current Premises to prepare the same for Tenant’s occupancy during the Expansion Premises Term. Tenant shall accept the Expansion Premises in its as-is condition as of the Expansion Date, and Landlord shall have no obligation to make or pay for any alterations, additions, improvements or renovations in or to the Expansion Premises to prepare the same for Tenant’s occupancy, except that Landlord shall construct a demising wall in the location depicted on **Exhibit A** and cause the construction of an opening between the Current Premises and Expansion Premises in a location to be mutually agreed upon by Landlord and Tenant. The improvements will be made by Landlord at Landlord’s sole cost and expense using materials as Landlord determines appropriate in its business judgment within a reasonable period of time after the mutual execution of this Amendment.

7. Tenant’s Proportionate Share. During such period that the definition of Premises includes both the Current Premises and Expansion Premises, Tenant’s Proportionate Share set forth in the Lease shall be adjusted to 48.25% (35,183/72,919).

8. Insurance. Prior to Tenant taking possession of the Expansion Premises, Tenant shall provide to Landlord evidence reasonably satisfactory to Landlord that Tenant’s insurance, as required in the Lease, shall be in effect and include the Expansion Premises as of the time of possession.

9. Real Estate Brokers. Notwithstanding anything to the contrary contained in the Lease, Landlord and Tenant each represents and warrants to the other party that it has not authorized or employed, or acted by implication to authorize or employ, any real estate broker or salesperson to act for it in connection with this Amendment, except for CBRE, on behalf of Landlord, and Tim Olsen of Carlson Partners, on behalf of Tenant, each of whom shall be paid a commission by Landlord pursuant to a separate written agreement. Landlord and Tenant each indemnify, defend, and hold the other party harmless from and against any and all claims by any other real estate broker or salesperson whom the indemnifying party authorized or employed, or acted by implication to authorize or employ, to act for the indemnifying party in connection with this Amendment.

10. Option Rights. All option rights, if any, contained in the Lease, including, without limitation, options to extend or renew the term of the Lease or to expand the Premises, are hereby deleted and are of no force and effect, except for the one (1) three-year Option set forth in Section 10 of the Fifth Amendment. For clarity, the Option contained in Section 10 of the Fifth Amendment extends to and includes the Expansion Premises.

11. Further Assurances. Landlord and Tenant each agree to execute any and all documents and agreements reasonably requested by the other party to further evidence or effectuate this Amendment.

12. Successors and Assigns. This Amendment is binding upon and inures to the benefit of the parties and their successors and assigns.

13. Reaffirmation. Except as modified herein, all other terms and conditions of the Lease remain in full force and effect, and nothing herein may be construed to relieve either Landlord or Tenant of any obligations as set forth therein.

14. Conflicts. In case of any conflict between any term or provision of this Amendment and the Lease, the term or provision of this Amendment will govern.

15. Counterparts. This Amendment may be executed in one or more counterparts, each of which is deemed an original, but all of which when taken together will constitute one agreement.

16. Signatures and Delivery. This Amendment or any other document contemplated herein, other than those to be recorded in the public records, may be electronically signed through DocuSign or a similar third-party electronic signature provider, which electronic signature technology identifies and authenticates the signer and the signer's intent to sign. Alternatively, a copy of the signature page to this Amendment or any other document contemplated herein bearing a handwritten signature may be delivered by facsimile transmission or by email in Portable Document Format and the parties agree that such delivery will have the same binding effect as delivery of the physical document bearing the handwritten signature. Landlord and Tenant intend to be bound by said forms of signatures and methods of delivery, are aware that the other party will rely on said form of signatures and methods of delivery, and hereby waive any defenses to the enforcement of the terms of this Amendment or any related document based on said form of signature and method of delivery. In the event any hand-signed documents are delivered by facsimile or email, the hand-signed originals must also be promptly exchanged by the parties, but

the failure to subsequently deliver those originals will not affect the enforceability of the document delivered by facsimile or email.

17. Construction. This Amendment shall be construed under the laws of the State in which the Premises is located. Whenever possible, each provision of this Amendment shall be interpreted in a manner that would render it effective and valid under applicable law. If any provision of this Amendment is determined to be invalid or unenforceable, that provision will be ineffective only to the extent of the prohibition or invalidity without invalidating or otherwise affecting the remaining provisions of this Amendment. All captions, headings, titles, and numerical references are for convenience only and shall have no effect on the interpretation of this Amendment.

18. Corporate Authority. Landlord and Tenant represent and warrant to the other that each has the power and authority to enter into this Amendment and that the person duly executing this Amendment on behalf of each party has the requisite power and authority to do so.

19. Entire Agreement. The Lease, this Amendment, and any exhibits attached hereto, constitute the entire understanding of the parties with respect to this transaction, and supersede all prior agreements and understandings between the parties with respect to the subject matter. No representations, warranties, undertakings or promises, whether oral, implied, written, or otherwise, have been made by any party to any other party unless expressly stated in the above-referenced documents, or unless mutually agreed to in writing between the parties after the date hereof, and neither party has relied upon any verbal representations, agreements, or understandings not expressly set forth herein.

20. Effectiveness. The parties agree that the submission of a draft or copy of this Amendment for review or signature by a party is not intended, nor will it constitute or be deemed, by either party to be an offer to enter into a legally binding agreement with respect to the subject matter hereof and may not be relied on for any legal or equitable rights or obligations. Any draft or document submitted by Landlord or its agents to Tenant will not constitute a reservation of or option or offer in favor of Tenant. The parties will be legally bound with respect to the subject matter hereof pursuant to the terms of this Amendment only if, as and when all the parties have executed and delivered this Amendment to each other. Before the complete execution and delivery of this Amendment by all parties, each party will be free to negotiate the form and terms of this Amendment in a manner acceptable to that party in its sole and absolute discretion. The parties acknowledge and agree that the execution and delivery by one party before the execution and delivery of this Amendment by the other party will be of no force and effect and will in no way prejudice the party that executed this Amendment or the party that has not executed this Amendment.

*[Signature Page Follows]*

IN AGREEMENT, the parties have executed this Amendment as of the day and year first written above.

LANDLORD:

TCI TT, LLC,  
a Delaware limited liability company

By: /s/ Michael Moriarty  
Name: Michael Moriarty  
Title Vice President

TENANT:

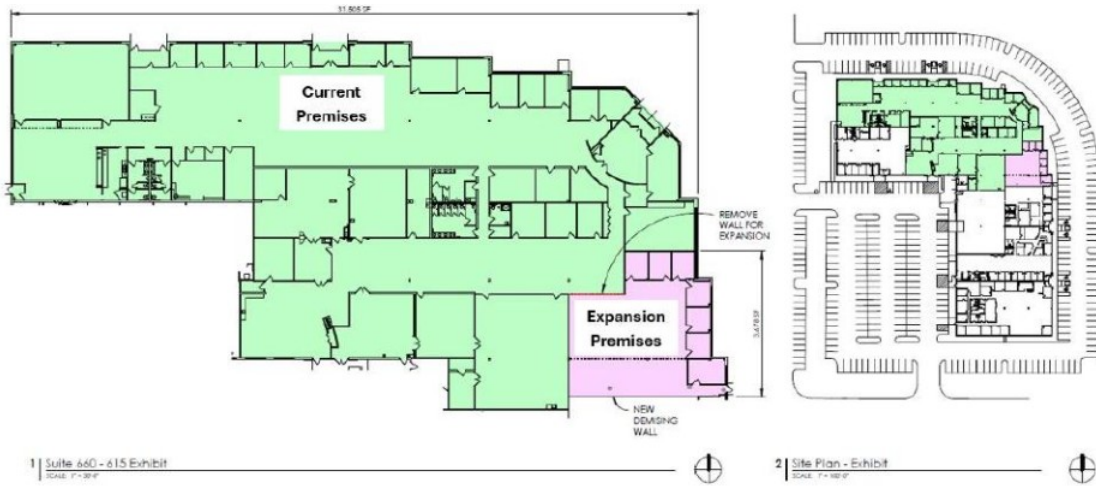
CVRx, Inc.,  
a Delaware corporation

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

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# EXHIBIT A

## Depiction of Premises



## CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Kevin Hykes, 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: August 5, 2025

By: /s/ Kevin Hykes

Name: Kevin Hykes

Title: President and Chief Executive Officer

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## 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: August 5, 2025

By: /s/ Jared Oasheim

Name: Jared Oasheim

Title: Chief Financial Officer

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**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 June 30, 2025 (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: August 5, 2025

By: /s/ Kevin Hykes

Name: Kevin Hykes

Title: President and Chief Executive Officer

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**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 June 30, 2025 (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: August 5, 2025

By: /s/ Jared Oasheim

Name: Jared Oasheim

Title: Chief Financial Officer

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