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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2024

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File Number: 001-40545

CVRx, Inc .

(Exact name of registrant as specified in its charter)

Delaware	**41-1983744**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

9201 West Broadway Avenue
Suite 650
Minneapolis , MN 55445
(Address of principal executive offices) (Zip Code)

(763) 416-2840
(Registrant's telephone number, including area code)

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

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the shares of common stock on The Nasdaq Global Select Market on June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter was approximately $ 152.5 million.

As of February 11, 2025, there were 26,036,032 shares of the registrant's common stock, par value $0.01 per share outstanding.

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Cautionary Note on Forward-Looking Statements

This Annual Report on Form 10-K 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K 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 this Annual Report on Form 10-K, which are summarized below. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K 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 this Annual Report on Form 10-K. 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

Item 1. Business

Overview

CVRx is a commercial-stage medical device company focused on developing, manufacturing, and commercializing innovative and minimally invasive neuromodulation solutions for patients with cardiovascular disease. Barostim is the first medical technology approved by the U.S. Food and Drug Administration (the "FDA") that uses neuromodulation to improve the symptoms of patients with heart failure ("HF"). Barostim is an implantable device that delivers electrical pulses to baroreceptors located in the wall of the carotid artery to counteract decreased baroreceptor signaling, which creates an imbalance in the brain's Autonomic Nervous System ("ANS") resulting in excess neurohormones that drive HF progression. Barostim provides Baroreflex Activation Therapy ("BAT," or "Barostim Therapy"), which links the cardiovascular system to the ANS. This therapy complements the pharmaceutical neurohormonal blockade, or Guideline Directed Medical Therapy ("GDMT"), by increasing the signaling of the baroreceptors, thereby, reducing symptoms of HF. Barostim received the FDA Breakthrough Device designation and is FDA-approved for use in HF patients in the U.S. We estimate that our annual market opportunity for HFrEF is $2.2 billion in the U.S. and $2.8 billion in select European Markets (Germany, France, Italy, Spain, and the United Kingdom, or "European Five").

HF is one of the most prevalent and devastating cardiovascular diseases. We estimate that there are approximately 64 million people worldwide suffering from HF, including approximately 6.7 million people in the U.S. and 10.5 million people in the European Five. HF is characterized by the heart's inability to effectively circulate blood throughout the body resulting in insufficient levels of oxygen and nourishment to various body parts. This impacts a patient's ability to function and leads to a variety of symptoms such as shortness of breath, extreme fatigue, exercise intolerance, swelling, and fluid retention that affects the patient's quality of life, both physically and emotionally. HF worsens over time due to maladaptive responses from the body's control systems, mediated by the ANS, that lead to excessive neural and hormonal activation. Autonomic activation is also a significant mechanism involved with multiple other cardiovascular diseases, such as hypertension, angina pectoris, and cardiac arrhythmia, as well as other diseases, such as chronic kidney disease.

We are currently focused on the treatment of patients with HF with reduced Ejection Fraction ("HFrEF"), which represent approximately 31% of the patients with HF. In HFrEF, the left ventricle loses its ability to contract properly, resulting in insufficient power to pump and push the necessary quantities of blood into circulation. Approximately 75% of HFrEF patients die within five years of being admitted to the hospital for HFrEF. Patients with HFrEF are typically placed on a treatment progression plan during which they are initially given Guideline Directed Medical Therapy ("GDMT") to help manage symptoms, and then progress to more invasive and costly treatment options involving other implantable devices with the most severe patients often requiring Left Ventricular Assist Devices ("LVADs") or heart transplants. These other implantable devices mostly target different HFrEF patient populations, may require an invasive procedure that places hardware directly inside the heart, and are not designed to address the imbalance of the ANS that causes the disease. We believe there is a significant need and market opportunity for a safe, effective, and minimally invasive device-based treatment option for HFrEF.

We believe Barostim offers meaningful benefits for patients, physicians and payers that will continue to drive adoption of our therapy. The primary benefits include:

- **Addresses significant unmet medical need.** Barostim addresses a life-threatening disease for patients who failed to receive adequate benefits from existing treatments and who have no alternative treatment options. Based on this, the FDA granted Barostim a Breakthrough Device designation for HFrEF in June 2015.

- **Safe and effective treatment.** Our BeAT-HF pivotal trial demonstrated compelling safety and effectiveness data regarding the clinical benefits of Barostim for HFrEF. The pre-market data demonstrated safety and effectiveness leading to FDA approval, and safety and effectiveness were confirmed by the post-market data. These results showed significant improvement in the following patient-centered outcomes:

    - **Exercise capacity (measured by the standardized 6 Minute Hall Walk ("6MHW") distance test):** Our therapy demonstrated that patients in the Barostim group were able to improve the distance they walked in a six-minute period by 56 meters and 44 meters more than patients in the control group at six months and at one year, respectively, following implant, meaning the improvement was sustained. A 25-meter improvement in walking distance is considered clinically meaningful.

    - **Quality of life (measured by Minnesota Living with Heart Failure ("MLWHF") questionnaire):** Our therapy improved quality of life by 14-points at six months, 8-points at one year and 10-points after two years of therapy compared to patients receiving GDMT alone. Patients receiving Barostim Therapy for two years reported persistent improvement in their ability to work around the house, sleep, their sense of control, and their mobility, while feeling like less of a burden to their family or friends. A 5-point improvement in the MLWHF questionnaire is considered clinically meaningful.

    - **Functional status (determined by New York Heart Association ("NYHA") classification):** Our therapy demonstrated the following improvements in NYHA functional status versus the control group at the specific points in time, meaning Barostim demonstrated greater and sustained improvement: at six months, 67% in the Barostim group and 37% in the control group, favoring the Barostim group by 30 percentage points; at one year, 73% in the Barostim group and 41% in the control group, favoring the Barostim group by 32 percentage points; and, at two years, 68% in the Barostim group and 41% in the control group, favoring the Barostim group by 27 percentage points.

    - **Freedom from All-Cause Death, LVAD, or Transplant.** Patients in the Barostim group had a directionally favorable 34% reduction in all-cause death or the use of LVAD or heart transplant versus the control group.

    - **Improvement in Hierarchical Composite Outcomes.** Based on a hierarchical composite outcomes analysis (including cardiovascular ("CV") mortality, LVAD/transplant, HF hospitalization and quality of life), the Win Ratio (defined below) was 1.26 in favor of the Barostim group.

    - **Implant safety.** The major adverse neurological or cardiovascular system or procedure-related event ("MANCE") free rate exceeded the performance criteria of 85%, with 121 out of 125 implanted patients being event free, resulting in an event-free rate of 97% ($p < 0.001$; 95% 1-sided CI: 93% to 100%).

In summary, the primary safety endpoint in the pre-market phase was previously met and subsequently confirmed in the post-market phase. In the pre-market phase, all effectiveness endpoints were previously met, demonstrating 6-month improvements in 6MHW, quality of life, NYHA Class and NT-proBNP (defined below). The post-market phase effectiveness primary endpoint of CV mortality and HF hospitalization was not met. Additional post-market phase effectiveness analyses (Win Ratio, freedom from all-cause mortality) suggested a favorable effect of Barostim Therapy. The totality of the 6, 12 and 24-month data demonstrated symptomatic improvements for HF patients who are NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed therapies and who have a LVEF ≤ 35% and a NT-proBNP<1600 pg/ml.

- **Widely accepted mechanism of action.** Our platform technology is based on a widely accepted mechanism of action and is designed to complement GDMT to further address the imbalance of the ANS and the consequent excess of neurohormones that cause HFrEF and other cardiovascular diseases to worsen over time.

- **Strong global clinical evidence.** The benefits of treatment with Barostim were shown to be similarly robust and reproducible across all three of our HF clinical studies, including BAT-in-HF (Phase I), HOPE4HF (Phase II) and BeAT-HF (Phase III pivotal trial), evaluating 624 patients in aggregate across the U.S., Germany, Italy, France, Canada and the United Kingdom. Barostim Therapy's trial results have been published in more than 65 peer-reviewed publications, approximately 25 of which relate to the treatment of HF, including, among others, the Journal of the American College of Cardiology and the European Journal of Heart Failure.

- **Minimally invasive implant procedure.** Barostim's implantable pulse generator ("IPG") and stimulation lead are implanted during a minimally invasive implant procedure typically performed in an outpatient setting that lasts approximately one hour and involves two small skin incisions. Our device does not require hardware to be implanted in the heart or vasculature, which is the case with most other device-based treatments indicated for different HFrEF patient populations. Patients typically recover quickly and are discharged from the hospital within 24 hours of the procedure.

- **Potential reduction in total healthcare costs for HFrEF patients.** A Company-sponsored and co-authored cost-impact analysis, which was published in *BMC Cardiovascular Disorders* , a peer-reviewed manuscript, predicted BAT plus GDMT would become the lower-cost alternative treatment within three years from implantation, as compared to GDMT alone, resulting in significant cost savings to healthcare systems.

- **Inherent patient compliance and durability.** Barostim ensures patient compliance, unlike most commercially available drug treatments, as it requires no device interaction by the patient. Our device has a battery that does not require recharging, has an average service life of five to six years and is replaced through a short outpatient procedure.

Barostim is a minimally invasive neuromodulation device that consists of two implantable components, an IPG and a stimulation lead and is programmed by a wireless clinician-controlled programmer that communicates with the IPG. The IPG contains the electronics and battery in a hermetic enclosure and controls and delivers the imperceptible and persistent electrical pulses to the carotid baroreceptors through the stimulation lead attached to the exterior wall of the carotid artery. Barostim has no intravascular components. These electrical pulses delivered to the baroreceptors increase signals to the brain to modulate the cardiovascular function, thereby improving symptoms of HFrEF. Our wireless programmer allows physicians to verify and customize the therapy to the patient's needs by adjusting the intensity and frequency of the electrical pulses.

We have developed a significant clinical data set that demonstrates the safety, effectiveness, patient adherence, and durable benefits of Barostim Therapy. Our BeAT-HF pivotal trial, which was a multi-center, prospective, randomized, controlled trial, met the primary safety and effectiveness endpoints and demonstrated meaningful improvement in the quality of life, both physically and emotionally, for patients suffering from HFrEF. These results led to FDA Premarket Approval ("PMA") approval of Barostim in August 2019 on an accelerated basis of only four months from the submission of the clinical trial report.

The BeAT-HF pivotal trial continued enrolling patients in the post-market stage of the trial in order to gather and evaluate additional, long-term data. In December 2023, the FDA approved expanded labeling for Barostim based on the BeAT-HF trial data, resulting in simplification and clarification of the indications for use, as well as inclusion of the primary endpoint results, the 6, 12 and 24 month symptomatic data, the Win Ratio and the all-cause mortality data in the "Clinical Summary" discussion included in Barostim's indications for use. We currently believe our annual market opportunity in the U.S. is an estimated $2.2 billion, or 76,000 patients, based on this new long-term safety and effectiveness data as well as our commercial experience and, as discussed below, the new reimbursement assignment for Barostim in 2025.

We continue to develop and expand upon our significant body of published clinical evidence that supports the meaningful benefits of Barostim Therapy. We are continuing to collect data through the U.S. patient registry

that we have established in order to evaluate and assess real world outcomes from HFrEF patients who have been implanted with Barostim.

We primarily sell Barostim to hospitals through a direct sales organization in the U.S. and Germany and through distributors in Austria, Spain, Italy, the Nordic region, and other European countries. Our global sales and marketing team engages in sales efforts and promotional activities focused on electrophysiologists ("EPs"), HF specialists, interventional cardiologists, general cardiologists, and vascular surgeons. We are prioritizing our sales and marketing efforts on high volume cardiology centers that are strategically located and on educating and training physicians. We support all aspects of the patient journey, which includes initial diagnosis, surgical support, and patient follow-up. We also highlight our compelling clinical benefits and value proposition to build awareness and adoption among physicians through targeted key opinion leader ("KOL") development, referral network education and direct-to-consumer marketing. We utilize direct communication channels to inform and educate patients about Barostim Therapy and utilize a qualification process to aid in the identification of the appropriate patients for our therapy. In the U.S., Barostim is reimbursed by the Centers for Medicare and Medicaid Services ("CMS") across all regions. We assist with reimbursement approvals, if required. We plan to continue actively expanding our direct sales force and commercial organization in the U.S., which is where we expect to focus most of our sales and marketing efforts in the near-term.

The primary focus of our research and development efforts in the near-term will be the continued technological advancement of Barostim. In the future, we plan to explore Barostim's potential to expand its indications for use to other cardiovascular diseases, including different forms of HF, hypertension, and arrhythmias. Expansions into these or other new indications would require additional FDA approvals and may involve additional clinical trials or modifications to Barostim to treat such indications. If clinical studies for future indications do not produce results necessary to support regulatory clearance or approval in the U.S. or elsewhere, we will be unable to commercialize our products for these indications.

Our primary activities include continuing to increase education and awareness among physicians, advanced practice providers and patients, develop a more robust portfolio of clinical evidence, and improve patient access to Barostim Therapy. We generated revenue of $51.3 million, a gross margin of 84% and a net loss of $60.0 million for the year ended December 31, 2024, compared to revenue of $39.3 million, a gross margin of 84% and a net loss of $41.2 million for the year ended December 31, 2023. Our accumulated deficit as of December 31, 2024 and 2023, was $537.3 million and $477.4 million, respectively.

Our market and industry

Overview of HF

It is estimated that HF currently affects approximately 64 million people globally, including approximately 6.7 million people in the U.S. and approximately 10.5 million people in the European Five. HF is associated with a five-fold increase in sudden cardiac death. There is no known prevention for HF other than the treatment of the common risk factors associated with the disease, such as hypertension, diabetes, and obesity.

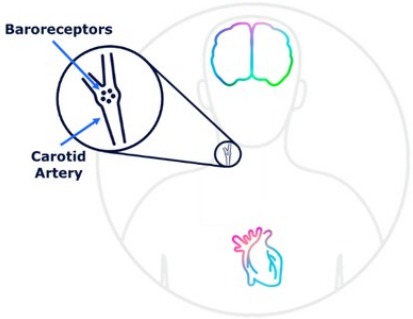
HF is a debilitating, progressive and potentially life-threatening condition where the heart does not pump enough blood throughout the body. Without proper blood circulation, insufficient levels of oxygen and nourishment are delivered to various body parts, impacting a person's ability to function and leading to a variety of symptoms that affect quality of life, both physically and emotionally, such as shortness of breath, extreme fatigue, exercise intolerance, swelling and fluid retention. HF worsens over time due to maladaptive responses from the body's control systems, mediated by the ANS, that lead to excessive neural and hormonal activation. Autonomic activation is also a significant mechanism involved with multiple other cardiovascular diseases, such as hypertension, angina pectoris and cardiac arrhythmia, as well as other diseases, such as chronic kidney disease.

The role of the imbalance of ANS in HF

The ANS, which is a part of the peripheral nervous system, plays a vital role in the function of the heart. It is a collection of receptors and neurons that acts outside of a person's conscious awareness, regulating bodily functions such as bodily fluid production, urination and sexual responses. There are two primary components of the ANS that impact heart functionality: the sympathetic system and the parasympathetic system.

The sympathetic system of the ANS is responsible for preparing the body for action through the "fight or flight" response, which consists of the release of specific neurohormones that act across the cardiovascular system. When the body perceives a threat in the environment, the sympathetic system stimulates the release of these neurohormones, which increase the heart rate, widen the airways to allow for easier breathing, release stored energy, increase strength in the muscles, and slow digestion and other bodily processes that are not as critical for taking action. These changes prepare the body to respond appropriately to a threat in its environment.

The parasympathetic system of the ANS is responsible for restoring the body to a state of calm through the "rest and digest" counter response in order to maintain homeostasis. This is done by decreasing the heart rate, conserving energy, constricting the airways, relaxing the muscles, and increasing digestion.



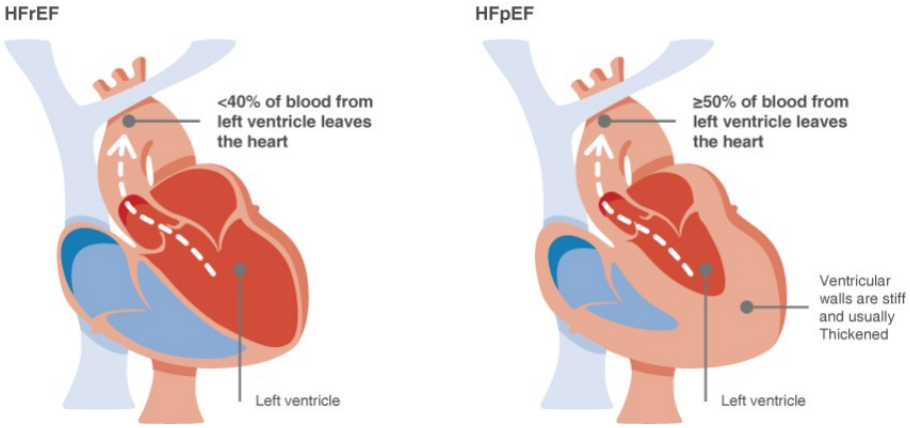
These two systems are strongly influenced by baroreceptors that are located in carotid artery walls. The baroreceptors regulate the baroreflex, which is one of the mechanisms of the ANS that help to maintain blood pressure at nearly constant levels (i.e., homeostasis). Baroreceptors provide beat-by-beat regulation of the body's circulatory system by sending electrical signals to the brain.

Healthy individuals have balanced sympathetic and parasympathetic activities due to normal baroreceptor signaling, promoting the effective function of the heart. However, there are many factors, including a person's diet, lifestyle, and underlying conditions such as diabetes and obesity that can contribute to an imbalance of the ANS and an excess of neurohormones. This imbalance, or the elevated levels of sympathetic activity and reduced levels of parasympathetic activity, may result in additional stress on the heart, leading to HF and potentially death.

Overview of HFrEF

When the heart pumps, oxygen-rich blood travels from the lungs, through the left atrium and into the left ventricle from where it is pumped to the rest of the body. Given that the left ventricle is responsible for the majority of the heart's pumping power, it is larger than the other chambers and critical for proper heart functionality. In left-sided or left-ventricular HF, the left side of the heart must work much harder to pump the same amount of blood it would under healthy conditions.

There are two types of left-sided HF, HFrEF, or systolic heart failure, and HF with preserved Ejection Fraction ("HFpEF"), or diastolic heart failure. In HFrEF, the left ventricle loses its ability to contract properly, resulting in insufficient power to pump and push the necessary quantities of blood into circulation. In HFpEF, the left ventricle loses its ability to relax properly (due to muscle stiffness), leading to the improper filling of blood in the heart during the resting period between heartbeats.



We are currently focused on the treatment of patients with HFrEF, which represents approximately 31% of the patients with HF. These patients currently have limited commercially available device-based treatment options that improve HFrEF symptoms such as shortness of breath, fatigue, weakness, swelling of the legs and feet, reduced ability to exercise, a persistent cough, an increased need to urinate and sudden weight gain. Approximately 75% of HFrEF patients die within five years of being admitted to the hospital for HFrEF.

Given HFrEF is a multifactorial and heterogeneous disease, physicians use a variety of indicators in the underlying pathology, severity of symptoms and a patient's functional limitations to classify HF patients. Below are some of the common indicators used by cardiologists to diagnose HF:

- **NYHA classification:** The NYHA classification guidelines are the most common measure of HF severity and allow physicians to classify patients into four groups based on observed symptoms and functional limitations. The least severe functional status is NYHA Class I (mild) with the most advanced being NYHA Class IV (critical). The majority of patients are initially identified as NYHA Class I or II and typically progress into subsequently worse states of the disease despite current treatment options. On average, patients who progress to a NYHA Class III either worsen to Class IV or die after 3.3 years. HFrEF patients are typically classified as NYHA Class II (moderate) or Class III (severe).

- **Level of N-terminal prohormone B-type natriuretic peptide ("NT-proBNP"):** NT-proBNP, a non-active prohormone in the heart, is released due to pressure changes inside the heart. NT-proBNP is considered to be at a normal level when it is < 125pg/ml for patients 0-74 years old and < 450pg/ml for patients 75-99 years old. Generally, patients with HF have elevated NT-proBNP levels, with those > 1600pg/ml associated with an extremely poor prognosis and low responses to treatments.

- **Left ventricular ejection fraction ("LVEF"):** LVEF is a widely utilized indicator of systolic heart function, or the heart's ability to pump blood throughout the body. It measures the percentage of blood that is ejected from the left ventricle with each beat. An LVEF < 50% is considered dysfunctional and indicative of HFrEF.

- **Co-morbidities / clinical fit:** A patient's co-morbidities, such as severe chronic obstructive pulmonary disease ("COPD"), kidney disease or carotid stenosis, as well as a patient's physical and psychological fit

contribute to a physician's treatment recommendation given the use of general anesthesia in most HF-related device-based treatment options.

- **QRS complex:** The QRS complex is a classification of ventricle depolarization, or the heart's ability to open once contracted. It measures the way in which electrical signals travel through the heart and considers the mechanics and duration of the ventricle depolarization. A narrow QRS complex, or a QRS < 120 milliseconds, is usually driven by a right bundle branch block, which is a blockage along the pathway that electrical pulses travel through to the right ventricle in order to generate a heartbeat. A wide QRS complex, or a QRS ≥ 150 milliseconds, is usually driven by a left bundle branch block, which is a blockage impacting the pathway to the left ventricle.

Existing treatments for HFrEF

Patients with HFrEF are typically placed on a treatment progression plan during which they are initially given GDMT to help manage symptoms. GDMT usually includes a progression or combination of prescribed drugs such as diuretics, beta-blockers, ACE Inhibitors, ARBs, ARNIs, SGLT2 inhibitors and sinus node inhibitors. After being treated with pharmaceuticals for a short period, if the symptoms persist, patients move to more invasive and costly treatment options involving other implantable devices, with the most severe patients often requiring LVADs or heart transplants.

Other commercially available implantable devices

Implantable Cardiac Defibrillators ("ICD")

ICDs are indicated for patients with NYHA Class II or III and LVEF ≤ 35% for both wide and narrow QRS. However, these devices are generally used to prevent sudden cardiac arrest rather than reduce HFrEF symptoms, as their electrical shocks focus on restoring a normal heartbeat when a heart beats too quickly or randomly. Given their purpose and mechanism of action, these devices are not a treatment for HFrEF but are used in conjunction with other treatment options that focus on reducing HF symptoms.

Cardiac Resynchronization Therapy ("CRT")

CRTs, or biventricular pacing, are indicated for patients with NYHA Class II or III, LVEF ≤ 35% and wide QRS. These devices are primarily used to reduce symptoms of HFrEF by generating electrical pulses to regulate the pace of a heartbeat. While CRTs can alleviate symptoms for patients with a wide QRS, they are not eligible for patients with a narrow QRS, which represents approximately 59% of patients with NYHA Class II or III and LVEF ≤ 35%. These devices can be combined with an ICD, which are referred to as CRT-D.

Cardiac Contractility Modulation ("CCM")

CCM is eligible for patients with NYHA Class III, LVEF 25-45%, narrow QRS and normal sinus rhythm. CCM requires an invasive procedure whereby an IPG is implanted under the skin of the upper chest with electrical leads running through the veins and attached inside the heart's ventricles, sending electrical pulses to the heart after it contracts. The device is rechargeable and therefore requires patients to recharge the battery on a regular basis.

Left Ventricular Assist Device ("LVAD")

LVAD is an irreversible, invasive surgery generally reserved for critical HFrEF patients with NYHA Class IV. An LVAD is a mechanical pump that is implanted inside a patient's chest and helps pump blood throughout the body. While LVADs do not replace the heart, they do require open chest surgery and often result in the destruction of a portion of the heart. Patients who do not respond to LVADs usually have no other treatment options and become candidates for heart transplants.

Despite currently available pharmaceutical and device-based treatments, HF remains underpenetrated and imposes significant direct and indirect costs on the healthcare system through patient care, morbidity, unpaid care costs, premature mortality and lost productivity. We estimate there are approximately 1.2 million HF hospitalizations every year in the U.S., representing approximately $39.5 billion in annual spending.

Barostim's market opportunity

In late 2023, we revised our U.S. annual market opportunity – based on the long-term safety and effectiveness data of BeAT-HF, our commercial experience and to account for the new reimbursement assignment for Barostim – to $2.2 billion, or 76,000 new patients per year. We have since also revised our estimate of the European Five annual HFrEF market opportunity to $2.8 billion, or 98,000 patients per year. This yields a total combined market of $5.0 billion, or 174,000 patients per year.

Our solution

We developed our Barostim platform technology to transform the treatment of HFrEF and other cardiovascular diseases and become the standard of care for this vulnerable and underpenetrated patient population. We believe Barostim offers meaningful benefits for patients, physicians and payers that will continue to drive adoption of our therapy.

Overview of Barostim Therapy

Our integrated platform technology, Barostim, leverages the power of the brain and its ANS to address the primary cause of HFrEF and other cardiovascular diseases. Our product, Barostim, is the first and only commercially available neuromodulation device indicated to improve symptoms for patients with HFrEF. Barostim Therapy utilizes a widely accepted mechanism of action and works by sending imperceptible and persistent electrical pulses to baroreceptors located in the wall of the carotid artery to counteract decreased baroreceptor signaling, which results in an excess of neurohormones that drives HF progression. Barostim provides BAT, which complements the neurohormonal blockade, or GDMT, by increasing the signaling of the baroreceptors. This increased signaling is well understood to normalize blood pressure, improve remodeling of the heart, increase vasodilation (widening of blood vessels), and improve kidney function. Based on the results of our BeAT-HF pivotal trial, Barostim has demonstrated its ability to meaningfully improve the quality of daily life, both physically and emotionally, for patients suffering from HFrEF.

Barostim

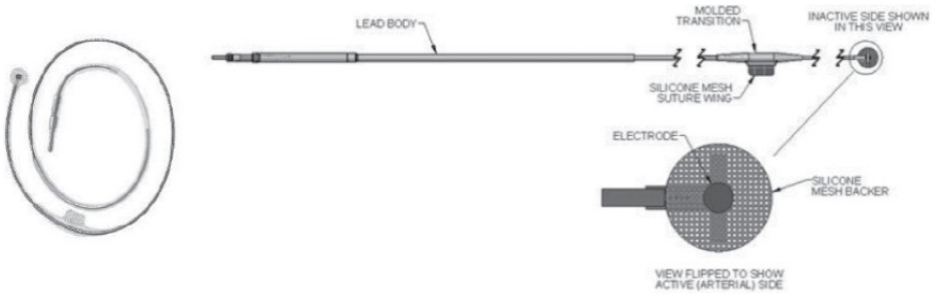
Barostim consists of two implantable components: an IPG and a stimulation lead. The image below depicts the relative location and size of Barostim under the patient's skin:

Implantable pulse generator

The current IPG contains the electronics and battery in a hermetic enclosure, has an average service life of five to six years and includes a battery that does not require any recharging. The IPG provides control and delivery of electrical pulses to baroreceptors located in the wall of the carotid artery through the stimulation lead. Nominal dimensions for the current IPG are listed in the figure below:

Stimulation lead

The stimulation lead is attached via six suture points to the exterior wall of the carotid artery and is connected to the current IPG. This allows the stimulation lead to carry the electrical pulses from the IPG to the baroreceptors located in the wall of the carotid artery. The stimulation lead terminates with a two-millimeter electrode. There are two lengths of the stimulation lead available to allow for anatomical variations to be used at the physician's discretion.



Ancillary surgical accessories

In addition to the IPG and stimulation lead, we provide physicians with single-use surgical tools, including the port plug, torque wrench, implant tool and implant adaptor, all of which were designed to facilitate the implantation of Barostim.

Programmer

Once implanted, Barostim is managed wirelessly by a programmer that communicates with the IPG. The programmer can be used to assist in verifying the desired location of the stimulation electrode during the implant procedure and allows physicians to input their patient's therapy parameters and retrieve information on the status of the IPG, including the remaining battery life, without touching the IPG or the patient.

Treating patients with Barostim

Patient selection

Barostim is indicated 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 ≤ 35% and a NT-proBNP < 1600 pg/ml. Barostim delivers BAT to improve patients' NYHA functional status, 6MHW and quality of life.

Once a patient is diagnosed with HFrEF and recommended for an ICD and/or CRT, interventional or general cardiologists will often refer them to EPs, who often conduct a series of diagnostic tests, including an electrocardiogram, ultrasound, and various blood tests, from which they will determine the patient's eligibility for our therapy. Many of our indicated patients may have already been pre-indicated for an ICD, whether or not they chose to undergo the ICD implantation procedure.

Implantation

Barostim is implanted during a short, minimally invasive procedure that is typically performed on an outpatient basis by a vascular surgeon and possibly an EP. The procedure has two steps. During the first step, a small incision is made on the right side of the neck to expose the carotid sinus. The physician uses the implant tool to hold the lead electrode in contact with the outside wall of the carotid artery while the lead is temporarily connected to the IPG to verify the location of the electrode. After the electrode is sutured in place, the second step begins by making a small incision below the right clavicle where a pocket is created under the skin to hold the IPG. The main body of the stimulation lead is tunneled under the skin, but over the clavicle, from the neck to the pocket. The lead connector is inserted and secured into the IPG header. Lastly, the IPG is placed in the pocket and a few stiches are used to close each incision.

This implantation procedure, which typically lasts one hour, is usually performed under general anesthesia and may require a short hospital stay. While patients may experience mild discomfort and swelling at the incision sites for a few days, this often can be managed with over-the-counter pain medications. Patients typically recover quickly and are discharged from the hospital within 24 hours of the procedure.

Activation/Titration

After Barostim is implanted and activated, the patient attends a few follow-up visits with their doctor, during which the device is progressively titrated from a moderate level to a higher amplitude of electrical stimulation. The primary objective of these follow-up visits is for the patient to reach the optimal level of stimulation, which is typically achieved approximately three months after implantation. The exact level of stimulation varies from patient to patient based on the response to Barostim Therapy. Barostim can be adjusted through a digital wireless programmer, allowing the clinician to monitor and customize the therapy to the patient's needs by adjusting the intensity and frequency of the electrical pulses being sent to the carotid artery. After the titration period, it is recommended that the patient attend a clinical visit two times each year to check impedance, battery longevity and adequacy of programming.

Key benefits for patients, physicians and payers

Barostim is designed to advance patient care and provide a safe, effective, and economically attractive treatment option to an underserved patient population suffering from HFrEF. We believe the following factors offer meaningful benefits for patients, physicians and payers that will continue to drive broad adoption of our therapy:

- **Addresses significant unmet medical need.** Barostim addresses a life-threatening disease for patients who failed to receive adequate benefits from existing treatments and who have no alternative treatment options. Based on this, the FDA granted Barostim a Breakthrough Device designation for HFrEF in June 2015.

- **Safe and effective treatment.** Our BeAT-HF pivotal trial demonstrated compelling safety and effectiveness data regarding the clinical benefits of Barostim for HFrEF. The pre-market data demonstrated safety and effectiveness leading to FDA approval and safety and effectiveness were confirmed by the post-market data. These results showed significant improvement in the following patient-centered outcomes:

    - **Exercise capacity (measured by the standardized 6MHW distance test):** Our therapy demonstrated that patients in the Barostim group were able to improve the distance they walked in a six-minute period by 56 meters and 44 meters more than patients in the control group at six months and at one year, respectively, following implant, meaning the improvement was sustained. A 25-meter improvement in walking distance is considered clinically meaningful.

    - **Quality of life (measured by MLWHF questionnaire):** Our therapy improved quality of life by 14-points at six months, 8-points at one year and 10-points after two years of therapy compared to patients receiving GDMT alone. Patients receiving Barostim Therapy for two years reported persistent improvement in their ability to work around the house, sleep, their sense of control, and their mobility, while feeling like less of a burden to their family or friends. A 5-point improvement in the MLWHF questionnaire is considered clinically meaningful.

    - **Functional status (determined by NYHA classification):** Our therapy demonstrated the following improvements in NYHA functional status versus the control group at the specific points in time, meaning Barostim demonstrated greater and sustained improvement: at six months, 67% in the Barostim group and 37% in the control group, favoring the Barostim group by 30 percentage points; at one year, 73% in the Barostim group and 41% in the control group, favoring the Barostim group by 32 percentage points; and, at two years, 68% in the Barostim group and 41% in the control group, favoring the Barostim group by 27 percentage points.

    - **Freedom from All-Cause Death, LVAD, or Transplant.** Patients in the Barostim group had a directionally favorable 34% reduction in all-cause death or the use of LVAD or heart transplant versus the control group.

- **Improvement in Hierarchical Composite Outcomes.** Based on a hierarchical composite outcomes analysis (including CV mortality, LVAD/transplant, HF hospitalization and quality of life), the Win Ratio was 1.26 in favor of the Barostim group.

- **Implant safety.** The MANCE-free rate exceeded the performance criteria of 85%, with 121 out of 125 implanted patients being event free, resulting in an event-free rate of 97% ($p < 0.001$; 95% 1-sided CI: 93% to 100%).

The significant benefits of our therapy were observed despite a four-fold uptake of ARNI medication in the control arm, as compared to the device arm.

- **Widely accepted mechanism of action.** Our platform technology is based on a widely accepted mechanism of action and is designed to complement GDMT to further address the imbalance of the ANS and the consequent excess of neurohormones that cause HFrEF and other cardiovascular diseases to worsen over time.

- **Strong global clinical evidence.** The benefits of treatment with Barostim were shown to be similarly robust and reproducible across all three of our HF clinical studies, including BAT-in-HF (Phase I), HOPE4HF (Phase II), and BeAT-HF (Phase III pivotal trial), evaluating 624 patients in aggregate across the U.S., Germany, Italy, France, Canada and the United Kingdom. The BeAT-HF pivotal trial, which was a multi-center, prospective, randomized, controlled trial, met its primary endpoints and the positive safety and effectiveness data exceeded the pre-specified performance criteria across multiple dimensions, measuring the improvement in the quality of patients' daily lives. Barostim Therapy's trial results have been published in more than 65 peer-reviewed publications, approximately 25 of which relate to the treatment of HF, including, among others, the Journal of the American College of Cardiology and the European Journal of Heart Failure.

- **Minimally invasive implant procedure.** Barostim's IPG and stimulation lead are implanted during a minimally invasive implant procedure typically performed in an outpatient setting that lasts approximately one hour and involves two small skin incisions. Our device does not require hardware to be implanted in the heart or vasculature, which is the case with most other device-based treatments indicated for different HFrEF patient populations. Patients typically recover quickly and are discharged from the hospital within 24 hours of the procedure.

- **Potential reduction in total healthcare costs for HFrEF patients.** In addition to providing improved physical and health-related benefits and quality of life for patients, we estimate Barostim has the potential to result in cost savings to healthcare systems. A Company-sponsored and co-authored cost-impact analysis, which was published in *BMC Cardiovascular Disorders*, a peer-reviewed manuscript, predicted BAT plus GDMT would become the lower-cost alternative treatment within three years from implantation, as compared to GDMT alone, resulting in significant cost savings to healthcare systems.

- **Inherent patient compliance and durability.** Barostim ensures patient compliance, unlike most commercially available drug treatments, as it requires no device interaction by the patient. Our device has a battery that does not require recharging, has an average service life of five to six years and is replaced through a short outpatient procedure.

Clinical results and studies

The safety and effectiveness of Barostim in HFrEF is supported by compelling data, which demonstrated similarly robust and reproducible results across our three clinical trials evaluating 624 patients in aggregate across the U.S., Germany, Italy, France, Canada, and the United Kingdom. We designed our BeAT-HF (Phase III) pivotal trial in collaboration with the FDA under the Breakthrough Devices Program, which was implemented to accelerate the approval of novel therapies targeting unmet needs for debilitating or life-threatening conditions. The pre-market phase of our BeAT-HF pivotal trial met the primary safety and effectiveness endpoints and demonstrated meaningful improvement in the quality of life, both physically and

emotionally, for patients suffering from HFrEF. These results led to the FDA approval of Barostim in August 2019 on an accelerated basis of only four months from the submission of the final clinical trial report. The post-market phase BeAT-HF pivotal trial met the primary safety endpoint, and although it did not meet the primary effectiveness endpoint, showed sustained improvements in exercise capacity, quality of life and NYHA functional status, and favored Barostim in freedom from all-cause mortality, LVAD or transplant and in the Win Ratio. This led to the FDA approval of expanded labeling with these results and a simplification and clarification of the following indications for use.

Barostim is indicated for patients who are NYHA Class III or Class II (with a recent history of Class III) despite treatment with guideline-directed medical therapies (medications and devices), have a LVEF ≤ 35% and a NT-proBNP < 1,600 pg/ml. Barostim delivers BAT to improve patients' NYHA functional status, 6MHW and quality of life.

The safety and effectiveness of Barostim Therapy have been published in more than 65 peer-reviewed publications, approximately 25 of which relate to the treatment of HF, including, among others, the publications on the pivotal trial results in the Journal of the American College of Cardiology and the European Journal of Heart Failure.

We have established a U.S. patient registry to evaluate and assess real world patient outcomes from patients who have been implanted with Barostim. Investment in clinical evidence continues to be one of our core strategies, and we intend to continue to develop and expand upon a significant body of published clinical evidence that supports the safety and effectiveness of Barostim Therapy.

Pivotal Phase III Study: BeAT-HF

Overview

BeAT-HF was a multi-center, prospective, randomized, controlled trial that began in April 2016 to develop scientific evidence for the safety and effectiveness of BAT with Barostim. Between May 2016 and July 2020, 467 adult patients were randomized at 72 sites within the U.S. and one site in the United Kingdom.

The BeAT-HF study was designed to encompass two stages in an integrated and seamless approach:

(1) A pre-market stage that examined three primary effectiveness endpoints (quality of life, 6MHW and NT-proBNP), as well as one safety endpoint that included the MANCE-free rate.

(2) A post-market stage that examined the effects of BAT on rates of HF hospitalization and CV mortality, as well as sustained safety and symptomatic improvements, which expanded the labeling for Barostim.

Patients were eligible for the trial if they were NYHA Class III or Class II (with a recent history of Class III); had an LVEF ≤ 35% and NT-proBNP < 1,600 pg/ml; were able to complete a 6MHW distance of 150 to 400 meters; were on stable optimal GDMT for ≥ 4 weeks; had at least one carotid artery that was below the level of the mandible with no ulcerative carotid arterial plaques or stenosis ≥ 50%; and were an acceptable surgical candidate.

Patients who had a Class I indication for a CRT according to the American Heart Association/American College of Cardiology/European Society of Cardiology guidelines were excluded, and there were no restrictions for atrial fibrillation or atrial flutter.

In summary, the primary safety endpoint in the pre-market phase was previously met and confirmed in the post-market phase. In the pre-market phase, all effectiveness endpoints were previously met, demonstrating 6-month improvements in 6MHW, quality of life, NYHA Class and NT-proBNP. The post-market phase effectiveness primary endpoint of CV mortality and HF hospitalization was not met. Additional post-market phase effectiveness analyses (Win Ratio and freedom from all-cause mortality) suggested a favorable effect of Barostim Therapy. The totality of the 6, 12 and 24-month data demonstrated symptomatic improvements

for HF patients who are NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed therapies and who have a LVEF ≤ 35% and a NT-proBNP < 1600 pg/ml.

Pre-market phase results

The safety and effectiveness data in the BeAT-HF pivotal trial support the HFrEF clinical benefits of Barostim. These results demonstrated that BAT is safe in patients with HFrEF and significantly improves the patient-centered symptomatic endpoints of the quality-of-life score, 6MHW and NYHA functional status, as well as the confirmatory nature of the evidence provided by a reduction of NT-proBNP.

- **Quality of life (measured by MLWHF questionnaire):** BAT resulted in a 14-point improvement in quality of life for patients in the Barostim group relative to patients in the control group ($p < 0.001$; 95% CI: -19 to -9). MLWHF is a self-administered disease-specific questionnaire for HF, which is comprised of 21 questions rated on six-point Likert scales, representing different degrees of impact of HF on a patient's quality of life, and is approved by the FDA as a Medical Device Development Tool. According to the medical community, a 5-point improvement is considered to be clinically meaningful.

- **Exercise capacity (measured by the standardized 6MHW distance test):** BAT resulted in a 60-meter increase in the distance patients in the Barostim group were able to walk on a flat, hard surface in a six-minute period relative to that of patients in the control group ($p < 0.001$; 95% CI: 40 to 80 meters). According to the medical community, the 6MHW is an index of a patient's ability to perform daily activities; an improvement of 25 meters or more is considered to be clinically meaningful to HFrEF patients.

- **Functional status (determined by NYHA classification):** BAT demonstrated that 65% of patients in the Barostim group improved at least one NYHA class ($p < 0.001$; 95% CI: 22% to 46%) as compared to only 31% in the control group and 13% of patients in the Barostim group improved two NYHA classes as compared to only 2% in the control group.

- **NT-proBNP (serum biomarker used as indicator of severity of HF):** BAT resulted in a 25% greater reduction (improvement) in NT-proBNP for patients in the Barostim group relative to that of patients in the control group ($p=0.004$; 95% CI = -38% to -9%). According to independent research that took place in a large multicenter pharmaceutical clinical trial, a 10% change in NT-proBNP is associated with a change in the subsequent risk of CV mortality and HF hospitalization.

The MANCE-free rate exceeded the performance criteria of 85%, with 121 out of 125 implanted patients being event free, resulting in an event-free rate of 97% ($p < 0.001$; 95% 1-sided CI: 93% to 100%).

In addition to the results noted above, we observed a reduction in the rate of cardiovascular serious adverse events (non-HF related events) by 51% (events per patient-year; 0.101 Barostim group vs 0.206 control group; nominal $p= 0.023$; 95% CI: 0.10 to 0.73) and there were no significant differences in blood pressure or heart rate.

Post-market phase results

The BeAT-HF pivotal trial continued enrolling patients in the post-market stage of the trial to determine if Barostim demonstrates a statistically significant improvement in morbidity and mortality in patients with HFrEF. Between May 2019 and July 2020, an additional 59 adult patients were randomized at 17 sites within the U.S. as part of the post-market phase of the trial.

The safety and effectiveness data in the BeAT-HF pivotal trial support the HFrEF clinical benefits of Barostim. These results demonstrated that BAT is safe in patients with HFrEF, showed a directional reduction in the primary endpoint of CV mortality and HF morbidity (although not reaching statistical significance), and favored patient-centered symptomatic improvements at 6 and 12 months in 6MHW and at 6,12 and 24 months in the MLWHF quality of life questionnaire and NYHA Class.

- **Exercise capacity (measured by the standardized 6MHW distance test):** The Barostim group showed an improvement at both 6 and 12 months compared to the control group. The difference between the arms at 6 months was 56 meters and at 12 months the difference was sustained with 44 meters. These improvements between the groups are not only statistically significant, but they are approximately twice the clinically significant value of 25 meters.

Visit	BAT + group* N=163 Mean ± SD (95% CI)	Control group* N=160 Mean ± SD (95% CI)	Difference (95% CI)**
Baseline	313.7 ± 66.3	299.5 ± 71.3	
6-Month Change	46.8 (35.8, 57.8)	-8.7 (-22.5, 5.2)	55.5 (37.7, 73.3)
12-Month Change	40.6 (26.4, 54.7)	-3.0 (-13.5, 7.6)	43.5 (25.7, 61.4)

*Statistics are estimated mean improvement and 95% confidence interval from repeated measures model
**From generalized estimating equation repeated measures model with covariate for baseline value

- **Quality of life (measured by MLWHF questionnaire):** The Barostim group showed an improvement in quality of life points ranging from 17 to 20 points from baseline across the follow-up visits. The differences between the groups at 6, 12 and 24 months are -14, -8 and -10, respectively, which is not only statistically significant, but is greater than a clinically meaningful difference of 5 points.

Visit	BAT + group* N=163 Mean ± SD (95% CI)	Control group* N=160 Mean ± SD (95% CI)	Difference (95% CI)**
Baseline	52.7 ± 23.7	50.8 ± 24.0	
6-Month Change	-19.8 (-23.1, -16.5)	-6.3 (-9.5, -3.1)	-13.5 (-18.1, -8.9)
12-Month Change	-17.0 (-20.4, -13.6)	-8.6 (-11.8, -5.4)	-8.4 (-13.1, -3.7)
24-Month Change	-18.0 (-21.7, -14.2)	-8.0 (-12.0, -4.0)	-10.0 (-15.5, -4.5)

*Statistics are estimated mean improvement and 95% confidence interval from repeated measures model
**From generalized estimating equation repeated measures model with covariate for baseline value

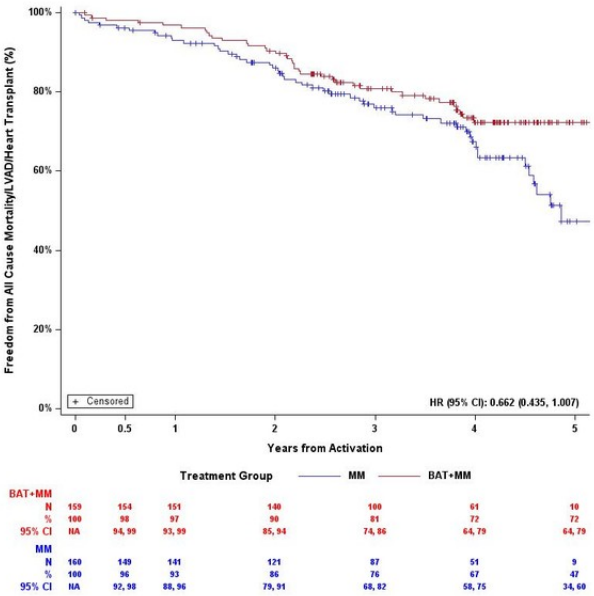
- **Functional status (determined by NYHA classification):** Approximately two-thirds of the Barostim group improved at least one NYHA class across the follow-up visits. Additionally, the percentage of subjects improving between the arms at 6, 12, and 24 months was higher in the Barostim group compared to the control group.

Visit	BAT + group*	Control group *	Difference (95% CI)**
Baseline			
Class I	0.0% (0/163)	0.0% (0/160)	
Class II	4.9% (8/163)	5.6% (9/160)	
Class III	95.1% (155/163)	94.4% (151/160)	
Class IV	0.0% (0/163)	0.0% (0/160)	
6-Month	66.6 (59.2, 74.0)	36.8 (29.1, 44.6)	29.8 (19.1, 40.5)
12-Month	72.7 (65.6, 79.7)	40.8 (32.9, 48.7)	31.9 (21.2, 42.5)
24-Month	68.0 (60.0, 76.0)	41.1 (31.5, 50.6)	26.9 (14.4, 39.4)
*Statistics are estimated mean improvement and 95% confidence interval from repeated measures model **From generalized estimating equation repeated measures model with covariate for baseline value			

- **Hierarchical Win Ratio:** The hierarchical composite analysis using the Win Ratio was evaluated using the components of the CV morbidity and HF mortality endpoints and the MLWHF quality of life (CV mortality, heart transplant or LVAD, number of hospitalizations or emergency visits for HF, number of unscheduled clinical visits with IV diuretic, and change from baseline in MLWHF at 12 months). This resulted in a Win Ratio of 1.26, reflecting beneficial trend in the heart transplant/LVAD over the course of the study and MLWHF at 12 months.

Endpoint Component	BAT+ group Win	Control group Win
CV Mortality	3085 (50.2%)	3060 (49.8%)
Heart transplant or LVAD	1420 (73.0%)	526 (27.0%)
HF Event (Expanded definition)	3091 (47.2%)	3453 (52.8%)
Unscheduled clinic visits w/IV diuretic (Expanded definition)	51 (17.3%)	243 (82.7%)
Change in MLWHF at 12 months with imputation for missing data	5701 (63.5%)	3284 (36.5%)
Win Ratio with the hierarchy of: 1) CV Death, 2) Heart transplant or LVAD, 3) Number of hospitalizations for Heart Failure using the expanded definition of HF, 4) Number of unscheduled clinic visits w/IV diuretic using the expanded definition for HF, 5) Change in MLWHF QoL at 12 months with imputation for missing data. Percent of Total BAT+MM vs MM comparisons that did not end in a tie is 95.2%		

- **Freedom from All-Cause Mortality:** In addition to the results above, freedom from all-cause mortality (all-cause death, LVAD and heart transplant) demonstrated a 34% reduction between the groups. In the Barostim group, the crude event rate was 7.0 per 100 years with 38 events during 544 patient-years at risk. In the control group, the crude event rate was 10.4 per 100 years with 51 events during 492 patient-years at risk. As shown below, the hazard ratio for all-cause mortality = 0.662 (95% CI 0.435, 1.007), representing a relative risk reduction of 34% in the Barostim group compared with the control group. The hazard ratio for all-cause mortality using a per protocol analysis = 0.589 (95% CI 0.380, 0.923), representing a relative risk reduction of 41% in the Barostim group compared with the control group.



The system or procedure related MANCE endpoint includes all events that occurred across the duration of follow-up. The analysis includes subjects in Barostim group who had an implant attempted (n=159), representing 6,664 total months of implant follow-up. All implant attempts were successful. As shown below, the MANCE-free rate is 96.9%, with 154 out of 159 implanted patients being event free with a lower bound one-sided 95% confidence level of 93.5% (p value <0.001 compared to a performance goal of 85%).

	Total Number of Subjects	Number of Subjects MANCE-Free	MANCE-Free Rate	One-Sided 95% Lower Bound	P-value
MANCE Event-Free	159	154	96.9%	93.5%	<.001

Phase II Study: HOPE4HF

HOPE4HF was a multinational, prospective, randomized, controlled trial that began in May 2012 to demonstrate the safety and performance of BAT with Barostim. A total of 146 patients (72 in the U.S. and 74 in Germany, Italy, France, and Canada) at 45 centers were randomized 1:1 with 76 patients in the Barostim group and 70 patients in the control group.

Patients were eligible for the study based on symptoms, historical treatment plan and anatomical criteria, including if they were NYHA Class III, received GDMT for their HF, had a LVEF ≤ 35% and were considered a suitable surgical candidate, among others. Patients were excluded from the study if they had recently experienced NYHA Class IV, recently received an ICD or CRT, or had known baroreflex failure, among others.

Results

The overall MANCE-free rate was 97% (lower 95% CI bound 91%). Patients assigned to Barostim group, compared with control group patients, experienced improvements in MLWHF quality of life score (–17 ± 2.8 points Barostim group vs. 2.1 ± 3.1 points control group; p < 0.001), 6MHW distance (60 ± 14 meters Barostim group vs. 1.5 ± 13 meters control group; p=0.004) and NT-pro BNP (-69 pg/ml Barostim group vs. 130 pg/ml control group; p =0.02). Barostim group patients also experienced at least a one-class improvement in NYHA class when compared to the control group (55% Barostim group vs 24% control group; p=0.002) and showed a trend toward fewer days hospitalized for HF (p=0.08) as compared to the control group.

Positive safety and performance results from the 146-patient combined, randomized, controlled clinical trials were presented in the late breaking clinical trial session of the American College of Cardiology and the European Society of Cardiology HF conference in 2015. The favorable data from this trial were published in the *Journal of the American College of Cardiology — Heart Failure* in 2015. These results led to CE Mark approval.

Phase I Study: BAT in HF

BAT in HF was our first-in-human study of Barostim Therapy for the treatment of HF that was published in 2014. This study was a single-center, open-label evaluation, designed to evaluate the safety and performance of Barostim Therapy in patients with NYHA Class III receiving optimized medical therapy for their HF and had an LVEF ≤ 40%. Patients who had been implanted with a CRT device were excluded from this trial until six months after activation. Eleven patients met the eligibility criteria and received Barostim. After six months of Barostim Therapy, the mechanism of action was assessed with serial measurement of muscle sympathetic nerve activity (“MSNA”) and clinical measures of quality of life and functional capacity.

Results

MSNA was reduced over six months from 45 ± 7.7 to 31 ± 8.3 bursts/minute and from 68 ± 13 to 45 ± 12 bursts/100 heartbeats, decreases of 31% and 33%, respectively (p < 0.01). Concomitant improvements occurred in baroreflex sensitivity, ejection fraction, NYHA class and quality of life as measured by the MLWHF and 6MHW distance (p ≤ 0.05 each). On an observational basis, hospitalization and emergency department visits for worsening HF were reduced.

This study provided the first evidence that chronic stimulation of carotid baroreceptors markedly and persistently reduced the sympathetic activation characterizing HF patients. It also demonstrated that the reduction is accompanied by the improvement of a major modulator of sympathetic activity, the arterial baroreflex and baroreflex activation is accompanied by favorable therapeutic impact on cardiac function and clinical profile, as shown in the improved quality of life, increased exercise tolerance and improved NYHA functional status.

Other clinical trials

BATwire implant toolkit

In the second half of 2020, the FDA approved a two-stage pivotal trial design to assess the safety and effectiveness of the BATwire implant toolkit. This trial was expected to enroll up to 400 subjects and follow up to 100 implanted subjects for one year. In April 2024, we suspended enrollment in the BATwire clinical trial

because of slow recruitment, due in part to trial candidates choosing the commercially approved procedure. All enrolled patients will be followed per the protocol until the trial is completed.

Hypertension

We have completed two clinical trials in Europe and North America for the treatment of drug-resistant hypertension using our first-generation Barostim Therapy device called Rheos, and determined this study was successful in achieving three of the required five safety and effectiveness endpoints ("*Baroreflex Activation Therapy Lowers Blood Pressure in Patients with Resistant Hypertension: Results from the Double-Blind, Randomized, Placebo-Controlled Rheos Pivotal Trial*," by John D. Bisognano, M.D. et al that was published in 2011 in the Journal of the American College of Cardiology, volume 58, No. 7, 2011). In 2014 we submitted a request for a Humanitarian Device Exemption ("HDE") to commercialize Barostim Legacy, our second generation IPG for the subjects that were enrolled in the Rheos Pivotal trial, who are benefitting clinically from Rheos (estimated at the time to be 70–80% of the subjects enrolled) and whose IPG battery had become depleted. In December 2014, after a favorable review of the long-term clinical data from the Rheos pivotal hypertension trial, the FDA granted the HDE to Barostim Legacy.

Since 2011, we have completed one clinical trial in Europe and North America for the treatment of drug-resistant hypertension using Barostim ("*Minimally Invasive System for Baroreflex Activation Therapy Chronically Lowers Blood Pressure with Pacemaker-like Safety Profile: Results from the Barostim Neo Trial*," by Uta C. Hoppe, M.D. et al, in the Journal of the American Society of Hypertension, volume 5, no. 4, 2012).

In August 2011, we received CE Mark approval for Barostim for the treatment of resistant hypertension. In October 2012, we received FDA approval to conduct a pivotal trial for the treatment of resistant hypertension entitled "*Barostim Hypertension Pivotal Study*." On April 12, 2013, the study had its first enrollment. However, a redirection of our limited available financial and personnel resources to develop Barostim Therapy in HFrEF led to putting the trial on hold. In December 2019, after review of the clinical data and the competitive landscape, FDA granted a Breakthrough Device designation for Barostim for the treatment of resistant hypertension.

HFpEF

In March 2020, after review of early clinical data and the competitive landscape, the FDA granted a Breakthrough Device designation for Barostim for the treatment of HFpEF. In 2023, the FDA admitted us into the Total Life Cycle Advisory Program ("TAP") for Barostim's treatment of HFpEF. TAP is an initial pilot program limited only to Breakthrough Device designated indications for new products.

Sales and marketing

We have established a systematic approach to market development which centers on active engagement across three key stakeholders in the HFrEF treatment paradigm—patients, physicians, and hospitals.

Barostim has FDA approval to improve symptoms of HFrEF in the U.S. and an Active Implantable Medical Device Directive ("AIMDD") CE Mark for the treatment of HFrEF and resistant hypertension in Europe. Additionally, the EU approved an amendment to the MDR (as defined below) which allows qualifying AIMDD CE certificates to be accepted through December of 2027. We have already met the qualifications identified within this amendment to allow continued distribution of Barostim through this time. We market our therapy in the U.S. to hospitals and clinics where EPs, HF specialists, interventional and general cardiologists and vascular surgeons treat patients with HFrEF.

We primarily sell Barostim to hospitals through a direct sales organization in the U.S. and Germany, and through distributors in Austria, Spain, Italy, the Nordic region, and other European countries. Our global sales and marketing team engages in sales efforts and promotional activities focused on EPs, HF specialists, interventional and general cardiologists, and vascular surgeons. We are continuing to actively expand our direct sales force and commercial organization in the U.S.

Our direct sales representatives, which we refer to as Account Managers, generally have substantial and applicable medical device experience, specifically in the cardiovascular space, and market our products directly to the approximately 2,500 EPs, 800 HF specialists and 20,000 general cardiologists in the U.S. We support all aspects of the patient journey, which includes initial diagnosis, surgical support, and patient follow-up. Our Account Managers are focused on prioritizing high volume cardiology centers that are strategically located and on educating and training physicians who have strong connectivity to the HFrEF patient population that may be eligible for our therapy. We also employ Field Clinical Specialists who generally have experience in medical device clinical support. Our Field Clinical Specialists work to ensure that every procedure is done correctly by educating the implanting physicians, including vascular surgeons and EPs, about the technical aspects of Barostim and the implantation procedure.

Similar to our direct sales team, our marketing team has a significant amount of relevant expertise and a strong track record of success in the medical device industry. Our marketing organization is focused on building physician awareness through targeted KOL development, referral network education and direct-to-consumer marketing.

In terms of patient education, we utilize direct communication channels to inform patients about Barostim Therapy and to enable them to connect with sites that offer Barostim. Our primary method of patient outreach is through digital social networks. We use a qualification process to aid in the identification of the appropriate patients for our therapy. The objective of this outreach is to inform potential patients about our education webinars and website, where they can find a wealth of information on HFrEF and the purpose and benefits of Barostim Therapy, based on our approved labeling.

In addition to driving broad awareness and increasing physician and patient education, our marketing team has developed the in-house resources necessary to obtain prior authorization approval for Barostim procedures and expand reimbursement coverage.

Third-party coverage and reimbursement

Coding and payment in the United States

In the U.S., we sell Barostim primarily to hospitals, where the device is implanted in outpatient and inpatient settings. Our customers bill various third-party payers, such as government agencies, administrative contractors, commercial payers and integrated managed care organizations, for the cost required to treat each patient.

Third-party payers generally require physicians and hospitals to identify the service for which they are seeking reimbursement for by using CPT codes, which are created and maintained by the American Medical Association. Implantation of Barostim is described by CPT code 0266T, a Category III code approved in July 2011 and effective as of January 2012. Hospitals are able to use this code to submit for a system implant payment. CPT code 0268T is used to submit for an IPG replacement procedure payment, and CPT codes 0272T and 0273T are used for interrogation and programming of the IPG, respectively. We believe these Category III codes will be transitioned to Category I codes on January 1, 2026.

Medicare provides reimbursement to hospitals using Barostim under the hospital outpatient prospective system (“OPPS”), which provides bundled amounts generally intended to reimburse a hospital for all facility costs related to procedures performed in its outpatient setting. On January 1, 2024, the Barostim implant procedure was reassigned to New Technology APC 1580, which carries an average payment amount of approximately $45,000. The APC payment of approximately $45,000 will continue in 2025, as published in the 2025 OPPS final rule. The IPG replacement will continue to be assigned to Level 5 Neurostimulator payment APC 5465, which has a national average of approximately $30,500.

In August 2024, CMS reassigned the Barostim implant procedure for the inpatient setting as part of the Medicare Hospital Inpatient Prospective Payment System (“IPPS”) final rule for CMS’ Fiscal Year 2025, which

took effect on October 1, 2024. On that date, Barostim was reassigned to MS-DRG 276, which carries a national average payment of approximately $44,000 in 2025. These payments generally cover the hospital's costs for the device and the implantation procedure.

The surgeon implanting Barostim is paid an additional physician payment under the Medicare Physician Fee Schedule, and the physician that manages the device performs multiple device interrogations and is paid using the payment code APC 5721, which has a national average of $156 per visit in 2025.

Reimbursement rates from commercial payers vary depending on a variety of factors, including the commercial payor and contract terms.

Government program and commercial payer coverage in the United States

Since approximately 67% of our target treatment population includes Medicare-eligible patients, we have prioritized CMS coverage while simultaneously developing processes to engage commercial payers. As of July 2020, all Medicare Administrative Contractors ("MACs") have retired automatic coverage denial policies, thereby allowing implants to be adjudicated on a case-by-case basis. CMS has committed to considering additional process improvements to increase access to innovative devices. We will continue to monitor developments in this space, including decisions made by private payers, if any.

We will continue to leverage 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. We believe our market access team is highly effective in obtaining prior authorizations, including navigating the appeals process. We believe that we will continue to benefit from this efficient prior authorization process in the near-and-long-term by expanding on our positive coverage policies with commercial payers. In our discussions with commercial payers, we highlight our compelling and robust clinical data, including the long-term post-market BeAT-HF data, the potential economic cost-savings associated with our highly compliant treatment, increased patient demand and support from leading medical societies and KOLs. As our operations continue to grow, we intend to continue to further expand our market access team accordingly.

Reimbursement outside of the United States

Outside the U.S., reimbursement levels vary by country and within some countries, by region. We are currently selling Barostim in Germany, where the German Institute of Medical Documentation and Information supports various codes for reimbursement coverage. OPS code 5-059.c6 covers the implantation or replacement of a device stimulating the peripheral nervous system by activating the baroreceptors. This OPS code is combined with G-DRG ICD I50.13 to cover reimbursement of Barostim for the treatment of HFrEF. It can also be combined with G-DRG ICD I10.10 to cover reimbursement of Barostim for the treatment of hypertension. These DRG codes for both indications are combined with ZE code ZE2021-86 to cover the cost of the device. Barostim also is eligible for reimbursement in certain other European countries, 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.

Research and development

Our research and development team has significant experience bringing innovative medical devices to market, including minimally invasive neuromodulation systems.

We are committed to ongoing research and development efforts of Barostim with an emphasis on improving clinical outcomes, optimizing patient adoption and comfort, increasing access for a greater number of patients and enabling more physicians to perform the procedure.

The primary focus of our research and development efforts in the near-term will be the continued technological advancement of Barostim.

While we are currently focused on the treatment of patients with HFrEF, we believe our platform technology can provide meaningful benefits to a broader set of patients suffering from cardiovascular diseases with significant unmet needs. Our longer-term goal is to explore Barostim's potential to expand the indications for use to other cardiovascular diseases, including different forms of HF, hypertension, and arrhythmias. Expansions into these or other new indications would require additional FDA approvals and may involve additional clinical trials or modifications to Barostim to treat such indications. If clinical studies for additional indications do not produce results necessary to support regulatory clearance or approval in the U.S. or elsewhere, we will be unable to commercialize our products for these indications.

For the years ended December 31, 2024 and 2023, we incurred research and development expenses of $11.1 million and $11.6 million, respectively.

Competition

Our industry is subject to rapid change from the introduction of new products and technologies and other activities of industry participants. We consider our primary competition to be other device-based therapies designed to treat patients with HFrEF and a narrow QRS complex.

There is only one other commercially available device-based option, CCM, that targets a limited subset of the same HFrEF patient population indicated for Barostim. CCM is offered by a privately-held medical technology company and has the potential to improve a patient's quality of life and reduce symptoms of HFrEF. However, CCM is associated with a number of drawbacks, including not being designed to address excess of neurohormones; less favorable clinical effectiveness results in patients with LVEF 25–35% as compared to patients with LVEF 35–45% related to exercise capacity, quality of life and NYHA functional status; implantation through an invasive procedure that includes running electrical leads through the veins and attaching them to the heart's ventricle, which may lead to increased risks to the patient; and the requirement that patients regularly charge the battery in their implanted device.

We believe that the primary competitive factors in the HFrEF treatment market are:

- product safety, reliability, and durability;
- quality and volume of clinical data;
- adoption by patients, physicians, and hospitals;
- adequate reimbursement for our device;
- product ease of use and patient comfort;
- sales force expansion, experience, and access;
- product availability, support, and service;
- manufacturing and supply chain;
- technological innovation and product enhancements; and
- intellectual property portfolio.

Aside from device-based treatments, pharmaceutical therapies are widely used to treat HFrEF and have been in use longer and are better known to physicians and patients than Barostim. However, because Barostim is designed to be used in conjunction with pharmaceutical therapies to alleviate the symptoms of HFrEF, we do not consider existing pharmaceutical therapies to be direct competition.

We also compete with other medical technology companies to recruit and retain qualified sales, training, and other personnel.

Intellectual property

We rely on a combination of patent, copyright, trademark and trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of December 31, 2024, we owned 49 issued U.S. patents and had six pending U.S. patent applications. Outside of the U.S., we owned nine patents in multiple countries and had 10 pending applications. Our trademark portfolio focuses on nine trademarks in the U.S. and multiple other countries. Our patents cover aspects of our integrated platform technology, Barostim, including baroreflex methods, stimulus regimes, mapping methods, electrode designs, disease treatments, closed loop control, burst intervals, connection structures and baroreceptor locations, as well as future product concepts. The term of individual patents depends on the law of the countries in which they are granted. In most countries, including the U.S., the patent term is generally 20 years from the earliest claimed filing date of a nonprovisional patent application in the applicable country. There is no active patent litigation involving any of our patents, and we have not received any notices of patent infringement.

We also rely, in part, upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality and assignment agreements with suppliers, employees, consultants, and others who may have access to our proprietary information.

Pending patent applications may not result in issued patents, and we cannot guarantee that any current or subsequently issued patents will protect our intellectual property rights or provide us with any competitive advantage. While there is no active litigation involving any of our patents or other intellectual property rights and we have not received any notices of patent infringement, we may be required to enforce or defend our intellectual property rights against third parties in the future. See “Risk Factors—Risks Related to Intellectual Property” for additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us.

Manufacturing and supply

We manage all aspects of manufacturing operations and product supply of Barostim, which include final assembly, testing and packaging of our IPG and stimulation lead, at our 31,505 square foot headquarters in Minneapolis, Minnesota. With minimal capital investment, our existing operations are capable of producing 5,000 IPGs and 5,000 stimulation leads per shift per year, and our manufacturing line was designed to be expandable and scalable in the future.

We currently source certain components for Barostim from a limited number of suppliers, including the module, module board, radio-frequency module, magnet switch, battery, and application-specific integrated circuits for the IPG and the electrode for the stimulation lead. Our suppliers manufacture and test the components they produce for us to meet our specifications. We maintain sufficient levels of inventory to mitigate potential supply disruption and to achieve more favorable volume-based pricing. We continue to seek to broaden and strengthen our supply chain through additional sourcing channels.

We select our suppliers to ensure that Barostim and its components are safe and effective, adhere to all applicable standards and regulations, are high quality and meet our supply needs. We employ a rigorous supplier assessment, qualification and selection process targeted to suppliers that meet the requirements of the FDA and relevant Canadian, European Economic Area (“EEA”) and Australian regulatory authorities and quality standards supported by internal policies and procedures. Our quality assurance process monitors and maintains supplier performance through qualification and periodic supplier reviews and audits. We received ISO certification for our quality management system and our most recent audits have not identified any major nonconformities. We are registered with the FDA as a medical device manufacturer and licensed by the State of Minnesota to manufacture our device.

Seasonality

We have seen seasonally lower rates of implants in our first fiscal quarter in recent years, which we believe is primarily due to U.S. patients shifting medical treatments to the later months of the year when they have better information about spending against the annual deductibility limits under their health insurance coverage, and we expect this trend to continue. Otherwise, mild seasonal variations are difficult to predict accurately and may vary among different markets.

Government regulation

Our products and operations are subject to extensive regulation by the FDA and other federal and state authorities in the U.S., as well as comparable authorities in the EEA. Our products are subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, effectiveness, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, device tracking, adverse event reporting, recalls, safety alerts, injunctions, seizures, bans, advertising, promotion, marketing and distribution and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition to U.S. regulations, we are subject to a variety of regulations in the EEA governing clinical trials and the commercial sales and distribution of our products. Whether we have or are required to obtain FDA clearance or approval for a product, we will be required to obtain authorization from the comparable regulatory authorities of countries outside of the U.S. before we can commence clinical trials or commercialize our products in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA clearance or approval.

FDA pre-market clearance and approval requirements

Unless an exemption applies, each medical device commercially distributed in the U.S. requires either FDA clearance of a 510(k) premarket notification, HDE, or PMA approval. Under the FDCA, medical devices are classified as Class I, Class II, Class III, or De Novo, depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation ("QSR"), facility registration and product listing, reporting of adverse medical events and truthful and non-misleading labeling, advertising and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries, and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices must submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. De Novo is a medical device with no predicate or premarket device for comparing substantial equivalence which is subject to the 510(k) premarket notification. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is "substantially equivalent" to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or another commercially available device that was cleared through the 510(k) process.

Devices deemed by the FDA to pose the greatest risks are placed in Class III, requiring approval of an HDE or PMA.

Our currently U.S.-marketed Barostim devices are Class III devices which have received both a PMA and an HDE approval.

PMA & HDE approval pathway

Class III devices require PMA or HDE approval before they can be marketed, although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, and the methods, facilities and controls used for manufacturing and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficient to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and at times can take up to several years. An Advisory Committee or panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facilities to ensure compliance with the QSR.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s) according to the instructions for use or labeling. The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance or study when deemed necessary to protect the public health or to provide additional safety and effectiveness data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups and make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which can affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and typically does not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the HDE constitute valid scientific evidence and that there is reasonable assurance that the device is safe and has probable benefit for its intended use(s) according to the instructions for use or labeling. The HDE approved devices are subject to the same requirement elements and changes as the above PMA devices. An additional limitation for HDE devices is they must be prescribed for a patient population that has a medical condition or disease that afflicts less than 8,000 people per year in the United States and have been designated as a Humanitarian Use Device by the FDA.

Clinical trials

Clinical trials are usually required to support a PMA and are sometimes required to support an HDE, 510(k) or De Novo submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption ("IDE"), regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must be approved prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a subject and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an institutional review board ("IRB"), for each clinical site. The IRB is responsible for the initial and continuing review of the IDE and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of subjects, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan, or the rights, safety, or welfare of human subjects.

During a study, the sponsor and clinical investigators are required to comply with the applicable FDA requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market regulation

After a device is cleared or approved for marketing, numerous regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provides adequate directions for use and that all claims are substantiated and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; FDA guidance on off-label dissemination of information and responding to unsolicited requests for information; and Federal Trade Commission guidance on endorsements and testimonials;

- the federal Physician Payments Sunshine Act and various state and foreign laws on reporting remunerative relationships with health care customers;

- the federal Anti-Kickback Statute (and similar state laws) prohibiting, among other things, soliciting, receiving, offering, or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation;

- the federal False Claims Act (and similar state laws) prohibiting, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing, or knowingly and improperly avoiding or decreasing, an obligation to pay or transmit money to the federal government. The government may assert that a claim includes items or services resulting from a violation of the federal Anti-Kickback Statute and thus constitutes a false or fraudulent claim for purposes of the false claims statute;

- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of a supplement for certain modifications to PMA and HDE devices;

- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;

- correction, removal, and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;

- the federal law and regulations requiring Unique Device Identifiers (“UDI”) on devices and also requiring the submission of certain information about each device to the FDA’s Global Unique Device Identification Database (“GUDID”);

- the FDA’s recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and

- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We may be subject to similar foreign laws that include post-marketing requirements such as safety surveillance. Our manufacturing processes must comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation, and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file and complaint files. As a manufacturer, our facilities, records and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR or other applicable regulatory requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, injunctions, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted; refusal to grant export or import approvals for our products; or
- criminal prosecution.

Regulation of medical devices in the EEA

To be placed on the market in the EEA, medical devices require a CE Mark and a corresponding declaration of conformity. For our medical devices, the CE Mark must be issued by an organization accredited by a Member State of the EEA to conduct conformity assessments, a so-called Notified Body. Conformity assessments are conducted to demonstrate that the medical device meets the legal requirements set forth in the regulations and standards to ensure that it meets general safety and performance criteria. Clinical investigations or evidence of the safety and clinical outcomes, among other things, may be required for issuance of a CE Mark. With a CE Mark, the medical devices are generally marketable in the entire EEA. A CE Mark was first issued for Barostim for the treatment of resistant hypertension in 2011 and for the treatment of HFrEF in 2014.

European Union ("EU") Legislation: medical devices regulation

The regulatory framework governing medical devices in the EEA underwent a major change on April 5, 2017, when the European Parliament passed the Medical Devices Regulation (Regulation (EU) 2017/745 — "MDR"). The MDR repealed and replaced the EU Medical Devices Directive (Council Directive 93/42/EEC — "MDD" or Council Directive 90/385/EEC).

Previously, medical devices regulated under the MDD and AIMDD were classified into one of four classes — Class I, Class IIa, Class IIb, or Class III — based on the extent of the regulatory controls necessary and sufficient to provide reasonable assurance of safety and effectiveness of the device. The AIMDD applied to implantable electrical active medical devices that were typically considered to be Class III under MDD and similar controls for the highest risk devices. The classification corresponded to the level of potential hazard inherent in the type of device concerned. Class I included devices with the lowest risk to the patient. Class IIa and Class IIb devices were higher risk devices and Class III devices were devices with a significant risk, which were subject to more regulatory oversight to ensure the safety and effectiveness of the device, such as performance standards and post-market surveillance. Barostim has been classified and regulated under the AIMDD.

The MDR entered into force on May 25, 2017 and is progressively replacing the MDD/AIMDD during a transition period, which was originally intended to become fully effective on May 26, 2021. The MDR, among other things, is designed to establish a uniform, transparent, predictable, and sustainable regulatory framework across the EEA for medical devices and to ensure a high level of safety and health while supporting innovation. The regulations impose strict demands on medical device manufacturers and the Notified Bodies whom they must involve in the conformity assessment procedure. Unlike directives, which must be implemented into the national laws of the EEA, the regulations are directly applicable in all EEA

member states and are intended to eliminate differences in the regulation of medical devices among EEA member states.

The new regulations:

- Require demonstration of clinically meaningful outcomes for the performance of the medical device;
- Require stricter control of Class IIb and Class III medical devices during the clinical investigational phase;
- Require rigorous post-market oversight by the manufacturer and increased post-market surveillance authority by the Notified Body, including unannounced audits and product sample checks and testing;
- Establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- Improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- Provide greater transparency by establishing a central database (EUDAMED) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- Strengthen rules for the assessment of certain high-risk devices, which may have to undergo an additional check by an independent expert panel before they are placed on the market.

To avoid market disruption and allow a smooth transition from the MDD/AIMDD to the MDR, several transitional provisions are in place, which include allowing devices lawfully placed on the market prior to expiration of their MDD/AIMDD CE Marks to remain available on the market and be put into service, both under certain prerequisites and until a certain time.

In 2022, we successfully completed the Stage 1 and 2 MDR Quality Management System ("QMS") audits, and our Notified Body officially issued an approval document stating that the QMS has been assessed to the MDR and approved. We have since received confirmation that all sections of the submission have been reviewed and all queries have been responded to and the responses accepted. The file remains under review.

Notably, the European Commission extended qualifying AIMDD CE certificates, including ours, through December 31, 2027. This extension was driven by delays in notified body reviews and approvals across the medical device industry as well as the fact that a substantial number of CE Mark certificates were continuing to expire during this unpredictable and extended transition period to MDR.

Regulation of medical devices under MDR

CE Marking

Manufacturers of medical devices must comply with the general safety and performance requirements of the MDR in order to obtain a CE Mark for the product and market the product in the EEA. To demonstrate compliance with the general safety and performance requirements, the manufacturer must undergo a conformity assessment procedure which requires the involvement of a Notified Body except for low-risk, self-certified medical devices of Class I. The Notified Body typically audits the quality management system of the manufacturer, which must comply with the current version of ISO 13485 requiring that manufacturers follow defined and approved design and development procedures, testing, control, documentation and other quality assurance procedures throughout the entire design and manufacturing process. The Notified Body also reviews the Technical File that includes the Biological Evaluation, Clinical Evaluation and Risk Management reports and Post Market Clinical Follow-Up ("PMCF"), among other items, submitted for approval of the CE

Mark. If the quality management system audit and the technical file review are successful, the Notified Body issues certificates of conformity. These certificates entitle the manufacturer to draw up the EU declaration of conformity and affix the CE Mark to the labeling of its medical devices and place the medical device on the EEA market.

CE marking in UK and UK Conformity Assessed marking

Since January 1, 2021, the UK (excluding Northern Ireland) has recognized medical devices with an EEA-issued CE Mark, and has since indicated it will continue to do so until December 31, 2027. Additionally, certificates issued by EU-recognized Notified Bodies will continue to be valid for the UK market until December 31, 2027. Since January 1, 2021, all medical devices placed on the UK market must be registered with the Medicines and Healthcare products Regulatory Agency (the "MHRA"). There are different grace periods depending on the type of medical device to allow time for compliance with the new registration process. Where a medical device is not already registered with the MHRA, a conformity assessment must be conducted by an "authorised" body (a so-called UK Approved Body, approved by the MHRA) and a separate dossier application for the UKCA marking must be submitted. However, the data to support an EEA-issued CE Mark is expected to be sufficient for a UKCA mark. Manufacturers based outside the UK who wish to place a device on the UK market need to appoint a single UK Responsible Person who will take responsibility for the product in the UK. We have registered with MHRA, have a UK Responsible Person, and are prepared to conduct a conformity assessment when necessary.

CE Marking in Switzerland

Switzerland and the EU had a bilateral mutual recognition agreement (MRA) on conformity assessment, which entered into force in 2002, but ceased to be enforced on May 26, 2021. Currently, Switzerland unilaterally recognizes EU certificates of conformity for medical devices. Labeling and CE marking requirements for medical devices placed on the Swiss market must follow EU CE labeling requirements. To place a product on the Swiss market as an economic operator located outside of Switzerland, manufacturers, distributors, and importers must have a Swiss authorized representative ("CH-REP"). Product labeling should include the CH-REP name and address to show compliance. MDD/AIMDD devices with certificates issued by EU-recognized Notified Bodies will continue to be valid until December 31, 2027. We have engaged a CH-REP and the devices may continue to be sold in Switzerland through 2027.

Clinical investigation

For our medical devices, clinical investigations or evidence will be required to demonstrate safety, performance, and the expected clinical outcomes. The term "performance" describes how the medical device functions. Under the MDR, performance must be linked to expected clinical metrics and outcomes. From a practical standpoint, "performance" is analogous to the term "effectiveness" when applied to our medical devices. Clinical investigations must be conducted in accord with Good Clinical Practices (ISO 14155) and are subject to audits by the Notified Bodies.

Post-market surveillance

After a medical device is placed on the market, numerous regulatory requirements apply, which link to the manufacturer's continuous review of risk management information. The manufacturer must establish and maintain a systematic procedure to proactively collect and review real-life experience and data gained from their devices placed on the market. Post-market surveillance is comprised of, but not limited to, reports of serious adverse events, device deficiency reports, product complaints from consumers and health care professionals, field safety corrective actions and post-marketing clinical studies/updated clinical evaluation reports. Manufacturers must guarantee that their medical device continues to provide the promised benefit to patients as well as the lack of any unacceptable risks, through a constant and systematic approach to post-market surveillance. Further, manufacturers, medical practitioners and medical institutions are obliged to report any incident involving a medical device, including any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which

might lead to or might have led to the death of a patient or to a serious deterioration in his or her state of health. The reporting also includes any device recalls. Manufacturers must prepare a periodic safety update report for each device summarizing the results and conclusions of the analyses of the post-market surveillance data gathered.

Non-compliance

If we fail to comply with applicable EU, UK and Swiss regulatory requirements, we may be subject to, among other things, fines, product recalls, seizure of products, operating restrictions, and criminal prosecution. Failure to comply with EU, UK or Swiss regulatory requirements could prevent us from developing, manufacturing and later selling the products in the respective region.

Federal, state, and foreign fraud and abuse and physician payment transparency laws

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal and state laws restrict our business practices. These laws include, without limitation, foreign, federal, and state anti-kickback and false claims laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value, including stock, stock options and the compensation derived through ownership interests.

Recognizing that the federal Anti-Kickback Statute is broad and may prohibit many innocuous or beneficial arrangements within the healthcare industry, the U.S. Department of Health, and Human Services (“HHS”) issued regulations in July 1991, which HHS has referred to as “safe harbors.” These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure medical device manufacturers, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Our arrangements with physicians, hospitals and other persons or entities who are in a position to refer may not fully meet the stringent criteria specified in the various safe harbors. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (described below).

Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal civil False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid. Liability under the federal Anti-Kickback Statute may also arise because of the intentions or actions of the parties with

whom we do business. While we are not aware of any such intentions or actions, we have only limited knowledge regarding the intentions or actions underlying those arrangements. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities. The majority of states also have anti-kickback laws that establish similar prohibitions and, in some cases, may apply more broadly to items or services covered by any third-party payer, including commercial insurers and self-pay patients.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. The federal civil False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the civil federal civil False Claims Act.

In addition, private parties may initiate “qui tam” whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit. Penalties for federal civil False Claims Act violations include fines for each false claim, plus up to three times the amount of damages sustained by the federal government and, most critically, may provide the basis for exclusion from the federally funded healthcare program. On May 20, 2009, the Fraud Enforcement Recovery Act of 2009 (“FERA”), was enacted, which modifies and clarifies certain provisions of the federal civil False Claims Act. In part, FERA amends the federal civil False Claims Act such that penalties may now apply to any person, including an organization that does not contract directly with the government, who knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim paid in part by the federal government. The government may further prosecute conduct constituting a false claim under the federal criminal False Claims Act. The federal criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the federal civil False Claims Act, requires proof of intent to submit a false claim. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $12,537 to $25,076 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid, and other federal healthcare programs.

The Civil Monetary Penalty Act of 1981 imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) also created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. For example, the advertising and promotion of our products is subject to EU Directives concerning misleading and comparative advertising and unfair commercial practices, as well as other EEA member state legislation governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Also, many U.S. states have

similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payer, in addition to items and services reimbursed under Medicaid and other state programs.

Additionally, there has been a recent trend of increased foreign, federal, and state regulation of payments and transfers of value provided to healthcare professionals or entities. The federal Physician Payments Sunshine Act imposes annual reporting requirements on certain drug, biologics, medical supplies and device manufacturers for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program for payments and other transfers of value provided by them, directly or indirectly, to physicians (including physician family members), certain other healthcare providers and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. A manufacturer's failure to submit timely, accurately, and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to $12,646 per failure up to an aggregate of $189,692 per year (or up to an aggregate of $1.265 million per year for "knowing failures"). Manufacturers must submit reports by the 90th day of each calendar year. Certain foreign countries and U.S. states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities.

Data privacy and security laws

We are also subject to various federal, state, and foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers, such as HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), in the U.S.

HIPAA established uniform standards governing the conduct of certain electronic healthcare transactions and requires certain entities, called covered entities, to comply with standards that include the privacy and security of protected health information ("PHI"). HIPAA also requires business associates, such as independent contractors or agents of covered entities that have access to PHI in connection with providing a service to or on behalf of a covered entity, of covered entities to enter into business associate agreements with the covered entity and to safeguard the covered entity's PHI against improper use and disclosure.

The HIPAA privacy regulations cover the use and disclosure of PHI by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain, or transmit PHI on behalf of a business associate. They also set forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity, including the right to access or amend certain records containing PHI, or to request restrictions on the use or disclosure of PHI. The security regulations establish requirements for safeguarding the confidentiality, integrity and availability of PHI that is electronically transmitted or electronically stored. HITECH, among other things, established certain health information security breach notification requirements. A covered entity must notify any individual whose PHI is breached according to the specifications set forth in the breach notification rule. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI or insofar as such state laws apply to personal information that is broader in scope than PHI as defined under HIPAA.

HIPAA requires the notification of patients, and other compliance actions, in the event of a breach of unsecured PHI. If notification to patients of a breach is required, such notification must be provided without unreasonable delay and in no event later than 60 calendar days after discovery of the breach. In addition, if the PHI of 500 or more individuals is improperly used or disclosed, we would be required to report the improper use or disclosure to HHS, which would post the violation on its website, and to the media. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $63,973 per violation, not to exceed $1.92 million per calendar year for non-compliance of an identical provision and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment.

HIPAA authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit against us in civil court, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities, such as us, and their business associates for compliance with the HIPAA privacy and security standards. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

Additionally, we may be subject to laws relating to our collection, control, processing, and other use of personal data (i.e., data relating to an identifiable living individual). We process personal data in relation to our operations. We process data of both our employees and our customers, including health and medical information. The data privacy regime in the EU includes the EU Data Protection Directive (95/46/EC) regarding the processing of personal data and the free movement of such data, the E-Privacy Directive 2002/58/EC and national laws implementing each of them. Each EU Member State has transposed the requirements laid down by the Data Protection Directive and E-Privacy Directive into its own national data privacy regime and therefore the laws may differ by jurisdiction, sometimes significantly. We must ensure compliance with the rules in each jurisdiction where we are established or are otherwise subject to local privacy laws.

The requirements include that personal data may only be collected for specified, explicit and legitimate purposes based on legal grounds set out in the local laws and may only be processed in a manner consistent with those purposes. Personal data must also be adequate, relevant, not excessive in relation to the purposes for which it is collected, be secure, not be transferred outside of the EEA unless certain steps are taken to ensure an adequate level of protection and must not be kept for longer than necessary for the purposes of collection. To the extent that we process, control, or otherwise use sensitive data relating to living individuals (for example, patients' health or medical information), more stringent rules apply, limiting the circumstances and the manner in which we are legally permitted to process that data and transfer that data outside of the EEA. In particular, in order to process such data, explicit consent to the processing (including any transfer) is usually required from the data subject (being the person to whom the personal data relates).

The EU-wide General Data Protection Regulation ("GDPR") became applicable on May 25, 2018, replacing the previous data protection laws issued by each EU Member State based on the Directive 95/46/EC. Unlike the Directive (which needed to be transposed at national level), the GDPR text is directly applicable in each EU member state, resulting in a more uniform application of data privacy laws across the EU. The GDPR imposes onerous accountability obligations, requiring data controllers and processors to maintain a record of their data processing and policies. It requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of information, increases requirements pertaining to pseudonymized (i.e., key-coded) data, introduces mandatory data breach notification requirements and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for non-compliance with the GDPR are significant—the greater of EUR 20 million or 4% of global turnover. The GDPR provides that EU Member States may introduce further conditions, including limitations, to the processing of genetic, biometric or health data, which could limit our ability to collect, use and share personal data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business. In the UK, the UK General Data Protection Regulation (the "UK GDPR") came into effect on January 1, 2021. Similar to the GDPR, the UK GDPR sets out the key principles, rights, and obligations for most processing of personal data in the UK. The Data Protection Act of 2018, which came into effect on May 25, 2018 and was amended on January 1, 2021, works alongside and supplements the UK GDPR.

We are subject to the supervision of local data protection authorities in those jurisdictions where we are established or otherwise subject to applicable law.

We depend on third parties in relation to our provision of our services, a number of which process personal data on our behalf. With each such provider we enter into contractual arrangements to ensure that they only process personal data according to our instructions, and that they have sufficient technical and organizational security measures in place. When we transfer personal data outside the EEA, we do so in compliance with the relevant data export requirements. We take our data protection obligations seriously, as any improper disclosure, particularly with regard to our customers' sensitive personal data, could negatively impact our business and/or our reputation.

Healthcare reform

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality, or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payers and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act in the U.S., for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The Affordable Care Act provided incentives to programs that increase the federal government's comparative effectiveness research and implemented payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in the future. Moreover, the Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act. In 2017, the Tax Cuts and Jobs Acts was enacted, which, among other things, removed penalties for not complying with the individual mandate to carry health insurance, effective in 2019.

In addition, other legislative changes have been adopted since the Affordable Care Act. For example, the Budget Control Act of 2011, among other things, included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2027 unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Anti-bribery and corruption laws

Our U.S. operations are subject to the U.S. Foreign Corrupt Practices Act (the "FCPA"). We are required to comply with the FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials to obtain or retain business or other benefits. In addition, the FCPA imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made. We also are subject to similar anticorruption legislation implemented

in Europe under the Organization for Economic Co-operation and Development's Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

Environmental laws

Our facilities and operations are also subject to complex federal, state, local and foreign environmental and occupational safety laws and regulations, including those relating to discharges of substances in the air, water and land, the handling, storage and disposal of wastes and the clean-up of properties contaminated by pollutants. We do not expect that the ongoing costs of compliance with these environmental requirements will have a material impact on our consolidated earnings, capital expenditures or competitive position.

Human capital management

Our human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants, and directors through the granting of stock-based compensation awards.

As of December 31, 2024, we had 206 employees worldwide, all of which were employed on a full-time basis. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Our mission

Our mission is to advance health for people everywhere, giving each patient a fuller life. In seeking to accomplish our mission, we rely on our values, which are central to our human capital management policies and practices. These values are:

- Commitments are Sacred — Honor relationships by doing what we say, when we say we'll do it.
- Bold Mindset, Driven Spirit — Always push the boundaries, energetically seeking out impactful opportunities and inspiring others.
- Pioneer with Purpose…and a Smile! — As individuals, team leaders and industry innovators, it's how we pave the way forward that defines us.
- Collaborate with Enjoyment — Achieve goals and celebrate as a team.
- Determination Overcomes Targets — Determine the pathway, overcome obstacles, accelerate, and successfully implement.
- Embrace the Challenge of Change — Have an eye for identifying when change is needed, and the flexibility to chart a new course.

Health and safety

We are acutely focused on the health and safety of our employees in the workplace. Our health and safety team monitors various metrics in an effort to ensure we are providing a safe environment to work. These results are shared with relevant regulatory agencies as required and presented to our management team.

Available Information

We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, available free of charge at our website as soon as reasonably practicable after they have been filed with, or

furnished to, the U.S. Securities and Exchange Commission (the "SEC"). Our website address is www.cvrx.com. Information on our website is not part of this Annual Report on Form 10-K. The SEC maintains a website that contains the materials we file with the SEC at www.sec.gov.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our reputation, business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks related to our business

We have a history of significant losses, which we expect to continue, and we may not be able to achieve or sustain profitability. If we do not achieve and sustain profitability, our financial condition could suffer.

We have experienced significant net losses since our inception and we expect to continue to incur losses for the foreseeable future. We incurred net losses of $60.0 million and $41.2 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024 and 2023, our accumulated deficit was $537.3 million and $477.4 million, respectively. We expect to continue to incur significant sales and marketing, research and development, regulatory, and other expenses as we grow our U.S. commercial sales force and expand our marketing efforts to increase adoption of Barostim, add new features to Barostim, obtain regulatory clearances or approvals for our planned or future products and conduct clinical trials on our existing and planned or future products.

We will need to continue to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our expected future operating losses, combined with our prior operating losses, may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

We have a limited history operating as a commercial company and are highly dependent on a single product, Barostim. The failure to increase market acceptance in the U.S. for Barostim would negatively impact our business, liquidity, and results of operations.

We first commercialized Barostim in the EEA in 2012 and in the U.S. in 2020 and therefore do not have a long history operating as a commercial company. We expect substantially all of our revenue to continue to be derived from sales of Barostim for the foreseeable future, the majority of which will be generated in the U.S. Although increasing as our commercial sales grow, Barostim still has limited product and brand recognition. In addition, demand for Barostim may decline or may not continue to increase as quickly as we expect. If we are unable to achieve significant market acceptance in the U.S. for Barostim, our results of operations will be adversely affected. Because we do not yet have other products currently in development, if we are unsuccessful in commercializing Barostim or are unable to market Barostim as a result of a quality problem, failure to maintain regulatory approvals, unexpected or serious complications or other unforeseen negative effects related to Barostim or the other factors discussed in these risk factors, we would lose our main source of revenue, and our business, reputation, liquidity and results of operations will be materially and adversely affected.

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.

In order to generate future revenue growth, we plan to continue to expand the size and geographic scope of our U.S. direct sales and marketing organization. In order to increase our sales and marketing efforts, we will need to continue to retain, grow and develop a substantial number of direct sales personnel, which is a significant investment. There is significant competition for sales personnel experienced in relevant medical device sales. Once hired, the training process is lengthy because it requires significant education for new sales representatives to achieve the level of clinical competency with our products expected by physicians. Upon completion of the training, our sales representatives typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our product will often require or benefit from direct support from us. If we are unable to attract, motivate, develop, and retain a sufficient number of qualified sales personnel, and if our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect, and our financial performance will suffer. Because the competition for direct medical sales personnel is high, we cannot be certain we will be able to hire and retain additional sales personnel on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales representatives would prevent us from expanding our business and generating anticipated revenue. Any of these risks may adversely affect our business.

We must demonstrate to physicians and patients the merits of Barostim.

Physicians play a significant role in determining the course of a patient's treatment and, subsequently, the type of product that will be used to treat a patient. As a result, our success depends, in large part, on effectively marketing Barostim to physicians. In order for us to sell Barostim, we must successfully demonstrate to physicians and patients the merits of Barostim Therapy for use in treating patients with HFrEF. Specifically, Barostim is indicated for patients with NYHA Class III or II (with recent history of III) despite treatment with guideline-directed medical therapies (medications and devices), have a LVEF ≤ 35% and a NT-proBNP < 1,600 pg/ml. Barostim delivers BAT to improve patients' NYHA functional status, 6MHW and quality of life. Acceptance of Barostim depends on educating physicians as to the distinctive characteristics, perceived benefits, safety, ease of use and cost-effectiveness of Barostim and communicating to physicians the proper application of Barostim Therapy for patients who meet Barostim's eligibility criteria. If we are not successful in convincing physicians of the merits of Barostim Therapy, they may not use Barostim and we may be unable to increase our sales, sustain our growth or achieve profitability.

In addition, physicians typically need to perform several procedures to become comfortable using Barostim. If a physician experiences difficulties during an initial procedure or otherwise, that physician may be less likely to continue to use our product or to recommend it to other physicians. It is critical to the success of our commercialization efforts to educate physicians on the proper use of Barostim, and to provide them with adequate product support during clinical procedures. If we do not provide support to physicians or do not adequately educate physicians on the benefits and proper use of Barostim, physicians may not use or advocate for Barostim. In such circumstances, our results of operations would be materially adversely affected.

Patients may not choose or be able to receive Barostim if, among other potential reasons, they are reluctant to receive an implantable device as opposed to an alternative, non-implantable treatment, they are worried about potential adverse effects of Barostim, or they are unable to obtain adequate third-party coverage or reimbursement.

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 HF 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.

The medical device industry is highly competitive and subject to technological change. Our success depends, in part, upon our ability to establish a competitive position in the market by securing broad market acceptance of Barostim Therapy and Barostim for the treatment of HFrEF. Any product we develop that achieves regulatory clearance or approval, including Barostim, will have to compete for market acceptance and market share against other therapies, including both devices and medications. We believe that the primary competitive factors in the market are demonstrated clinical effectiveness, product safety, reliability and durability, ease of use, product support and service, minimal side effects and salesforce experience. Many of our current and potential competitors that are addressing other HF indications are publicly traded, or are divisions of publicly-traded, established medical device companies that have substantially greater financial, technical, sales and marketing resources than we do, such as Medtronic plc, Boston Scientific Corporation, Abbott Laboratories and Johnson & Johnson. We may also face competition from other competitors, such as Impulse Dynamics, which is a private company with a medical device indicated for a subset of our target patient population, or companies with active system development programs that may emerge in the future, such as Johnson & Johnson's interatrial shunt system (formerly V-Wave). Many of the companies developing or marketing competing products enjoy several advantages over us, including, among others:

- more experienced sales forces;
- greater name recognition;
- more established sales and marketing programs and distribution networks;
- earlier regulatory approval;
- long established relationships with physicians and hospitals;
- significant patent portfolios, including issued U.S. and foreign patents and pending patent applications, as well as the resources to enforce patents against us or any of our third-party suppliers and distributors;
- the ability to acquire and integrate our competitors and/or their technology;
- demonstrated ability to develop product enhancements and new product offerings;
- established history of product reliability, safety, and durability;
- the ability to offer rebates or bundle multiple product offerings to offer greater discounts or incentives;
- greater financial and human resources for product development, sales, and marketing; and
- greater experience in and resources for conducting research and development, clinical studies, manufacturing, preparing regulatory submissions, obtaining regulatory clearance or approval for products and marketing approved products.

Our competitors may develop and patent processes or products earlier than us, obtain patents that may apply to us at any time, obtain regulatory clearance or approvals for competing products more rapidly than us or develop more effective or less expensive products or technologies that render our technology or products obsolete or less competitive. We also face fierce competition, particularly in this tight labor market, in recruiting and retaining qualified sales, scientific and management personnel, establishing clinical trial sites and enrolling patients in clinical studies. If our competitors are more successful than us in these matters, our business may be harmed. In addition, we face a particular challenge overcoming the long-standing practices by some physicians of using the products of our larger, more established potential competitors. Physicians who have completed many successful implants using the products made by these competitors may be reluctant to try new products from a source with which they are less familiar. If these physicians do not try and subsequently adopt our product, then our revenue growth will slow or decline.

If we fail to receive access to hospitals, our sales may decrease.

In the U.S., in order for physicians to use Barostim, hospitals where these physicians treat patients typically require us to enter into purchasing contracts. This process can be lengthy, time-consuming and require extensive negotiations and management time, which could include an approval by a customer's value analysis committee. In the EEA, from time-to-time certain institutions require us to engage in a contract bidding process in the event that such institutions are considering making purchase commitments that exceed specified cost thresholds, which vary by jurisdiction. These processes are only open at certain periods of time, and we may not be successful in the bidding process. If we do not receive access to hospitals via these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, our sales may decrease and our operating results may be harmed. Furthermore, we may expend significant effort in these time-consuming processes and still may not obtain a purchase contract from such hospitals.

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.

We currently source certain components for Barostim from a limited number of suppliers. Our ability to supply Barostim commercially depends, in part, on our ability to obtain a supply of these components that has been manufactured in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We have not entered into manufacturing, supply, or quality agreements with some of our limited suppliers, some of which supply components critical to our products, such as modules, batteries, and electrodes. We cannot guarantee that our suppliers will be able to meet our demand for their products and services, either because of the nature of our arrangements with those suppliers, our limited experience with those suppliers, or due to our relative importance as a customer to those suppliers. Further, due to our limited operating history and expected future expansion, it may be difficult for us to assess their ability to timely meet our demand in the future based on past performance.

Our suppliers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including, among others:

- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- third parties may threaten or enforce their intellectual property rights against our suppliers, which may cause disruptions or delays in shipment, or may force our suppliers to cease conducting business with us;
- we may not be able to obtain an adequate supply of components in a timely manner or on commercially reasonable terms;
- our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the effectiveness or safety of Barostim or cause delays in shipment;
- we may have difficulty locating and qualifying alternative suppliers;
- switching components or suppliers may require product redesign and possibly submission to the FDA, EEA, or other foreign regulatory bodies, which could significantly impede or delay our commercial activities;
- one or more of our limited source suppliers may be unwilling or unable to supply components of Barostim;

- other customers may use fair or unfair negotiation tactics and/or pressures to impede our use of the supplier;
- we do not conduct rigorous, formal environmental, social or governance due diligence on our supply chain and thus may not be aware if our suppliers pose such risks;
- the occurrence of a fire, natural disaster or other catastrophe impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner; and
- our suppliers may encounter financial, geopolitical, or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

Establishing additional or replacement suppliers for the components or processes used in Barostim, if required, could be time-consuming and expensive. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the limited sourced components and materials used in our products, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders. Given our reliance on certain limited source suppliers, we are especially susceptible to supply shortages because we have limited alternate suppliers currently available.

Manufacturing risks may adversely affect our ability to manufacture our product and could reduce our gross margin and profitability.

Our business strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis so as to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements, and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including:

- quality or reliability defects in product components that we source from third-party suppliers, including manufacturing compliance with federal and state regulations;
- our inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our failure to increase production of products to meet demand;
- our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements; and
- potential damage to or destruction of our manufacturing equipment or manufacturing facility.

As demand for Barostim increases, we have invested, and expect to continue to invest, additional resources to purchase components, hire and train employees and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, although we expect some of our product candidates in development to share product features and components with Barostim, manufacturing of these product candidates may require the modification of our production lines, the hiring of specialized employees, the identification of new suppliers for specific components, or the development of new manufacturing technologies. It may not be possible for us to manufacture these product candidates at a cost or in quantities sufficient to make these product candidates commercially viable. Any of these factors may affect our ability to manufacture our product and could reduce our gross margin and profitability.

We operate at a facility in one location and any disruption at this facility could harm our business.

Our principal offices and our only manufacturing facility are located in Minneapolis, Minnesota. Substantially all of our operations are conducted at this location, including our manufacturing processes, research,

development and engineering activities, customer and technical support and management and administrative functions. In addition, substantially all of our inventory of component supplies and finished goods is held at the manufacturing facility. Vandalism, terrorism or a natural or other disaster, such as a fire or flood, could damage or destroy our manufacturing equipment or our inventory of component supplies or finished goods, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our facility may harm our business, financial condition, and operating results.

Our manufacturing facility in Minneapolis, Minnesota is our only manufacturing facility, and if it is damaged or rendered inoperable or inaccessible due to political, social or economic upheaval or due to natural or other disasters, it would be difficult or impossible for us to manufacture our product for a period of time, which may lead to a loss of customers and significant impairment of our financial condition and operating results.

Our international operations subject us to certain operating risks, which could adversely impact our results of operations and financial condition.

The sale and shipment of Barostim across international borders, as well as the purchase of components from international sources, subjects us to U.S. and foreign governmental trade, import and export and customs regulations and laws.

Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the FCPA, as well as export controls laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting.

Our international operations expose us and our distributors to risks inherent in operating in foreign jurisdictions. These risks include, among others:

- difficulties in enforcing our intellectual property rights and in defending against third-party threats and intellectual property enforcement actions against us, our distributors, or any of our third-party suppliers;
- reduced or varied protection for intellectual property rights in some countries;
- potential pricing pressure;
- a shortage of high-quality sales representatives and distributors;
- competitive disadvantage to competition with established business and customer relationships;
- foreign currency exchange rate fluctuations;
- the imposition of additional U.S. and foreign governmental controls or regulations;
- economic instability;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of restrictions on the activities of foreign agents, representatives, and distributors;
- scrutiny of U.S. and foreign tax authorities, which could result in significant fines, penalties and additional taxes being imposed on us;
- laws and business practices favoring local companies;
- longer payment cycles;
- difficulties in maintaining consistency with our internal guidelines;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. or international sanctions against a country, company, person, or entity; and
- the imposition of new trade restrictions.

If any of these risks are realized, our sales in non-U.S. jurisdictions may be adversely affected and our results of operations would suffer.

Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell Barostim at prices necessary to support our current business strategies.

Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third-party payers. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for price concessions in the future. Additionally, group purchasing organizations, independent delivery networks and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals. We expect that market demand, government regulation, third-party coverage, provider constraints, reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our future customers, which may exert further downward pressure on the prices of Barostim.

If we fail to properly manage our growth effectively, our business could suffer.

We intend to continue to grow and may experience periods of rapid growth and expansion, which could place a significant additional strain on our limited personnel, information technology systems and other resources. In particular, the hiring of our direct sales force requires significant management, financial and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

To achieve our revenue goals, we must continue to successfully increase manufacturing output to meet expected customer demand. We may experience difficulties with manufacturing yields, quality control, component supply and shortages of qualified personnel, such as skilled operators who can assemble our product, among other problems. Any of these problems could result in delays in product availability and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate revenue.

Future growth will continue to impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure.

In order to manage our operations and growth, we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and may have an adverse effect on our business, financial condition, and results of operations.

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

We will likely need to conduct additional clinical studies in the future to support approval for new indications. Clinical testing takes many years, is expensive and carries uncertain outcomes. The initiation and completion of studies may be prevented, delayed, or halted for numerous reasons, including, but not limited to, the following:

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

Clinical trials can fail at any stage. Our clinical studies may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional clinical or non-clinical studies in addition to those we have planned. In addition, if the FDA determines for any reason, including safety or their risk-benefit analysis, that the results of a trial are negative, the FDA may decide to modify or revoke our existing approval or such data may impact the adoption of Barostim. Moreover, a negative perception of clinical results for one indication for use could impact the use of Barostim for other FDA approved and clinically supported indications for use.

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

Even if our products are approved in the U.S. and the EEA, comparable regulatory authorities of additional foreign countries must also approve the manufacturing and marketing of our products in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S. or the EEA, including additional preclinical studies or clinical trials. Any of these occurrences may harm our business, financial condition, and prospects significantly.

We may face product liability claims that could be costly, divert management's attention and harm our reputation.

Manufacturing and marketing of Barostim and clinical testing of Barostim Therapy may expose us to product liability claims. The coverage limits of our liability insurance policies may not be adequate and one or more successful claims brought against us may have a material adverse effect on our business and results of operations. Further, interpretation of product liability laws may change in the future due to court rulings. It is possible evolving interpretations of product liability laws could further expose us to increased litigation risk in connection with our products. These product liability claims could, among other things, divert management's attention from our primary business and negatively affect our reputation, continued product sales and our ability to obtain and maintain regulatory approval for our 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.

Our future success depends, in part, on our ability to continue to retain our executive officers and other key employees and recruit and hire new employees. All of our executive officers and other employees are at-will employees, and therefore may terminate employment with us at any time with no advance notice. In particular, we are highly dependent upon our management team, especially our President and Chief Executive Officer and the rest of our senior management. The replacement of key personnel involves significant time and costs, may significantly delay or prevent the achievement of our business objectives and may harm our business. In addition, we do not carry any "key person" insurance policies that could offset potential loss of service under applicable circumstances.

Transitions in executive leadership can adversely affect relationships with our customers, suppliers, and employees, make it difficult to attract and retain talent, and disrupt execution of our strategy, sales growth, and our efforts to enhance our operations. Additionally, such transitions can require significant payments to recruit and attract qualified employees to join our company and may involve severance payments to certain departing employees. Changes in key management positions may temporarily affect our financial performance and results of operations as the new management becomes familiar with our business and establishes their team dynamic. For example, in February 2024, we appointed a new Chief Executive Officer who replaced our prior Chief Executive Officer, who had been in the role for 17 years. We experienced some disruption within the sales organization at the time of the Chief Executive Officer transition, which led to decreased productivity and higher salesforce turnover, as well as the termination of employment of our Senior Vice President of U.S. Sales. Since the beginning of the second quarter of fiscal 2024, we have hired new leaders for sales, medical affairs, clinical, reimbursement and human resources, completing the expansion of the executive team. Accordingly, our future financial performance will depend on our ability to attract, motivate, integrate, and retain our senior management and employees, and effectively manage this period of transition under our new leadership.

In addition, many of our employees have become vested in a substantial amount of stock or number of stock options. Our employees may be more likely to leave us if the shares they own or the shares underlying their vested options have significantly appreciated in value relative to the original purchase prices of the shares or the exercise prices of the options, or if the exercise prices of the options that they hold are significantly below the market price of our common stock.

Although non-compete agreements are becoming more disfavored and, in some cases, banned, many executive officers and employees in the medical device industry are still subject to strict non-compete or confidentiality agreements with their employers. In addition, some of our existing and future employees are subject to confidentiality agreements with previous employers. Our competitors may allege breaches of and seek to enforce such non-compete agreements or initiate litigation based on such confidentiality agreements. Such litigation, whether or not meritorious, may impede our ability to attract or use executive officers and other key employees who have been employed by our competitors and may result in claims against us.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.

We rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, marketing, procurement, and supply chain, manufacturing, and distribution. We use enterprise information technology systems to record, process and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory, financial reporting, legal and tax requirements. Our information technology systems, some of which are managed by third parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases, or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. If our systems suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may suffer.

If important assumptions about the potential market for our product are inaccurate, or if we have failed to understand what people with HF are seeking in a treatment, we may not be able to increase our revenue or achieve profitability.

Our business strategy was developed based on a number of important assumptions about the HF market in general, any one or more of which may prove to be inaccurate. For example, we believe that the benefits of Barostim as compared to other common HF devices will continue to drive growth in the market for Barostim. Despite our review of studies reporting on the trends of HF incidence in the U.S., the actual incidence of HF and the actual demand for our product or competitive products could differ materially from our expectations. In addition, our strategy of focusing exclusively on patients with HFrEF who are looking for an improvement in the symptoms associated with HFrEF may limit our ability to increase sales or achieve profitability, especially if there are any significant clinical breakthroughs or product or drug introductions that significantly delay or reduce the need for heart disease therapy. Moreover, a percentage of our indicated patients may be ineligible to undergo a Barostim procedure if they have certain co-morbidities or other disqualifying factors as determined by their physicians.

Our estimates of the annual total addressable market for Barostim are based on a number of internal and third-party estimates, including, without limitation, the number of patients with HFrEF and the assumed prices at which we can sell our device. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for Barostim may prove to be incorrect. If the actual number of patients who would benefit from our product, the price at which we can sell our product, or the annual total addressable market for our product is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

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

Our results of operations could be adversely affected by general conditions in the economy and the financial markets. Concerns over economic and political stability, inflation levels and related efforts to mitigate inflation, a potential recession, the level of U.S. national debt, currency fluctuations and volatility, the rate of growth of Japan, China and other Asian economies, unemployment, the availability and cost of credit, trade relations, including the imposition of various sanctions and tariffs, infectious diseases or pandemics, climate-related events, energy costs and geopolitical uncertainty and conflict have contributed to increased volatility and diminished expectations for the economy and markets in general. An economic downturn could result in a variety of risks to our business, including weakened demand for Barostim and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our manufacturers or suppliers, resulting in supply disruption, or causing our customers to delay making

payments for our services. Certain of the foregoing have harmed and could in the future harm our business, and we cannot anticipate all of the ways in which the economic climate and financial market conditions may further affect our business.

We may enter into strategic collaborations, in-licensing arrangements, or alliances with third parties that may not result in the development of commercially viable products or the generation of significant future revenue.

In the ordinary course of our business, we may enter into strategic collaborations, in-licensing arrangements, or alliances to develop product candidates and to pursue new markets. Proposing, negotiating, and implementing strategic collaborations, in-licensing arrangements or alliances may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology, or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenue and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. We have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' or our future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could impair our ability to execute our business strategies.

From time to time, we may consider opportunities to acquire other products or technologies that may enhance our Barostim platform technology, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including, among others:

- problems assimilating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls, and policies;
- unanticipated costs associated with acquisitions;
- diversion of management's attention from our existing business;
- risks associated with entering new markets in which we have limited or no experience; and
- increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters.

We have no current commitments with respect to any acquisition. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our inability to integrate any acquired products or technologies effectively could impair our ability to execute our business strategies. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses.

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

Medicare reimbursement levels are important to increasing adoption of Barostim and establishing Barostim as the standard of care because nearly two-thirds of the target patient population for Barostim is over the age of 65. On January 1, 2024, Barostim was reassigned to New Technology APC 1580, which carries an average payment amount of $45,000. The APC payment of approximately $45,000 will continue in 2025, as published in the 2025 OPPS final rule. In August 2024, CMS reassigned the Barostim implant procedure for the inpatient setting as part of the IPPS final rule for CMS' Fiscal Year 2025, which took effect on October 1, 2024. On that date, Barostim was reassigned to MS-DRG 276, which carries a national average payment of approximately $44,000 in 2025, a significant increase from the previous payment range of $17,000-$23,000. Additionally, the American Medical Association's CPT Editorial Panel approved new Category I codes for Barostim therapy, expected to take effect January 1, 2026.

Any future decline in the amount Medicare is willing to reimburse our customers for procedures using Barostim could make it difficult for new customers to adopt Barostim and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business, or establish Barostim as the standard of care. From time to time, physicians and hospitals have in the past experienced, and others may experience, denials in Medicare and commercial reimbursement, which have delayed or may delay their willingness to schedule additional Barostim procedures.

A pandemic, epidemic or outbreak of an infectious disease in the U.S. or worldwide could adversely affect our business.

Pandemics, epidemics, or outbreaks of an infectious disease may adversely affect our business. Numerous state and local jurisdictions have historically imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of infectious disease. Such orders or restrictions previously resulted, and may in the future result, in reduced operations at our headquarters, slowdowns and delays, travel restrictions and cancellation of events and restrictions on the ability of our front-line sales representatives to attend procedures in which our products are used, among other effects, thereby negatively impacting our operations. Other disruptions or potential disruptions include restrictions on the ability of our sales representatives and other personnel to travel and access customers for training and case support; the ability of hospitals and surgical centers to staff and conduct procedures; inability of our suppliers to manufacture components and parts and to deliver these to us on a timely basis, or at all; disruptions in our production schedule and ability to manufacture and assemble products; inventory shortages or obsolescence; delays in actions of regulatory bodies; and delays in clinical trials and studies, especially if study subjects are reluctant to present themselves at medical facilities.

While the potential economic impact brought by and the duration of any pandemic, epidemic or outbreak of an infectious disease may be difficult to assess or predict, it may result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. To the extent a pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

Risks related to intellectual property

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.

Our success depends in part on obtaining, maintaining, and enforcing patents and other intellectual property rights and not infringing the patents or violating the other proprietary rights of others. Intellectual property disputes can be costly to defend and may cause our business, operating results, and financial condition to

suffer. Significant litigation regarding patent rights occurs in the medical device industry. Whether merited or not, it is possible that third parties controlling U.S. and foreign patents allege such patents cover our products, or we may decide to initiate infringement claims or litigation to protect our patents or other intellectual property rights. We may also face allegations that our employees have misappropriated the intellectual property rights of their former employers or other third parties. Our competitors in both the U.S. and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use, sell, or export our products. These competitors may have one or more patents for which they can threaten or initiate patent infringement actions against us or any of our third-party suppliers. Further, if such patents are successfully asserted against us, this may result in an adverse impact on our business, including injunctions, damages, or attorneys' fees. Moreover, if we initiate an infringement proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable or that the patent in question does not cover the technology at issue. From time to time and in the ordinary course of business, we may develop noninfringement or invalidity positions with respect to third-party patents, which may or may not be ultimately adjudicated as successful by a judge or jury if such patents were asserted against us.

We may receive in the future, particularly as a public company, communications from patent holders, including non-practicing entities, alleging infringement of patents or other intellectual property rights or misappropriation of trade secrets, or offering licenses to such intellectual property. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. At any given time, we may be involved as either a plaintiff or a defendant in a number of patent infringement actions, the outcomes of which may not be known for prolonged periods of time.

The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved and the uncertainty of litigation significantly increase the risks related to any patent litigation. Any potential intellectual property litigation also could require us to do one or more of the following:

- stop selling, making, using, or exporting products that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, making, exporting, or using products, which license may require substantial royalty payments and may not be available on reasonable terms, or at all;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, potentially including treble damages if the court finds that the infringement was willful;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products and services;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- find non-infringing substitute products, which could be costly and create significant delay due to the need for FDA regulatory clearance;
- find alternative supplies for infringing products or processes, which could be costly and create significant delay due to the need for FDA regulatory clearance; or
- redesign those products or processes that infringe any third-party intellectual property, which could be costly, disruptive, or infeasible.

If a court determines that we failed to secure necessary patents, competitors may be able to market competing products and make, use or sell products that are substantially the same as ours without incurring the sizeable development costs that we have incurred, which would adversely affect our ability to compete. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their

normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Finally, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If any of the foregoing occurs, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Further, as the number of participants in our industry grows, the possibility of intellectual property infringement disputes increases.

In addition, we may indemnify our customers, suppliers and international distributors against claims relating to the infringement of the intellectual property rights of third parties relating to our products, methods, and/or manufacturing processes. Third parties may assert infringement claims against our customers, suppliers, or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, suppliers, or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products, or our suppliers may be forced to stop providing us with products.

Similarly, interference or derivation proceedings provoked by third parties or brought by the United States Patent and Trademark Office (the “USPTO”) or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re-examination or opposition proceedings, before the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property rights of others. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (the “Leahy-Smith Act”) was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switched the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, became effective on March 16, 2013. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications.

Furthermore, the U.S. and foreign courts are continually interpreting various aspects of patent law. We cannot predict with any reasonable certainty how the evolution of the interpretation of these laws will affect our business. However, it is possible that changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

We may not be able to adequately protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products, and our competitive position in the international market would be harmed.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-disclosure or confidentiality agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information about former employers or competitors. Although we have procedures in place that seek to prevent our employees and consultants from using the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may

in the future be subject to claims that we caused an employee to breach the terms of his or her non-disclosure or confidentiality agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor, resulting in litigation. Even if we are successful in defending against these claims, the litigation could be costly and a distraction to management. If we are unsuccessful in defending against these claims, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products would have a material adverse effect on our business, and may prevent us from selling our products or from practicing our processes. In addition, we may lose valuable intellectual property rights.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential partners or customers in our markets of interest. In addition, third parties have registered trademarks similar and identical to our trademarks in foreign jurisdictions, and may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we were not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our consultants and vendors and our employees. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, however, any of these parties may breach the agreements and disclose our trade secrets and other unpatented or unregistered proprietary information, and once disclosed, we are likely to lose trade secret protection. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be sufficient. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are reluctant or unwilling to enforce trade secret protection.

Further, our competitors may independently develop knowledge, methods, and know-how similar, equivalent, or superior to our proprietary technology. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology, or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, our key employees, consultants, suppliers, or other individuals with access to our proprietary technology and know-how may incorporate that technology and know-how into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technology or know-how and any such dispute may not be resolved in our favor. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those with whom they share it, from using that technology or information to compete with us and our competitive position could

be adversely affected. If our intellectual property is not adequately protected to protect our market against competitors' products and methods, our competitive position and business could be adversely affected.

Risks related to our financial and operating results

We may be required to obtain additional funds in the future, and these funds may not be available on acceptable terms or at all.

Our operations have consumed substantial amounts of cash since inception, and we anticipate our expenses will increase as we continue to build our commercial sales force in the U.S., investigate the potential use of Barostim for the treatment of other HF conditions, continue to grow our business and operate as a public company. We believe that our growth will depend, in part, on our ability to fund our commercialization and research and development efforts. We believe that our existing cash, cash equivalents, short-term investments and revenue will be sufficient to meet our capital requirements and fund our operations for at least the next three years. However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our available financial resources much faster than we currently expect. As a result, we may need to seek additional funds in the future. If we are unable to raise funds on favorable terms, or at all, we may not be able to support our commercialization efforts or increase our research and development activities and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. For the fiscal years ended December 31, 2024 and 2023, net cash used in operating activities was $39.1 million and $39.0 million, respectively. Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including, among others:

- the scope and timing of our continued investment in our U.S. commercial infrastructure and sales force;
- the costs of commercialization activities, including product sales, marketing, manufacturing, and distribution and hiring additional members for our direct sales and marketing team in the U.S.;
- the degree and rate of market acceptance of Barostim;
- the research and development activities we intend to undertake in order to pursue product enhancements and expand HF 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; and
- the emergence of competing technologies or other adverse market developments.

To finance certain of these activities, we may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings and collaborative arrangements with corporate partners. We may be unable to raise funds on favorable terms, or at all.

The sale of additional equity or convertible debt securities could result in additional dilution to our stockholders. If we borrow additional funds or issue debt securities, these securities could have rights superior to holders of our common stock and could contain covenants that will restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation, or asset sale transactions. For example, our Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Fund I, LP ("Innovatus") restricts us from paying dividends or making other distributions or payments on our capital stock, subject to limited exceptions. We might have to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies, product candidates or products that we otherwise would not relinquish. If we do not obtain additional resources, our ability to capitalize on business opportunities will be limited, we may be unable to compete effectively and the growth of our business may be adversely affected.

Our operating results may vary significantly annually or from quarter to quarter, which may negatively impact our stock price in the future.

Our revenue and results of operations may fluctuate annually or from quarter to quarter due to, among others, the following reasons:

- physician and payer acceptance of Barostim and Barostim Therapy;
- the timing, expense and results of research and development activities, clinical trials, and regulatory approvals;
- fluctuations in our expenses associated with expanding our commercial operations and operating as a public company;
- the introduction of new products and technologies by our competitors;
- the productivity of our sales representatives;
- supplier, manufacturing, or quality problems with our products;
- the timing of stocking orders from our distributors;
- changes in our pricing policies or in the pricing policies of our competitors or suppliers; and
- changes in coverage amounts or government and third-party payers' reimbursement policies.

Because of these and other factors, it is possible that our operating results will not meet investor expectations or those of public market analysts.

Any unanticipated change in revenues or operating results is likely to cause our stock price to fluctuate. New information may cause investors and analysts to revalue our business, which could also cause a fluctuation in our stock price.

We are required to maintain high levels of inventory, which could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges.

Our product consists of a substantial number of individual components. In order to market and sell Barostim effectively, we often must maintain high levels of inventory. The manufacturing process requires lengthy lead times, during which components of our products may become obsolete, and we may over- or under-estimate the amount needed of a given component, in which case we may expend extra resources or be constrained in the amount of end product that we can produce. As compared to direct manufacturers, our dependence on third-party manufacturers for our component parts exposes us to greater lead times.

The seasonality of our business creates variance in our quarterly revenue, which makes it difficult to compare or forecast our financial results.

We have seen seasonally lower rates of implants in our first fiscal quarter in recent years, which we believe is primarily due to U.S. patients shifting medical treatments to the later months of the year when they have better information about spending against the annual deductibility limits under their health insurance coverage, and we expect this trend to continue. Otherwise, mild seasonal variations are difficult to predict accurately and may vary among different markets.

We are subject to risks associated with currency fluctuations, and changes in foreign currency exchange rates could impact our results of operations.

A portion of our current business is located outside the U.S. and, as a result, we generate revenue and incur expenses denominated in currencies other than the U.S. dollar, a majority of which is denominated in Euros. As a result, changes in the exchange rates between such foreign currencies, particularly the Euro and the U.S. dollar, could materially impact our reported results of operations and distort period to period

comparisons. Fluctuations in foreign currency exchange rates also impact the reporting of our receivables and payables in non-U.S. currencies. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations. In addition, to the extent that fluctuations in currency exchange rates cause our results of operations to differ from our expectations or the expectations of our investors, the trading price of our common stock could be adversely affected. In the future, we may engage in exchange rate hedging activities in an effort to mitigate the impact of exchange rate fluctuations. If our hedging activities are not effective, changes in currency exchange rates may have a more significant impact on our results of operations.

Our ability to use our net operating losses and tax credits to offset future taxable income and taxes may be subject to certain limitations, and we may not be able to utilize a significant portion of our net operating loss and tax credit carryforwards prior to their expiration.

We have generated and expect to continue to generate significant federal and state net operating loss ("NOLs") and tax credit carryforwards. As of December 31, 2024, we had federal and state NOL carryforwards of approximately $429.7 million and $8.1 million, respectively. The federal NOLs began expiring in 2021 and 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 and state tax credit carryforwards began expiring in 2021 and begin expiring in 2028, respectively. These NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the legislation enacted on December 22, 2017 commonly referred to as the "Tax Cuts and Jobs Act," as modified by the Coronavirus Aid, Relief, and Economic Security Act, federal NOLs incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs incurred in taxable years beginning after December 31, 2020 is limited.

In addition, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs and specified other tax credit carryforwards, such as research and development tax credits, to offset future taxable income and taxes. We may have previously experienced, and may in the future experience, one or more "ownership changes" for purposes of the rules under Section 382 and 383 of the Code, including in connection with our initial public offering (the "IPO"). If so, or if we do not generate sufficient taxable income, we may not be able to utilize a material portion of our NOLs and tax credits, even if we achieve profitability. If we are limited in our ability to use our NOLs and tax credits in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs and tax credits. This could materially and adversely affect our results of operations by effectively increasing our future tax obligations.

We are subject to complex tax rules, and any audits, investigations or tax proceedings could have a material adverse effect on our business, results of operations, and financial condition.

We are subject to income and/or non-income taxes in the U.S., Switzerland, Italy, Germany, France, and the Netherlands, as well as the tax laws and regulations related to such matters. Tax accounting and compliance often involves complex issues, and judgment and interpretation is required in determining our provision for income taxes and other tax liabilities as well as the application of tax laws and regulations. In that respect, many jurisdictions have detailed transfer pricing rules, which require that all transactions with related parties be priced using arm's length pricing principles within the meaning of such rules. The application of such transfer pricing rules, as well as of withholding taxes, goods and services taxes, sales taxes and other taxes is not always clear, and we may be subject to tax audits relating to such rules or taxes.

We believe that our tax positions are reasonable, and our tax provisions and reserves are adequate to cover any potential liability. However, various items cannot be accurately forecasted, and future events may be treated as discrete to the period in which they occur. In addition, the Internal Revenue Service or other taxing authorities may disagree with our positions. If the Internal Revenue Service or any other tax authorities were successful in challenging our positions, we may be liable for additional tax and penalties and interest related

thereto or other taxes, as applicable, in excess of any reserves established therefor, which may have a significant impact on our results, operations and future cash flow.

Changes in U.S. and non-U.S. tax laws could adversely affect our financial condition and results of operations.

The rules dealing with U.S. and non-U.S. tax matters are constantly under review by persons involved in the legislative, judicial, administrative, regulatory, and related governmental processes and authorities. Changes to tax laws or the interpretation and application thereof (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U.S. and non-U.S. tax laws could have a material adverse effect on our business, cash flow, financial condition, or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U.S. and non-U.S. tax laws on an investment in our common stock.

Risks related to regulation of our industry

Barostim is subject to extensive governmental regulation, and our failure to comply with applicable requirements could cause our business to suffer.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies and authorities, such as the EU legislative bodies and the EEA member state competent authorities. The FDA and other U.S., EEA and foreign governmental agencies and authorities regulate and oversee, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content, and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales, and distribution;
- pre-market regulatory clearance and approval;
- conformity assessment procedures;
- record-keeping procedures;
- advertising and promotion;
- recalls and other field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies; and
- product import and export.

The laws and regulations to which we are subject are complex and have tended to become more stringent over time. Legislative or regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

Our failure to comply with U.S. federal and state regulations or EEA or other foreign regulations applicable in the countries where we operate could lead to the issuance of warning letters or untitled letters, fines, injunctions, suspensions or loss of regulatory clearance or approvals, recalls or seizures of products, termination of distribution, or civil penalties. In the most extreme cases, criminal sanctions or closure of our

manufacturing facilities are possible. If any of these risks materialize, our business would be adversely affected.

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

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

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

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

Our business is subject to extensive governmental regulation that could make it more expensive and time consuming for us to market Barostim in the U.S. and introduce new or improved products.

Our products must comply with regulatory requirements imposed by the FDA in the U.S. and similar agencies in foreign jurisdictions. These requirements involve lengthy and detailed laboratory and clinical testing

procedures, sampling activities, extensive agency review processes and other costly and time-consuming procedures. It often takes several years to satisfy these requirements, depending on the complexity and novelty of the product. We also are subject to numerous additional licensing and regulatory requirements relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. Some of the most important requirements we must comply with include:

- the FDCA and the FDA's implementing regulations (Title 21 CFR);
- EU CE mark requirements;
- Medical Device Quality Management System Requirements (ISO 13485:2003);
- Occupational Safety and Health Administration requirements; and
- California Department of Health Services requirements.

Current or evolving government regulation may impede our ability to conduct clinical studies and to manufacture and sell our existing and future products. Such government regulation also could delay our marketing of new products for a considerable period of time and impose costly procedures on our activities. The extended times EU notified bodies are taking to review and approve both the original MDR application and significant changes once approved, may limit or cause delays in our ability to make necessary or desired changes to the design, manufacturing processes, materials, or quality management system.

Our products remain subject to strict regulatory controls on manufacturing, marketing, and use. We may be forced to modify or recall a product after release in response to regulatory action or unanticipated difficulties encountered in general use. Any such action could have a material effect on the reputation of our products and on our business and financial position. Further, regulations may change, and any additional regulation could limit or restrict our ability to use any of our technologies, which could harm our business. We could also be subject to new international, federal, state, or local regulations that could affect our research and development programs and harm our business in unforeseen ways. If this happens, we may have to incur significant costs to comply with such laws and regulations, which will harm our results of operations.

The misuse or off-label use of our product may harm our image in the marketplace, result in injuries that lead to product liability suits, which could be costly to our business, or result in costly investigations and sanctions from the FDA and other regulatory bodies if we are deemed to have engaged in inappropriate promotion.

Barostim has been indicated for the improvement of symptoms of HFrEF by the FDA and the treatment of HFrEF in the EEA. We may only promote or market Barostim for its specifically approved indications as described on the approved label. We train our marketing and sales force against promoting our products for uses outside of the approved indications for use, known as “off-label uses.” We cannot, however, prevent a physician from using our product off-label when, in the physician’s independent professional medical judgment, he or she deems appropriate. There may be increased risk of injury to patients if physicians attempt to use our product off-label. Furthermore, the use of our product for indications other than those approved by the applicable regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

Physicians may also misuse our product or use improper techniques, potentially leading to injury and an increased risk of product liability. If our product is misused or used with improper technique, we may become subject to costly product liability claims or other litigation by our customers or their patients. In addition, if the FDA determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute inappropriate promotion, including promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and/or administrative

penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

Further, the advertising and promotion of our products is subject to EEA member state laws implementing the MDD, Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, as well as other EEA member state legislation governing the advertising and promotion of medical devices. EEA member state legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national codes of conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

The discovery of serious safety issues with Barostim, or a recall of Barostim either voluntarily or at the direction of the FDA or another governmental authority, could harm our reputation, business, and financial results.

The FDA, the competent authorities of the EEA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture that could affect patient safety or in the event that a product poses an unacceptable risk to health. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. We may also choose to conduct a product notification or recall to inform physicians of changes to instructions for use, or if a deficiency in a device is found or suspected. A government-mandated recall or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects, packaging defects or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Recalls, which include certain notifications and corrections as well as removals, of Barostim could divert managerial and financial resources and could have an adverse effect on our financial condition, harm our reputation and reduce our ability to achieve expected revenue.

In addition, the manufacturing of our products is subject to extensive post-market regulation by the FDA and foreign regulatory authorities, and any failure by us or our contract manufacturers or suppliers to comply with regulatory requirements could result in recalls, facility closures and other penalties. We and our suppliers and contract manufacturers are subject to the FDA's QSR, and comparable foreign regulations which govern the methods used in, and the facilities and controls used for, the design, manufacture, quality assurance, labeling, packaging, sterilization, storage, shipping, and servicing of medical devices. These regulations are enforced through periodic inspections of manufacturing facilities. Any manufacturing issues at our or our suppliers' or contract manufacturers' facilities, including failure to comply with regulatory requirements, may result in warning or untitled letters, manufacturing restrictions, voluntary or mandatory recalls or corrections, fines, withdrawals of regulatory clearances or approvals, product seizures, injunctions, or the imposition of civil or criminal penalties, which would adversely affect our business results and prospects.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals for the device before we may market or distribute the corrected device. Seeking such approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement actions, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending

ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA and European regulators, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition, and results of operations.

Under the FDA medical device reporting regulations, medical device manufacturers are required to submit information to the FDA when they receive a report or become aware that a device has or may have caused or contributed to a death or serious injury or has or may have a malfunction that would likely cause or contribute to death or serious injury if the malfunction were to recur. All manufacturers placing medical devices on the market in the EEA are legally bound to report incidents involving devices they produce or sell to the regulatory agency, or competent authority, in whose jurisdiction the incident occurred. Under the MDD, an incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA or European regulators could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device approval, seizure of our products or delay in clearance or approval of future products.

We are subject to certain federal, state, and foreign fraud and abuse laws, transparency and privacy and security laws and regulations, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws and regulations could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims, and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. We are subject to privacy and security regulation related to patient, customer, employee, and other third-party information by both the federal government and the states and foreign jurisdictions in which we conduct our business. In the U.S., the laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;
- federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence

the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- the federal HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;
- the federal physician payments sunshine requirements under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to HHS information related to payments and other transfers of value to certain healthcare providers and teaching hospitals;
- state and foreign law analogs of each of the above federal laws, such as state anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of personal and health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA.

These laws and regulations, among other things, constrain our business, marketing, and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians, or other potential purchasers of our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies continue to increase their scrutiny of interactions between healthcare companies and healthcare providers. The Office of the Inspector General of HHS also has issued compliance program guidance for pharmaceutical manufacturers which is routinely applied to medical device companies. All of this has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry, including for medical device companies. Responding to investigations can be time and resource consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Healthcare legislative reform measures may have a material adverse effect on us.

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the Affordable Care Act was enacted in the U.S., which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the Affordable Care Act:

- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implemented payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models; and
- expanded the eligibility criteria for Medicaid programs.

The expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payers for Barostim and any future products and/or reduced medical procedure volumes, all of which may have a material adverse effect on our business, financial condition, and results of operations.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services.

Additionally, on April 5, 2017, the European Parliament passed the MDR, which repeals and replaces the MDD and the AIMDD. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations are directly applicable (i.e., without the need for adoption of the EEA member state laws implementing them), in all EEA member states and are intended to eliminate differences in the regulation of medical devices among the EEA member states. The MDR, among other things, is intended to establish a uniform, transparent, predictable, and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

The MDR is set to become effective in January 2028 and, among other things is designed to:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

This regulation has not yet had a material effect on the way we conduct our business in the EEA. However, it is possible the regulation will change in the future, and we cannot be certain that future changes will not have an adverse effect on our business operations.

Risks related to our common stock

We expect that the price of our common stock will fluctuate substantially, and you may not be able to resell shares of our common stock at or above the price you paid.

The market price of our common stock has been and may continue to be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control or are related in complex ways, including:

- results from, or any delays in, clinical trial programs relating to our product candidates, including the ongoing and future U.S. clinical trials for Barostim;
- announcements of new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- our operating results;
- changes or developments in laws or regulations applicable to our products;
- any adverse changes in our relationship with any manufacturers or suppliers;
- the success of our efforts to acquire or develop additional products;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the medical device industry in general;
- achievement of expected product sales and profitability;
- manufacturing, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry or other healthcare reform measures in the U.S.;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future;
- general economic and market conditions and overall fluctuations in the U.S. equity markets; and
- the loss of any of our key scientific or management personnel.

In addition, the stock markets in general, and the markets for medical device stocks in particular, have experienced volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile or decreases significantly, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could seriously harm our results of operations and financial position. Any adverse determination in litigation could also subject us to significant liabilities.

Securities analysts may not publish favorable research or reports about our business or may publish no information at all, which could cause our stock price and trading volume to decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If no or few securities or industry analysts cover us, the trading price for our stock would be negatively impacted. If any of the analysts who cover us issues an adverse or misleading opinion regarding us, our business model, our intellectual property, or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We are an "emerging growth company," and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Because we have opted to take advantage of the JOBS Act provision which allows us to delay implementing new accounting standards, our financial statements may not be directly comparable to other public companies.

Pursuant to the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies 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. Because we have elected to take advantage of this provision of the JOBS Act, our financial statements and the reported results of operations contained therein may not be directly comparable to those of other public companies.

If we are unable to maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected.

To comply with the requirements of being a public company, we are undertaking and expect to continue to undertake various actions, including implementing and maintaining new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We have developed and expect to continue to refine our disclosure controls and other procedures that are designed to ensure that

information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. The Sarbanes-Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm, to the extent we are no longer an "emerging growth company," as defined by the JOBS Act, and are not a non-accelerated filer. We do not expect to have our independent registered public accounting firm attest to our management report on internal control over financial reporting for so long as we are an emerging growth company.

Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. If we fail to develop and maintain effective internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We have designed and implemented and expect to continue to refine the internal control over financial reporting required to comply with this obligation, which process will be time-consuming, costly, and complicated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or, when required in the future, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, or if our internal control over financial reporting is perceived as inadequate or we are unable to produce timely or accurate financial statements, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline and we could become subject to investigations or removal by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

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.

As of December 31, 2024, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 43% of our outstanding voting stock. One of our non-employee directors is also affiliated with one of our principal stockholders. Therefore, if they act together, these stockholders will have the ability to influence us through this ownership position and matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of the Company, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company or our assets, and might affect the prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law (the "DGCL") or any action asserting a claim

against us that is governed by the internal affairs doctrine. The exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation also provides that the U.S. federal district courts are the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees, or agents and arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. Under the Securities Act, federal and state courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Accordingly, there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under the Securities Act. We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, and results of operations.

Anti-takeover provisions included in our amended and restated certificate of incorporation and amended and restated bylaws, as well as under Delaware law, could discourage a takeover.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that may discourage, delay, or prevent a merger, acquisition, or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace or remove current members of our management team. These include the following provisions that:

- permit our Board of Directors to issue shares of preferred stock, with any rights, preferences, and privileges as they may designate, without stockholder approval, which could be used to dilute the ownership of a hostile bidder significantly;
- provide that the authorized number of directors may be changed only by resolution of our Board of Directors and that a director may only be removed with cause by the affirmative vote of the holders of at least a majority of our outstanding voting stock, voting together as a single class;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that our amended and restated bylaws may only be altered, amended, or repealed by our stockholders upon the affirmative vote of a two-thirds majority of the voting power of all of our outstanding voting stock, voting together as a single class;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the

acquiror's own slate of directors or otherwise attempting to obtain control of our company;

- prohibit cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; and
- provide that special meetings of our stockholders may be called only by the Chairman of the board, the Chief Executive Officer, or a majority of the Board of Directors then in office, which may delay the ability of our stockholders to force consideration by our company of a take-over proposal or to take certain corporate actions, including the removal of directors.

In addition, Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This provision could have the effect of delaying or preventing a change in control of our company, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay, or prevent someone from acquiring us or merging with us.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk management and strategy

We rely on our information technology to operate our business and provide our Barostim Therapy to patients. We have policies and processes designed to protect our information technology systems, some of which are managed by third parties, and resolve issues in a timely manner in the event of a cybersecurity threat or incident.

As part of our broader risk management framework, we have identified the potential cybersecurity risks to our business. We have designed our business applications and hosting services to minimize the impact that cybersecurity incidents could have on our business and have identified back-up systems where appropriate. We seek to further mitigate cybersecurity risks through a combination of monitoring and detection activities, use of anti-malware applications, employee training, quality audits and communication and reporting structures, among other processes. We have an incident response plan in place that outlines containment, eradication, and recovery plans in the event of a cybersecurity threat or incident.

We engage a third-party consultant to assist us with designing controls and our cybersecurity risk management framework. We are also engaging with a third party to perform penetration testing. We also retain third parties to assist with the monitoring and detection of cybersecurity threats and responding to any cybersecurity threats or incidents.

With respect to third parties that manage or use our information technology or data, we obtain reports to assess the security of their systems and processes. We engage in ongoing monitoring of all third-party providers to ensure compliance with our cybersecurity standards.

We have not encountered cybersecurity threats or incidents that have had a material impact on our business.

Governance

Our Board of Directors assigned specific oversight responsibility for cybersecurity to our Audit Committee , which also oversees our general risk management. The Audit Committee reviews and discusses with management our policies, practices, and risks related to information security and cybersecurity.

Our chief financial officer has primary responsibility for assessing, monitoring, and managing cybersecurity risks. Leaders of our information technology and device engineering, together with members of our finance team, comprise our Cybersecurity Committee, which meets to assess cybersecurity risks and identify new risks and assess our risk management framework on a quarterly basis . Among the members of this committee are employees who are knowledgeable about our products and systems, have prior experience managing cybersecurity risks, and maintain an active Certified Information Systems Security Professional certification.

Our chief financial officer provides an update to the Audit Committee on any risks related to cybersecurity on a quarterly basis. Our incident response plan includes notifying the Audit Committee, and then the Board of Directors, of any material threats or incidents that arise.

Item 2. Properties

We lease 31,505 square feet of office space in Minneapolis, Minnesota, which houses our principal executive offices and our manufacturing facility. We lease this space under an operating lease agreement that commenced December 1, 2008 and expires August 31, 2028. We intend to add new facilities as we grow and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Item 3. 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 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock trades on the Nasdaq Global Select Market under the symbol "CVRX."

Holders

As of February 11, 2025, there were approximately 62 holders of record of our common stock. This number does not include stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our capital stock. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our Board of Directors, subject to applicable laws, and will depend on then existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects, and other factors our Board of Directors may deem relevant. Our Loan Agreement with Innovatus restricts us from paying dividends or making other distributions or payments on our capital stock, subject to limited exceptions.

Item 6. [Reserved]

Item 7. 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 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 BAT 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 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 ≤ 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 EPs, HF specialists, interventional and general cardiologists, and vascular surgeons because they are the primary users of our technology. However, we consider hospitals, where the procedures are performed primarily in an outpatient setting, to be our customers, as they are the purchasing entities of Barostim in the U.S. We intend to continue making significant investments building our U.S. commercial infrastructure by expanding and training our U.S. sales force. We have dedicated significant resources to educate physicians who treat HFrEF about the advantages of Barostim and train them on the implant procedure.

The costs for the device and implantation procedure are reimbursed through various third-party 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 CMS while simultaneously developing processes to engage commercial payers. All MACs have retired their official automatic coverage denial policies for our CPT 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 EEA, such as Germany, where annual healthcare budgets for the hospital generally determine the number of patients to be treated and the prices to be paid for the related devices that may be purchased.

We manage all aspects of manufacturing operations and product supply of Barostim, which include final assembly, testing and packaging of our 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 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 consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We had $50.0 million in outstanding Term Loans under the Loan Agreement at December 31, 2024. As a result of these investments and our commercialization efforts, we expect to continue to incur net losses for the next several years, which may require additional funding and could include future equity and debt financing.

Recent developments

On November 4, 2024, we announced that CMS assigned the Barostim procedure to New Technology APC 1580. The APC payment of approximately $45,000 will continue in 2025, as published in the 2025 OPPS final rule.

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.

Provision for income taxes

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

Results of operations

Consolidated results of operations for the year ended December 31, 2024, compared to the year ended December 31, 2023

	Year ended December 31,		Change	
(in thousands)	2024	2023	$	%
Revenue	$ 51,292	$ 39,295	$ 11,997	31 %
Cost of goods sold	8,334	6,256	2,078	33 %
Gross profit	42,958	33,039	9,919	30 %
Gross margin	84 %	84 %		
Operating Expenses:				
Research and development	11,131	11,633	(502)	(4)%
Selling, general and administrative	91,317	64,509	26,808	42 %
Total operating expenses	102,448	76,142	26,306	35 %
Loss from operations	(59,490)	(43,103)	(16,387)	38 %
Interest expense	(4,397)	(1,799)	(2,598)	144 %
Other income, net	3,977	3,850	127	3 %
Loss before income taxes	(59,910)	(41,052)	(18,858)	46 %
Provision for income taxes	(55)	(147)	92	(63)%
Net loss	$ (59,965)	$ (41,199)	$ (18,766)	46 %

Revenue

	Revenue by Geography			
	Year ended December 31,		Change	
(in thousands)	2024	2023	$	%
United States	$ 47,167	$ 35,111	$ 12,056	34 %
Europe	4,125	4,184	(59)	(1)%
Total Revenue	$ 51,292	$ 39,295	$ 11,997	31 %

Revenue was $51.3 million for the year ended December 31, 2024, an increase of $12.0 million, or 31%, over the year ended December 31, 2023.

Revenue generated in the U.S. was $47.2 million for the year ended December 31, 2024, an increase of $12.1 million, or 34%, over the year ended December 31, 2023. HF revenue units in the U.S. totaled 1,506 and 1,123 for the years ended December 31, 2024 and 2023, respectively. HF revenue in the U.S. totaled $46.8 million and $34.6 million for the years ended December 31, 2024 and 2023, respectively. The increase was primarily driven by continued growth as a result of the expansion into new sales territories and new accounts, as well as increased physician and patient awareness of Barostim.

As of December 31, 2024, we had a total of 223 active implanting centers in the U.S., as compared to 178 as of December 31, 2023. Active implanting centers are customers that have completed at least one commercial HF implant in the last 12 months. As of December 31, 2024, we had 48 sales territories in the U.S. as compared to 38 sales territories as of December 31, 2023.

Revenue generated in Europe was $4.1 million for the year ended December 31, 2024, a decrease of $0.1 million, or 1%, over the year ended December 31, 2023. Total revenue units in Europe decreased to 204 for the year ended December 31, 2024, from 207 for the prior year. As of December 31, 2024, we had five sales territories in Europe as compared to six sales territories as of December 31, 2023.

Cost of goods sold and gross margin

Cost of goods sold increased $2.1 million, or 33%, to $8.3 million for the year ended December 31, 2024, compared to the year ended December 31, 2023. This increase was primarily due to higher sales of Barostim.

Gross profit was $43.0 million for the year ended December 31, 2024, an increase of $9.9 million, or 30%, over the year ended December 31, 2023. Gross margin was 84% for both the years ended December 31, 2024 and 2023.

Research and development expenses

R&D expenses decreased $0.5 million, or 4%, to $11.1 million for the year ended December 31, 2024, compared to the year ended December 31, 2023. This change was primarily driven by a $0.5 million decrease in consulting expenses, a $0.3 million decrease in compensation expenses, and a $0.2 million decrease in travel expenses, partially offset by a $0.5 million increase in clinical study expenses.

Selling, general and administrative expenses

SG&A expenses increased $26.8 million, or 42%, to $91.3 million for the year ended December 31, 2024, compared to the year ended December 31, 2023. This change was driven by a $12.7 million increase in non-cash stock-based compensation expense, an $11.0 million increase in compensation expenses, mainly as a result of increased headcount, a $1.3 million increase in travel expenses, a $0.6 million increase in bad debt expenses, and a $0.5 million increase in consulting expenses. Approximately $8.4 million of the increase in non-cash stock-based compensation expense is related to 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 consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Interest expense

Interest expense increased $2.6 million to $4.4 million for the year ended December 31, 2024, compared to the year ended December 31, 2023. This increase was driven by the interest expense on higher levels of borrowings under the Loan Agreement entered into on October 31, 2022.

Other income, net

Other income, net was $4.0 million for the year ended December 31, 2024, compared to $3.9 million for the year ended December 31, 2023. This increase was primarily driven by greater interest income on our interest-bearing accounts.

Provision for income taxes

Provision for income taxes was nominal for the years ended December 31, 2024 and 2023.

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 December 31, 2024 and 2023, we had cash and cash equivalents of $105.9 million and $90.6 million, respectively. For the years ended December 31, 2024 and 2023, our net losses were $60.0 million and $41.2 million, respectively. Our net cash used in operating activities for the years ended December 31, 2024 and 2023 was $39.1 million and $39.0 million, respectively.

On October 31, 2022, we entered into the Loan Agreement under which we may borrow, subject to our achievement of certain milestones, up to a total of $50.0 million in a series of Term Loans described in Note 4 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We had $50.0 million in outstanding Term Loans under the Loan Agreement at December 31, 2024.

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 issued 3,251,198 shares of common stock for gross proceeds of $33.8 million under the ATM offering during the year ended December 31, 2024. We have remaining capacity to issue and sell up to $16.2 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:

	Year ended December 31	
(in thousands)	**2024**	**2023**
Net cash (used in) provided by:		
Operating activities	$ (39,144)	$ (39,021)
Investing activities	(1,361)	(591)
Financing activities	55,870	23,984
Effect of currency exchange on cash and cash equivalents	(1)	3
Net change in cash and cash equivalents	$ 15,364	$ (15,625)

Cash used in operating activities

Net cash used in operating activities for the year ended December 31, 2024 was $39.1 million and consisted primarily of a net loss of $60.0 million, partially offset by $19.1 million from non-cash stock-based compensation expense, an increase in net operating assets of $0.9 million, $0.6 million from the depreciation of property and equipment, and $0.2 million from amortization of deferred financing costs and loan discount. Net operating assets consisted primarily of inventory, accounts receivable, prepaid expenses and other current assets, accrued expenses to support the growth of our operations and accounts payable.

Net cash used in operating activities for the year ended December 31, 2023 was $39.0 million and consisted primarily of a net loss of $41.2 million and a decrease in net operating assets of $4.8 million, partially offset by $6.3 million from non-cash stock-based compensation expense, $0.5 million from the depreciation of property and equipment and $0.2 million from amortization of deferred financing costs and loan discount. Net operating assets consisted primarily of inventory, accounts receivable, prepaid expenses and other current assets, accrued expenses to support the growth of our operations and accounts payable.

Cash used in investing activities:

Cash used in investing activities was $1.4 million and $0.6 million for the years ended December 31, 2024 and 2023, respectively, and consisted of purchases of property and equipment.

Cash provided by financing activities:

Net cash provided by financing activities for the year ended December 31, 2024 was $55.9 million and consisted of $32.5 million related to proceeds from the issuance of common stock through the ATM offering, $20.0 million related to proceeds under the Loan Agreement, $2.7 million related to proceeds from the exercise of common stock options, and $0.8 million related to proceeds from the Employee Stock Purchase Plan ("ESPP"), partially offset by $0.2 million related to debt financing costs.

Net cash provided by financing activities for the year ended December 31, 2023 was $24.0 million and consisted of $22.5 million related to proceeds from debt financing, $0.9 million related to proceeds from the ESPP and $0.7 million related to proceeds from the exercise of common stock options, partially offset by debt financing costs of $0.2 million.

Indebtedness

On October 31, 2022, we entered into the Loan Agreement with Innovatus, as the collateral agent and a lender, 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. On the closing date, we borrowed the minimum amount of $7.5 million under the Loan Agreement. On March 10, 2023, we borrowed the $7.5 million remaining under the first tranche of the Loan Agreement. On December 15, 2023, we borrowed $15.0 million under the second tranche of the Loan Agreement. On September 30, 2024, we borrowed the remaining $20.0 million under the third and final tranche of the Loan Agreement. The term loans advanced pursuant to the Loan Agreement (collectively, the "Term Loans") bear interest at a floating rate per annum equal to the sum of (a) the greater of (i) the prime rate and (ii) 5.50% plus (b) 2.65%. The Term Loans mature on January 31, 2028 and require interest-only payments until November 1, 2027. 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.

Critical accounting policies and estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires our management to make estimates and judgments that affect the amounts reported in our consolidated financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable and supportable under the circumstances. The results of this evaluation then form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions, and such differences may be material to our consolidated financial statements.

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

Stock-based compensation

We maintain an equity incentive plan that was adopted in 2001 to provide long-term incentives for employees, consultants, and members of the Board of Directors. The plan allows for the issuance of non-statutory and

incentive stock options to employees and non-statutory stock options to consultants and non-employee directors. In connection with the IPO, we adopted the 2021 Equity Incentive Plan under which we may grant equity incentive awards to eligible employees (including our named executive officers), non-employee directors and consultants in order to enable us to obtain and retain services of these individuals, which we deem as essential to our long-term success.

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

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

- Fair value of common stock — For valuations after the completion of the IPO, our Board of Directors determines the fair value of each share of common stock based on the closing price of our common stock as reported on the date of grant. Future expense amounts for any particular period could be affected by changes in our assumptions or market conditions.

- Expected share price volatility — We make assumptions with respect to expected stock price volatility based upon the historical volatility of our stock price.

- Expected term of an award — Determined based on our analysis of historical exercise behavior while taking into consideration various participant demographics and option characteristics. We utilize the simplified method to develop the estimate of the expected term.

- Risk-free interest rate — Based on a treasury instrument whose term is consistent with the expected term of the stock options.

- Expected dividend yield — We assume an expected dividend yield of zero, as we have never paid dividends and have no current plans to pay any dividends on our common stock.

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

JOBS Act accounting election

The Jumpstart Our Business Startups Act of 2012 ("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 consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Item 7A. 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 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 statements of operations and comprehensive loss. To date, foreign currency transaction realized gains and losses have not been material to our 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 December 31, 2024 and 2023, 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 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
CVRx, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of CVRx, Inc. (a Delaware corporation) and subsidiary (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2016.

Minneapolis, Minnesota
February 18, 2025

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

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 105,933	$ 90,569
Accounts receivable, net of allowances of $ 780 and $ 508 , respectively	9,268	7,551
Inventory	12,107	10,983
Prepaid expenses and other current assets	2,505	2,987
Total current assets	129,813	112,090
Property and equipment, net	2,505	1,763
Operating lease right-of-use asset	1,069	1,349
Other non-current assets	27	27
Total assets	$ 133,414	$ 115,229
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,582	$ 1,884
Accrued expenses	8,180	5,980
Total current liabilities	10,762	7,864
Long-term debt	49,273	29,222
Operating lease liability, non-current portion	877	1,160
Other long-term liabilities	1,447	1,036
Total liabilities	62,359	39,282
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $ 0.01 par value, 200,000,000 authorized as of December 31, 2024 and 2023; 25,324,684 and 20,879,199 shares issued and outstanding as of December 31, 2024 and 2023, respectively	253	209
Additional paid-in capital	608,354	553,326
Accumulated deficit	(537,346)	(477,381)
Accumulated other comprehensive loss	(206)	(207)
Total stockholders' equity	71,055	75,947
Total liabilities and stockholders' equity	$ 133,414	$ 115,229

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

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

	Year ended December 31,	
	2024	**2023**
Revenue	$ 51,292	$ 39,295
Cost of goods sold	8,334	6,256
Gross profit	42,958	33,039
Operating expenses:		
Research and development	11,131	11,633
Selling, general and administrative	91,317	64,509
Total operating expenses	102,448	76,142
Loss from operations	(59,490)	(43,103)
Interest expense	(4,397)	(1,799)
Other income, net	3,977	3,850
Loss before income taxes	(59,910)	(41,052)
Provision for income taxes	(55)	(147)
Net loss	(59,965)	(41,199)
Cumulative translation adjustment	1	—
Comprehensive loss	$ (59,964)	$ (41,199)
Net loss per share, basic and diluted	$ (2.65)	$ (1.99)
Weighted-average common shares used to compute net loss per share, basic and diluted	22,596,229	20,754,375

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

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

	Common stock		Additional paid-in	Accumulated	Accumulated other comprehensive	Total stockholders'
	Shares	Amount	capital	deficit	loss	equity
Balances as of December 31, 2022	20,663,736	$ 207	$ 545,362	$ (436,182)	$ (207)	$ 109,180
Exercise of stock options	144,187	1	727	—	—	728
Proceeds from Employee Stock Purchase Plan	71,276	1	934	—	—	935
Employee stock compensation	—	—	6,303	—	—	6,303
Net loss for the year ended December 31, 2023	—	—	—	(41,199)	—	(41,199)
Balances as of December 31, 2023	**20,879,199**	**$ 209**	**$ 553,326**	**$ (477,381)**	**$ (207)**	**$ 75,947**
Exercise of stock options	510,669	5	2,693	—	—	2,698
Proceeds from Employee Stock Purchase Plan	79,618	1	802	—	—	803
Employee stock compensation	—	—	19,050	—	—	19,050
Issuance of common stock, net of costs	3,251,198	32	32,489	—	—	32,521
Issuance of common stock upon net exercise of common warrants	604,000	6	(6)	—	—	—
Net loss for the year ended December 31, 2024	—	—	—	(59,965)	—	(59,965)
Cumulative translation adjustment	—	—	—	—	1	1
Balances as of December 31, 2024	**25,324,684**	**$ 253**	**$ 608,354**	**$ (537,346)**	**$ (206)**	**$ 71,055**

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

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

	Year ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (59,965)	$ (41,199)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	19,050	6,303
Depreciation of property and equipment	619	522
Loss on disposal of equipment	—	4
Amortization of deferred financing costs and loan discount	203	154
Changes in operating assets and liabilities:		
Accounts receivable	(1,717)	(2,047)
Inventory	(1,124)	(4,026)
Prepaid expenses and other current assets	531	1,273
Accounts payable	698	165
Accrued expenses	2,561	(170)
Net cash used in operating activities	(39,144)	(39,021)
Cash flows from investing activities:		
Purchase of property and equipment	(1,361)	(591)
Net cash used in investing activities	(1,361)	(591)
Cash flows from financing activities:		
Proceeds from the exercise of common stock options	2,698	728
Proceeds from Employee Stock Purchase Plan	803	935
Proceeds from the issuance of common stock	32,521	—
Proceeds from debt financing	20,000	22,500
Debt financing costs	(152)	(179)
Net cash provided by financing activities	55,870	23,984
Effect of currency exchange on cash and cash equivalents	(1)	3
Net change in cash and cash equivalents	15,364	(15,625)
Cash and cash equivalents at beginning of year	90,569	106,194
Cash and cash equivalents at end of period	$ 105,933	$ 90,569
Supplemental Information:		
Cash paid for interest	$ 3,614	$ 1,396
Cash paid for income taxes	—	4

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

CVRx, INC.
Notes to Consolidated Financial Statements

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 consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and with the applicable rules and regulations of the U.S. Securities and Exchange Commission (“SEC”).

The consolidated financial statements include the accounts of CVRx, Inc., its wholly owned subsidiary, CVRx Switzerland LLC, and its sales branch in Italy, which was closed during 2023. 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 consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the 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 December 31, 2024 and 2023, cash equivalents consisted of money market funds, which are stated at cost and approximate fair value. Additionally, as of December 31, 2024 and 2023, 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 in consideration of actual loss experiences, projected future demand and remaining shelf life to record a provision for excess and obsolete inventory when appropriate.

Leases

Operating leases are included in operating lease right-of-use ("ROU") asset, accrued expenses, and operating lease liability – non-current portion in our consolidated 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 consolidated statements of operations and comprehensive loss based on their grant date fair values. We estimate the grant date fair value of stock options using the Black-Scholes option pricing model. We 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 November 2023, the FASB issued Accounting Standards Update ("ASU") 2023-07, *Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which requires public companies to disclose for each reportable segment the significant expense categories and amounts for such expenses. ASU 2023-07 became effective for us for annual periods beginning December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. Accordingly, we have expanded our financial statement disclosures in order to comply with the guidance.

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 ended December 31, 2025.

3. Selected balance sheet information

Inventory consists of the following at:

(in thousands)	December 31, 2024	December 31, 2023
Raw material	$ 6,857	$ 4,714
Work-in-process	353	654
Finished goods	4,897	5,615
	$ 12,107	$ 10,983

Property and equipment, net consists of the following at:

(in thousands)	December 31, 2024	December 31, 2023
Office furniture and equipment	$ 512	$ 402
Lab equipment	3,144	2,721
Computer equipment and software	994	776
Leasehold improvements	542	98
Capital equipment in process	720	554
	5,912	4,551
Less: Accumulated depreciation and amortization	3,407	2,788
	$ 2,505	$ 1,763

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 $ 0.6 million and $ 0.5 million for the years ended December 31, 2024 and 2023, respectively.

Accrued expenses consist of the following at:

(in thousands)	December 31, 2024	December 31, 2023
Bonuses	$ 3,621	$ 3,335
401(k) employer match	1,106	—
Paid time off	947	770
Customer rebates	592	411
Accrued interest payable	437	220
Operating lease liability, current portion	282	231
Clinical trial and other professional fees	182	277
Taxes	135	125
Other	878	611
	$ 8,180	$ 5,980

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. On the closing date, we borrowed the minimum amount of $ 7.5 million under the Loan Agreement. On March 10, 2023, we borrowed the $ 7.5 million remaining under the first tranche of the Loan Agreement. On December 15, 2023, we borrowed an additional $ 15.0 million under the second tranche of the Loan Agreement. On September 30, 2024, we borrowed the remaining $ 20.0 million under the third and final tranche of the Loan Agreement. The Loan Agreement initially requires interest only payments through November 2027, followed by three monthly principal and interest payments. A final payment of $ 2.3 million, equal to 4.5 % of the original borrowed principal, is due in January 2028. The term loans advanced pursuant to the Loan Agreement (collectively, the “Term Loans”) bear interest at a floating rate per annum equal to the sum of (a) the greater of (i) the prime rate and (ii) 5.50 % plus (b) 2.65 %. The Term Loans are secured by substantially all of 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 December 31, 2024.

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:

(in thousands)	December 31, 2024
2025	$ —
2026	—
2027	33,333
2028	16,667
	50,000
Less: Unamortized debt costs and discounts	(727)
Long-term debt	$ 49,273

5. Leases

We lease 31,505 square feet of office space in Minneapolis, Minnesota, which houses our principal executive offices and our manufacturing facility. We lease this space under an operating lease agreement that commenced December 1, 2008, and was scheduled to expire August 31, 2024. On April 21, 2023, we extended the operating lease for our office space in Minneapolis, Minnesota for an additional 49 consecutive months through August 31, 2028. On November 7, 2023, we expanded our existing office space with the addition of 7,615 square feet of property adjacent to our principal executive offices and our manufacturing facility. The term on this expanded property is for 57 consecutive months that will run 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 consolidated balance sheets:

(in thousands)	December 31, 2024	December 31, 2023
Right-of-use assets:		
Operating lease right-of-use asset	$ 1,069	$ 1,349
Operating lease liabilities:		
Accrued expenses	282	231
Operating lease liability, non-current portion	877	1,160
Total operating lease liabilities	$ 1,159	$ 1,391

Maturities of our lease liability for our operating lease are as follows as of December 31, 2024:

(in thousands)	December 31, 2024
2025	$ 350
2026	362
2027	374
2028	223
Total undiscounted lease payments	1,309
Less: imputed interest	(150)
Present value of lease liability	$ 1,159

As of December 31, 2024, the remaining lease term was 3.7 years, and the weighted average discount rate was 6.7 %. The operating cash outflows from our operating lease were $ 0.5 million and $ 0.4 million for the years ended December 31, 2024 and 2023, respectively.

6. Stockholders' equity

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 and 716,131 shares of common stock upon conversion at a weighted average exercise price of $ 2.39 per share outstanding at December 31 2024 and 2023, respectively. 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 year ended December 31, 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 3,251,198 shares of common stock for gross proceeds of $ 33.8 million under the ATM offering during the year ended December 31, 2024. We have remaining capacity to issue and sell up to approximately $ 16.2 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 1,043,959 shares being reserved for issuance under the 2021 Plan as of January 1, 2024. 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 December 31, 2024, there were 1,142,918 shares available for future issuance under the 2021 Plan.

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

During the years 2008 through 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
			(in thousands)
Balance as of December 31, 2022	3,756,835	$ 8.28	$ 36,616
Granted	1,161,926	$ 14.20	
Cancelled / Forfeited	(285,729)	$ 10.52	
Exercised	(144,187)	$ 5.05	
Balance as of December 31, 2023	4,488,845	$ 9.77	$ 97,266
Granted	3,237,758	$ 12.77	
Cancelled / Forfeited	(1,665,515)	$ 10.16	
Exercised	(510,669)	$ 5.28	
Balance as of December 31, 2024	5,550,419	$ 11.81	$ 18,771
Options exercisable as of December 31, 2024	2,854,762	$ 9.24	$ 13,390

As of December 31, 2024, stock options outstanding included 4,402 options that were not granted under the 2001 Plan or the 2021 Plan. For options outstanding as of December 31, 2024, the weighted average remaining contractual life was 7.0 years. For options exercisable as of December 31, 2024, the weighted average remaining contractual life was 5.5 years.

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 208,791 shares being reserved for issuance under the ESPP as of January 1, 2024. 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 year ended December 31, 2024, 79,618 shares of common stock were purchased under the ESPP for $ 0.8 million of employee contributions. As of December 31, 2024, there were 632,807 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. 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 the offering period for ESPP purchase rights. The amount of stock-based compensation expense recognized for stock option awards during a period is based on the portion of the awards that are ultimately expected to vest. The amount of stock-based compensation expense recognized for ESPP purchase rights during a period is based on the estimated purchase rights as of the grant date. 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 years ended December 31, 2024 and 2023:

	December 31,	
	2024	2023
Weighted average fair value of options granted	$ 10.31	$ 10.65
Expected term (in years) — non-officer employees	5.0 to 6.1	5.5 to 6.1
Expected term (in years) — officer employees	2.5 to 6.1	2.5 to 6.1
Expected volatility	87.7 % to 98.9 %	77.2 % to 79.6 %
Expected dividend yield	— %	— %
Risk-free interest rate	3.67 % to 4.71 %	3.40 % to 4.89 %

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 years ended December 31, 2024 and 2023:

	December 31,	
	2024	2023
Weighted average fair value per ESPP purchase right	$ 5.23	$ 5.64
Expected term (in years)	0.5	0.5
Expected volatility	74.0 % to 96.9 %	76.2 % to 84.6 %
Expected dividend yield	— %	— %
Risk-free interest rate	5.24 % to 5.37 %	4.77 % to 5.53 %

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:

	Year Ended December 31,	
(in thousands)	2024	2023
Stock options	$ 18,633	$ 5,901
Employee Stock Purchase Plan	417	402
Total stock-based compensation expense	$ 19,050	$ 6,303
Selling, general & administrative	$ 17,746	$ 5,073
Research & development	1,174	1,152
Cost of goods sold	130	78
	$ 19,050	$ 6,303

As of December 31, 2024, unrecognized compensation expense related to unvested stock-based compensation arrangements was $ 26.5 million. As of December 31, 2024, the related weighted average period over which the expense is expected to be recognized is approximately 2.7 years.

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 year ended December 31, 2024.

8. Income taxes

As of December 31, 2024 and 2023, a valuation allowance was recorded against all deferred tax assets due to our cumulative net loss position.

The components of our provision for income taxes are as follows for the periods indicated:

	Year Ended December 31,	
(in thousands)	**2024**	**2023**
Current		
Federal and state	$ —	$ —
Foreign	55	147
Total provision for income taxes	$ 55	$ 147

The reconciliation of taxes at the federal statutory rate to our provision for income taxes are as follows for the periods indicated:

	Year Ended December 31,	
	2024	**2023**
Tax at federal statutory rate	21.0 %	21.0 %
Permanent differences	(4.2)	(4.3)
Research and development ("R&D") tax credit	0.8	1.4
Uncertain tax position	(0.1)	(0.3)
State, net of federal benefit	2.0	2.6
Deferred rate change	(0.3)	0.4
Change in valuation allowance	(19.3)	(21.2)
Total	(0.1)%	(0.4)%

Significant components of net deferred tax assets were as follows for the periods indicated:

(in thousands)	Year Ended December 31, 2024	2023
Deferred tax assets		
Net operating loss carryforwards	$ 98,329	$ 89,173
R&D tax credits	10,147	9,664
Capitalized R&D expenses	8,015	8,963
Non-qualified stock options	4,482	1,473
Start-up costs	452	680
Accrued vacation	227	179
Other	450	420
Total deferred tax assets	122,102	110,552
Valuation allowance	(122,102)	(110,552)
Net deferred tax assets	$ —	$ —

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.

The changes to our gross unrecognized tax benefits were as follows for the periods indicated:

(in thousands)	Year Ended December 31, 2024	2023
Gross unrecognized tax benefits at beginning of year	$ 2,221	$ 2,046
Gross increases:		
Prior year tax positions	—	12
Current year tax positions	182	185
Gross decreases:		
Prior year tax positions	(57)	(22)
Gross unrecognized tax benefits at end of year	$ 2,346	$ 2,221

All of these unrecognized tax benefits, if recognized, would impact the effective tax rate before taking consideration of the valuation allowance. The amount of unrecognized tax benefits subjected to the valuation allowance was $ 1.8 million and $ 1.7 million for the years ended December 31, 2024 and 2023, respectively. We recognized a nominal amount and approximately $ 0.1 million of interest or penalties for each of the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024 and 2023, total accrued interest and penalties were both $ 0.5 million. We recognize accrued interest and penalties related to unrecognized tax positions as a component of income tax expense. We do not expect a significant change in the amount of unrecognized tax benefits in the next year.

We are subject to U.S. federal income tax as well as income tax of multiple state and foreign jurisdictions. Tax years from 2005 through present remain open for audit under the applicable statute of limitations due to

the carryover of the unused NOLs and tax credit carryforwards. We do not have any tax audits or other proceedings pending.

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):

	Year Ended December 31,	
	2024	2023
Numerator:		
Net loss	$ (59,965)	$ (41,199)
Denominator:		
Weighted average common shares outstanding — basic and diluted	22,596,229	20,754,375
Net loss per share attributable to common stockholders — basic and diluted	$ (2.65)	$ (1.99)

Our potentially dilutive securities, which include stock options and warrants to purchase shares of common stock, have been excluded from the computation of diluted net loss per share attributable to common stockholders, as the effect would be to reduce the net loss per share attributable to common stockholders. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. 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:

	Year Ended December 31,	
	2024	2023
Options to purchase common stock	5,550,419	4,488,845
Warrants to purchase common stock	103,349	716,131
	5,653,768	5,204,976

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 December 31, 2024 or December 31, 2023.

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 $ 1.1 million and $ 0 for the years ended December 31, 2024 and 2023, respectively.

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 consolidated statements of operations and comprehensive loss in this Annual Report on Form 10-K.

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:

	Year ended December 31,	
(in thousands)	**2024**	**2023**
U.S.	$ 47,167	$ 35,111
Germany	3,460	3,690
Other countries	665	494
	$ 51,292	$ 39,295

As of December 31, 2024 and 2023, long-lived assets were located primarily in the U.S.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. 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 Annual Report on Form 10-K. 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 Annual Report on Form 10-K.

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 three months ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of consolidated financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Management assessed our internal control over financial reporting as of December 31, 2024 based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on this assessment, management has concluded that our internal control over financial reporting was effective as of the end of the fiscal year to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external reporting purposes in accordance with U.S. GAAP. We reviewed the results of management's assessment with the audit committee of our board of directors.

Item 9B. Other Information

During the three months ended December 31, 2024, none of our directors or officers adopted , modified or terminated a “Rule 10 b 5 -1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2025 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

Item 11. Executive Compensation

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2025 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2025 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2025 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

Item 14. Principal Accountant Fees and Services

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2025 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

PART IV

Item 15. Exhibit and Financial Statement Schedules

(a) 1. Financial Statements:

The following consolidated financial statements of the Company are set forth in Part II, Item 8:

Report of Independent Registered Public Accounting Firm (PCAOB ID 248)

Consolidated Balance Sheets as of December 31, 2024 and 2023

Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2024 and 2023

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2024 and 2023

Consolidated Statements of Cash Flows for the years ended December 31, 2024 and 2023

Notes to Consolidated Financial Statements

2. Financial Statement Schedules:

All financial statement schedules are omitted as the required information is inapplicable or the information is presented in the consolidated financial statements or related notes.

3. Exhibits:

See the response to Item 15(b) below.

(b) Exhibits:

EXHIBIT INDEX

Exhibit No.	Description
3.1	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)
3.2	Amended and Restated By-Laws of CVRx, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on July 7, 2021)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1/A filed on June 23, 2021)
4.2*	Warrant to Purchase Stock, dated as of July 21, 2015, issued by the Company to Life Science Loans, LLC (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)
4.3*	Warrant to Purchase Stock, dated as of July 21, 2015, issued by the Company to Silicon Valley Bank (incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)

4.4*	Warrant to Purchase Stock, dated as of May 31, 2016, issued by the Company to Oxford Finance LLC (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)
4.5*	Warrant to Purchase Stock, dated as of May 31, 2016, issued by the Company to Oxford Finance LLC (incorporated by reference to Exhibit 4.8 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)
4.6*	Warrant to Purchase Stock, dated as of May 31, 2016, issued by the Company to Oxford Finance LLC (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)
4.7*	Warrant to Purchase Stock, dated as of May 31, 2016, issued by the Company to Oxford Finance LLC (incorporated by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)
4.8	Warrant to Purchase Shares of Series G Preferred Stock (Loan A), dated as of September 30, 2019, issued by the Company to Horizon Technology Finance Corporation, as assigned to Horizon Credit II LLC on February 6, 2020 (incorporated by reference to Exhibit 4.13 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)
4.9	Warrant to Purchase Shares of Series G Preferred Stock (Loan B), dated as of September 30, 2019, issued by the Company to Horizon Technology Finance Corporation, as assigned to Horizon Credit II LLC on February 6, 2020 (incorporated by reference to Exhibit 4.14 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)
4.10	Warrant to Purchase Shares of Series G Preferred Stock (Loan C), dated as of September 30, 2019, issued by the Company to Horizon Technology Finance Corporation, as assigned to Horizon Funding Trust 2019-1 on February 18, 2020 (incorporated by reference to Exhibit 4.15 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)
4.11	Warrant to Purchase Shares of Series G Preferred Stock (Loan D), dated as of September 30, 2019, issued by the Company to Horizon Technology Finance Corporation as assigned to Horizon Funding Trust 2019-1 on February 18, 2020 (incorporated by reference to Exhibit 4.16 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)
4.12	Description of the Company's Common Stock (incorporated by reference to Exhibit 4.16 to the Company's Annual Report on Form 10-K filed on February 22, 2022)
10.1	Lease, dated October 13, 2008, by and between the Company and Duke Realty Limited Partnership (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1/A filed on June 23, 2021)
10.2	First Lease Amendment, dated November 30, 2010, by and between the Company and Duke Realty Limited Partnership (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1/A filed on June 23, 2021)
10.3*	Second Lease Amendment, dated October 22, 2012, by and between the Company and Duke Realty Limited Partnership (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1/A filed on June 23, 2021)
10.4*	Lease Amending Agreement No. 3, dated April 21, 2016, by and between the Company and AX CROSSTOWN VI L.P. (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1/A filed on June 23, 2021)

10.5	Lease Amending Agreement No. 4, dated May 18, 2020, by and between the Company and AX CROSSTOWN VI L.P. (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A filed on June 23, 2021)
10.6	Fifth Amendment to Lease, dated April 21, 2023, by and between the Company and TCI TT, LLC (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 11, 2023)
10.7	Sixth Amendment to Lease, dated November 7, 2023 by and between the Company and TCI TT, LLC (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K filed on February 9, 2024)
10.8	Eighth Amended and Restated Investors' Rights Agreement, dated July 1, 2020, by and among the Company and the holders listed therein (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1/A filed on June 23, 2021)
10.9#	2001 Stock Incentive Plan, as amended and restated (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1/A filed on June 23, 2021)
10.10#	Form of Stock Option Agreement (Employees/Officers) pursuant to 2001 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-8 filed on July 1, 2021)
10.11#	Form of Stock Option Agreement (Non-Employee Directors) pursuant to 2001 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-8 filed on July 1, 2021)
10.12#	2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1/A filed on June 23, 2021)
10.13#	Form of Stock Option Agreement (Employees/Officers) pursuant to 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-8 filed on July 1, 2021)
10.14#	Form of Stock Option Agreement (Non-Employee Directors) pursuant to 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-8 filed on July 1, 2021)
10.15#	Form of Non-Plan Stock Option Agreement (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-8 filed on July 1, 2021)
10.16	Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K filed on February 22, 2022)
10.17#	Form of Executive Officer Employment Agreement (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1/A filed on June 23, 2021)
10.18	Form of Indemnification Agreement between the Company and its directors and officers (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1/A filed on June 23, 2021)
10.19*	Loan and Security Agreement, dated as of October 31, 2022, among the Company, Innovatus Life Sciences Fund I, LP, as the collateral agent and a lender, and the other lenders from time to time party thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 1, 2022)

10.20	Equity Distribution Agreement, dated as of November 4, 2022, by and between the Company and Piper Sandler & Co. (incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 filed on November 4, 2022)
10.21#	Employment Agreement between the Company and Kevin Hykes dated January 26, 2024 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 31, 2024)
10.22#	Transition and Consulting Agreement between the Company and Nadim Yared dated January 30, 2024 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 31, 2024)
19.1†	CVRx, Inc. Insider Trading Policy
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed on February 22, 2022)
23.1†	Consent of Grant Thornton LLP, independent registered public accounting firm
31.1†	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2†	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1†	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2†	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	CVRx, Inc. Mandatory Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K filed on February 9, 2024)
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.

# Indicates management contract or compensatory plan.

* Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K under the Securities Act. The Company agrees to furnish supplementally any omitted exhibits and schedules to the SEC upon request.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: February 18, 2025

CVRX, INC.

By: /s/ Kevin Hykes
Name: Kevin Hykes
Title: President and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: February 18, 2025

Signature	Title	Date
/s/ Kevin Hykes **Kevin Hykes**	President and Chief Executive Officer (Principal Executive Officer)	February 18, 2025
/s/ Jared Oasheim **Jared Oasheim**	Chief Financial Officer (Principal Financial and Accounting Officer)	February 18, 2025
/s/ Kevin Ballinger **Kevin Ballinger**	Director	February 18, 2025
/s/ Mitch Hill **Mitch Hill**	Director	February 18, 2025
/s/ Mudit Jain **Mudit Jain**	Director	February 18, 2025
/s/ Kirk Nielsen **Kirk Nielsen**	Director	February 18, 2025
/s/ Martha Shadan **Martha Shadan**	Director	February 18, 2025
/s/ Joseph Slattery **Joseph Slattery**	Director	February 18, 2025

Exhibit 19.1

CVRx, INC.
INSIDER TRADING POLICY

Purpose

Federal and state securities laws prohibit individuals from trading in the securities of a company while they are aware of material information about that company that is not generally known or available to the public. Such trading is often referred to as "insider trading." The purpose of this Insider Trading Policy is to prevent insider trading or allegations of insider trading, and to protect the reputation for integrity and ethical conduct of CVRx, Inc. ("CVRx" or the "Company").

Applicability of Policy and Certain Definitions

A. ***Material Nonpublic Information*** means material information (described below) that has either not been disclosed to the public generally, or has been disclosed so recently that sufficient time has not yet passed to allow the information to become widely available among investors and the financial community. Information has been disclosed publicly when it has been disclosed through a press release, a filing with the Securities and Exchange Commission or a pre-announced broadly-accessible webcast or conference call.

B. ***Material Information*** means information, whether positive or negative, about a company that would be expected to affect the investment decisions of a reasonable investor or that could reasonably be expected to have an effect on the price of that company's securities. While the materiality of information will depend on the specific facts and circumstances, examples of categories of information that are more likely to be considered material, or may be presumptively material, include:

- Financial results or financial condition
- Projections of future earnings or losses
- New product announcements of a significant nature
- Significant regulatory developments, such as product approvals
- Significant product developments, such as product modifications or product recalls
- Significant pricing changes
- Gain or loss of a significant customer or supplier relationship
- New equity or debt offerings
- Significant litigation or regulatory exposure due to actual or threatened litigation or regulatory action
- Significant cybersecurity or data privacy incidents
- Significant management changes or changes in control of the company
- A pending or proposed significant merger, or significant divestiture or acquisition
- Default under a significant financing arrangement, or financial liquidity problems

- Significant restructuring actions or asset impairments
- Changes in auditors
- Significant events regarding a company's securities (such as defaults, redemptions, stock splits, repurchase plans, changes in dividends)

C. ***Covered Persons*****.** This Policy applies to:

1. *All CVRx Personnel.* All directors, officers and employees of CVRx and its subsidiaries ("CVRx Personnel"), as well as members of their immediate families and others living in the same household.

2. *Consultants and Advisors.* All consultants and advisors to CVRx and its subsidiaries whose work brings them into contact with material nonpublic information and who are advised they are subject to this Policy.

3. *Related Parties.* Any other person or entity, including a trust, corporation, partnership or other association, whose transactions in the Company's securities are directed by any person covered by paragraph C(1) or C(2) or are subject to that person's influence or control.

The individuals and entities described in paragraphs C(1), C(2) and C(3) are "Covered Persons."

D. ***Covered Companies.*** This Policy applies to trading in the securities of the following, as set forth below:

1. CVRx; and

2. any other company about which the Covered Person obtained material nonpublic information in the course of the Covered Person's service to CVRx or any of its subsidiaries, such as customers, suppliers, competitors or companies with which a major transaction such as a merger, acquisition or divestiture may be or is being contemplated or negotiated (collectively, with CVRx, "Covered Companies").

E. ***Covered Transactions.*** The securities trading that this Policy covers includes purchases and sales of common stock, options to acquire common stock and any other securities CVRx may issue from time to time, such as preferred stock, warrants and convertible debentures, and purchases and sales of derivative securities relating to CVRx's stock, whether or not issued by CVRx, such as exchange-traded options. Trading covered by this Policy may or may not include transactions under CVRx sponsored plans and bona fide gifts as follows:

1. *Stock Option Exercises.* This Policy's trading restrictions do not apply to the purchase of CVRx stock through the exercise of stock options granted by CVRx (whether by cash exercise, stock swap or net exercise, to the extent such forms of exercise are permitted by CVRx). The trading restrictions do apply to any subsequent sale of CVRx stock acquired through an option exercise; and, therefore, do apply to a broker-assisted cashless exercise.

2. *Employee Stock Purchase Plan Purchases.* This Policy's trading restrictions do not apply to the purchase of CVRx stock through any Employee Stock Purchase Plan (the ESPP) CVRx may maintain from time to time (but this Policy's trading restrictions do apply to the sale of any shares acquired under the ESPP).

3. *Restricted Stock/Unit and Performance Stock/Unit Awards.* This Policy's trading restrictions do not apply to the vesting of restricted stock/units or performance stock/units, or to the

exercise of a tax withholding right pursuant to which the person elects to have CVRx withhold shares of stock to satisfy tax withholding requirements upon vesting, to the extent such withholding is permitted by CVRx. The trading restrictions do apply to any market sales of shares.

4. *Bona Fide Gifts*. This Policy's trading restrictions do not apply to any *bona fide* gift of CVRx securities if either of the following applies: (i) the recipient of the gift of CVRx securities is a Covered Person subject to the same provisions of this Policy as applicable to the Covered Person making the gift, or (ii) the Covered Person making the gift has a reasonable basis for believing that the recipient of the gift will not sell the CVRx securities during any blackout period or other trading restriction applicable to the Covered Person at the time the gift is made.

F. Transactions by the Company. From time to time, the Company may engage in transactions in its own securities. It is the Company's policy that any transactions by the Company will comply with applicable laws with respect to insider trading, guided by the principles in this Policy as applicable.

Statement of Policy

Insider trading involves trading at any time when the person making the purchase or sale *is aware* of material nonpublic information regarding the company whose securities are being traded. If you have a doubt or question about whether you are aware of or in possession of material nonpublic information concerning CVRx or another company, you should contact CVRx's Chief Financial Officer.

A. *No Trading on Material Nonpublic Information*

1. *CVRx Securities*. If you are a Covered Person, you must not purchase or sell any CVRx securities, or otherwise advise or assist any third-party trading CVRx securities, while you are aware of material nonpublic information regarding CVRx.

2. *Other Companies' Securities*. If you are a Covered Person and you obtain material nonpublic information about any other publicly held company as a result of your work on behalf of CVRx or any of its subsidiaries, you must not trade in that company's securities.

B. *No Disclosure to Others Who Might Trade.* If you are a Covered Person, you must not communicate material nonpublic information about CVRx or any other Covered Company to any person who does not need that information for a legitimate business purpose, or recommend to anyone the purchase or sale of securities when you are aware of material nonpublic information about the company involved. This practice, known as "tipping," also violates the securities laws and can result in the same civil and criminal penalties that apply to insider trading, even though you did not actually trade and did not benefit from another's trading.

C. *Protect Material Nonpublic Information.* In order to reduce the possibility that material nonpublic information will be inadvertently disclosed:

1. You must treat material nonpublic information as confidential, exercise the utmost caution in preserving the confidentiality of that information, and should not discuss it with any other person who does not need to know it for a legitimate business purpose.

2. You should refrain from discussing material nonpublic information relating to CVRx or any public company in public places where such discussions can be overheard.

3. If you become aware of any unauthorized disclosure of material nonpublic information, whether inadvertent or otherwise, you should report such disclosure immediately to CVRx's

Chief Financial Officer.

D. ***Event-Specific Blackout Periods.*** From time to time, material developments known only to a limited number of CVRx Personnel may occur and cause CVRx to impose on an appropriate group of CVRx Personnel additional restrictions on trading. You will be notified if you become part of such a group, and you should not disclose to others the fact that you have been so notified or that additional restrictions on your trading have been imposed.

Policy Prohibiting Pledging, Hedging and Other Speculative Trading

CVRx Personnel, as well as family members and anyone designated to engage in securities transactions on behalf of CVRx Personnel, are prohibited at all times from engaging in the following transactions with respect to CVRx securities:

- holding any CVRx securities in a margin account or pledging CVRx securities as collateral for a loan;
- engaging in transactions in puts, calls, or other derivative transactions relating to CVRx securities;
- short sales of CVRx securities (selling securities not owned at the time ofsale);
- purchasing any financial instruments (including prepaid variable forward contracts, equity swaps, zero cost collars and exchange funds) that are designed to hedge or offset any decrease in the market value of CVRx securities; and
- engaging in limit orders or other pre-arranged transactions that execute automatically, except for “same-day” limit orders and approved 10b5-1 plans.

These restrictions apply to all CVRx securities owned directly or indirectly by CVRx Personnel, including CVRx securities owned by family members where the CVRx Personnel is deemed to beneficially own such securities, and their respective designees. However, the restrictions do not prevent any CVRx Personnel or their family members or their designees from engaging in general portfolio diversification or investing in broad-based index funds.

Obligations After Ceasing to be a Covered Person

If a person ceases to be a Covered Person at a time when the Covered Person is aware of material nonpublic information, the applicable provisions of this Policy will continue to apply to such person until that information has become public or is no longer material. Accordingly, certain provisions of this Policy, including the Addendum, if applicable, may continue to apply to a person after he or she ceases to be a Covered Person, based on the circumstances in effect at the time he or she separates from the Company.

Additional Restrictions on Access Persons

Directors and Section 16 officers of CVRx and other officers and key employees of CVRx and its subsidiaries who have been designated as “Access Persons” by the Chief Financial Officer, as well as related parties of such individuals, are subject to additional restrictions on trading CVRx securities as set out in the attached **Addendum**.

Implementation Procedures

The current version of this Policy will, at all times, be accessible upon request to the Company’s General Counsel. The Company will notify Access Persons of the applicable blackout dates for each quarter. The

Company provides training and information on this Policy and the insider trading laws to appropriate CVRx Personnel from time to time, and CVRx Personnel are required to attend all trainings assigned to them.

Consequences of Violating Laws and Policy

A. ***Disciplinary Action****.* CVRx Personnel who fail to comply with this Policy will be subject to appropriate disciplinary action, which may include, among other consequences, the ineligibility to participate in CVRx's equity incentive plans or termination of employment.

B. ***Civil and Criminal Penalties.*** Under federal securities laws, the penalties for violating insider trading laws are severe. If you trade on (or tip) material nonpublic information, you are subject to civil penalties of up to three times the profit gained or loss avoided, criminal fines of up to $5,000,000 and up to 20 years imprisonment. If CVRx fails to take appropriate steps to prevent insider trading, CVRx and its directors, officers and other supervisory CVRx Personnel may be subject to "controlling person" liability and potential civil and criminal penalties.

Questions

Questions regarding any of the provisions or procedures of this Insider Trading Policy should be directed to the Chief Financial Officer.

Revised: January 23, 2025

ADDENDUM TO INSIDER TRADING POLICY

Additional Requirements and Responsibilities for Access Persons

Purpose

This Addendum supplements the CVRx Insider Trading Policy and applies to Access Persons, as defined below. Access Persons are subject to both the requirements of the Insider Trading Policy as well as to additional procedures and requirements described below to help prevent inadvertent violations of federal securities laws, to avoid even the appearance of impermissible insider trading, and to facilitate their compliance with certain legal requirements not applicable to CVRx Personnel generally.

Persons Covered

The individuals and entities described below are "Access Persons."

- ***Directors and Section 16 Officers.*** All provisions of this Addendum apply to the directors and officers of CVRx subject to Section 16 of the Securities Exchange Act of 1934 (referred to herein as "Section 16 Persons").
- ***Other Officers and Key Employees.*** Designated provisions of this Addendum apply to certain other officers and key employees of CVRx and its subsidiaries. These other officers and key employees, whose duties cause them to regularly have access to material nonpublic information about CVRx, will be notified by the Chief Financial Officer that they are subject to this Addendum.
- ***Related Parties.*** If you are covered by either of the above categories, then this Addendum also applies to the same extent to your immediate family members and other individuals living in your household ("Family Members"), and to any other person or entity, including a trust, corporation, partnership or other association, whose transactions in CVRx securities are directed by you or your Family Members or are subject to the influence or control of you or your Family Members. Also, you are responsible for informing all Family Members and such related parties of the requirements of this Addendum.

Quarterly Blackout Periods for Access Persons

Trading Not Permitted During Quarterly Blackout Periods. If you are an Access Person, you may not purchase, sell or otherwise trade CVRx securities during the period beginning on the 1st of the last calendar month of each fiscal quarter (effectively, 12:01 a.m. Central time on the 1st day of such calendar month) and continuing through the first full trading day following the public release of CVRx's financial results for that fiscal quarter (each such period being a "blackout period"). If a Access Person wishes to trade outside of a blackout period, the person may do so only if he or she is not then aware of any material nonpublic information and has complied with the notification and pre-clearance procedures described below.

Illustration – Quarterly Blackout Period: If financial results for the quarter ended March 31 are released after the stock market closes on April 26, then Access Persons are prohibited from trading from March 1 through April 27, but could trade from April 28 through May 31, assuming that April 27 is a trading day on the Nasdaq Stock Market and unless they are aware of material nonpublic information or have not complied with the notification and pre-clearance procedures below.

Pre-clearance Requirements for Trades Outside of Blackout Periods

Notices of Intended Transaction and Requests for Approval. If you are an Access Person, you may not engage in any transaction involving CVRx securities outside blackout periods without first obtaining pre-clearance of that transaction from CVRx's Chief Financial Officer. Prior to initiating any transaction in CVRx securities outside a blackout period, you must deliver to the Chief Financial Officer an electronic notice in the form specified in the attached Exhibit A during a permitted trading period requesting clearance to trade, which can be submitted by email. The Chief Financial Officer may approve modifications to this notice process and pre-clearance notice form.

To avoid signaling to others that something material and nonpublic may be happening with respect to CVRx, you should keep the response to your approval request entirely confidential. This confidentiality will be easier to maintain if you go through the required approval process prior to discussing a proposed trade with others, including your broker.

Clearance to Proceed with a Transaction. No pre-clearance notice will be an effective clearance to a trade unless and until the Chief Financial Officer responds to the notice with his or her approval in writing. Any such approval be valid for the period specified in the Chief Financial Officer's pre-clearance approval. A favorable response from the Chief Financial Officer should not be interpreted as approval by the Company of the advisability of the proposed trade. Furthermore, the overarching prohibition on trading when you are aware of material nonpublic information regarding CVRx remains in effect.

Additional Restrictions on Section 16 Persons

Section 16 Persons must also comply with the reporting obligations and limitations on short-swing trading transactions imposed by Section 16 of the Securities Exchange Act of 1934. Among other things, Section 16 requires directors and Section 16 officers to pay over to CVRx any profit realized from any purchase and sale (in either order) of CVRx securities that occur within six months of each other. Section 16 and its related rules are very complex, and CVRx will provide to each director and Section 16 officer additional information discussing compliance with Section 16 and its related rules.

Exceptions for Approved 10b5-1 Plans

Transactions by Access Persons in CVRx securities that are executed pursuant to a 10b5-1 plan approved in writing in advance by the Chief Financial Officer are not subject to prohibition on trading on the basis of material nonpublic information or the restrictions in this Addendum relating to the pre-clearance approval process or window periods.

Rule 10b5-1 provides an affirmative defense from insider trading liability under the federal securities laws for trading plans that meet certain requirements. In general, a 10b5-1 plan must be entered into during a permitted trading period and when you are not aware of material nonpublic information, and must comply with the other requirements set forth on Exhibit B.

EXHIBIT A

GENERAL FORM OF ACCESS PERSON REQUEST FOR APPROVAL TO TRADE

- I certify I do not have any material, non-public information;
- In connection with my proposed trade, I certify that, in making this request, I am complying with the applicable provisions of the CVRx, Inc. Insider Trading Policy;
- I understand that clearance for the transaction(s), if granted, will be valid only until the earlier of (i) the period specific in the pre-clearance approval and (ii) the trading window closing; and
- If I become aware of any material non-public information prior to the trade occurring, I will not execute the trade.

EXHIBIT B

Rule 10b5-1 Trading Plan Transactions Policy

Rule 10b5-1 under the Securities Exchange Act of 1934 provides a defense from insider trading liability under Rule 10b-5. In order to be eligible to rely on this defense, a person subject to this Policy must enter into a 10b5-1 Plan for transactions in CVRx securities that meets certain conditions specified in that rule. Once the plan is adopted, the person must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the date of the trade. The plan must either specify the amount, pricing and timing of transactions in advance or delegate discretion on these matters to an independent third party.

The following guidelines apply to all 10b5-1 Plans (unless otherwise approved by the Chief Financial Officer):

- For Section 16 Persons, no transaction may take place under a 10b5-1 Plan until expiration of a cooling-off period consisting of the later of (a) 90 days after adoption or modification (as specified in Rule 10b5-1) of the 10b5-1 Plan or (b) two business days following the disclosure of the Company's financial results in a Form 10-Q or Form 10-K for the fiscal quarter (the Company's fourth fiscal quarter in the case of a Form 10-K) in which the 10b5-1 Plan was adopted or modified (as specified in Rule 10b5-1), but in any event, this required cooling-off period is subject to a maximum of 120 days after adoption of the plan.
- For persons other than Section 16 Persons, no transaction may take place under a 10b5-1 Plan until the expiration of a cooling-off period that is 30 days following the adoption or modification (as specified in Rule 10b5-1) of a 10b5-1 Plan.
- Subject to certain limited exceptions specified in 10b5-1, you may not have more than one 10b5-1 Plan in effect at any same time.
- Subject to certain limited exceptions specified in Rule 10b5-1, you may only enter into a 10b5-1 Plan that is designed to effect an open market purchase or sale of the total amount of securities subject to the 10b5-1 Plan as a single transaction (a "single-transaction plan") if you have not entered into a "single-transaction plan" in the prior 12 months.
- You must act in good faith with respect to a 10b5-1 Plan. A 10b5-1 Plan cannot be entered into as part of a plan or scheme to evade the prohibition of Rule 10b-5. Therefore, although modifications to an existing 10b5-1 Plan are not prohibited, a 10b5-1 Plan should be adopted with the intention that it will not be amended or terminated prior to its expiration.
- Section 16 Persons must include a representation in the 10b5-1 Plan that (i) the person is not aware of material, nonpublic information about the Company or CVRx securities and (ii) the person is adopting the plan in good faith and not as part of plan or scheme to evade the prohibitions of Rule 10b-5.

For purposes of the above, a modification as specified in Rule 10b5-1 includes any modification of a 10b5-1 Plan that changes the amount, price or timing of the purchase or sale of securities underlying the 10b5-1 Plan.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We have issued our report dated February 18, 2025, with respect to the consolidated financial statements included in the Annual Report of CVRx, Inc. on Form 10-K for the year ended December 31, 2024. We consent to the incorporation by reference of said report in the Registration Statements of CVRx, Inc. on Forms S-8 (File No. 333-257616, File No. 333-262901, File No. 333-269696, File No. 333-276984, and File No. 333-276985) and on Form S-3 (File No. 333-268183).

/s/ GRANT THORNTON LLP

Minneapolis, Minnesota
February 18, 2025

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Kevin Hykes, certify that:

1. I have reviewed this annual report on Form 10-K 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: February 18, 2025

By: /s/ Kevin Hykes
Name: Kevin Hykes
Title: President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Jared Oasheim, certify that:

1. I have reviewed this annual report on Form 10-K 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: February 18, 2025

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

Exhibit 32.1

Certification of CEO Pursuant to 18 U.S.C. Section 1350,

As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the annual report of CVRx, Inc. (the "Company") on Form 10-K for the period ended December 31, 2024 (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: February 18, 2025

By: /s/ Kevin Hykes
Name: Kevin Hykes
Title: President and Chief Executive Officer

Exhibit 32.2

Certification of CFO Pursuant to 18 U.S.C. Section 1350,

As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the annual report of CVRx, Inc. (the "Company") on Form 10-K for the period ended December 31, 2024 (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: February 18, 2025

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