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, 2021

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**

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. ☐

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 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter was approximately $9.6 million.

As of February 14, 2022, there were 20,477,600 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, the impact of the ongoing and global COVID-19 pandemic on our business, financial results and financial position, clinical trial results, prospective products, product approvals, research and development costs, timing and likelihood of success and the plans and objectives of management for future operations.

In some cases, you can identify forward-looking statements by terms such as ‘‘may,’’ ‘‘will,’’ ‘‘should,’’ ‘‘expect,’’ ‘‘plan,’’ ‘‘anticipate,’’ ‘‘could,’’ ‘‘intend,’’ ‘‘target,’’ ‘‘project,’’ ‘‘contemplate,’’ ‘‘believe,’’ ‘‘estimate,’’ ‘‘predict,’’ ‘‘potential’’ or ‘‘continue’’ or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. The forward-looking statements in this 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 (four of whom are affiliated with our principal stockholders) own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval;
- we have a limited history operating as a commercial company and are highly dependent on a single product, Barostim and the failure to obtain market acceptance in the U.S. for Barostim would negatively impact our business, liquidity and results of operations;
- we have limited commercial sales experience marketing and selling Barostim, and if we are unable to establish and maintain sales and marketing capabilities, we will be unable to successfully commercialize Barostim or generate sustained and increasing product revenue;
- we must demonstrate to physicians and patients the merits of Barostim;

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

PART I

Item 1. Business

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 diseases. Our proprietary platform technology, Barostim, is designed to leverage the power of the brain to address the imbalance of the Autonomic Nervous System ("ANS"), which causes heart failure ("HF") 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 HF with reduced Ejection Fraction ("HFrEF"), or systolic HF. Barostim provides Baroreflex Activation Therapy ("BAT," or "Barostim Therapy") by sending imperceptible and persistent electrical pulses to baroreceptors located in the wall of the carotid artery to signal the brain to modulate the cardiovascular function. We have developed a significant body of published clinical evidence that supports the strong value proposition of Barostim Therapy and its ability to meaningfully improve the quality of life for patients suffering from HFrEF. We estimate that our initial annual market opportunity for HFrEF is $1.4 billion in the U.S. and $1.5 billion in select European Markets (Germany, France, Italy, Spain and the United Kingdom, or "EU5").

HF is one of the most prevalent and devastating cardiovascular diseases. We estimate that there are approximately 26 million people globally suffering from HF, including approximately 6.2 million people in the U.S. and 8.6 million people in EU5. Every year, 1.3 million and 1.4 million new patients are diagnosed with HF in the U.S. and select EU5, respectively. 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 usually develops from an imbalance of the ANS, which is also the primary cause of multiple other cardiovascular diseases, such as hypertension, angina pectoris and arrhythmia. The ANS plays a vital role in the function of the heart and is strongly influenced by baroreceptors located in certain arterial walls.

We are currently focused on the treatment of patients with HFrEF, which represents approximately 40% 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 payors 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 U.S. Food and Drug Administration (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. These results showed significant improvement in the following patient-centered outcomes:

- **Quality of life (measured by Minnesota Living with Heart Failure ("MLWHF")):** Our therapy demonstrated a 14-point improvement in quality of life for patients in the device arm relative to patients in the control arm. A 5-point improvement is considered clinically meaningful.

- **Exercise capacity (measured by the standardized 6 Minute Hall Walk ("6MHW") distance test):** Our therapy demonstrated that patients in the device arm were able to improve the distance they walked in a six-minute period by 60 meters more than patients in the control arm. A 25-meter improvement in walking distance is considered clinically meaningful.

- **Functional status (determined by New York Heart Association ("NYHA") classification):** Our therapy demonstrated that 65% of patients in the device arm improved at least one NYHA class as compared to only 31% in the control arm, with 13% of patients improving two NYHA classes in the device arm as compared to only 2% in the control arm.

- **Widely accepted mechanism of action.** Our platform technology is based on a widely accepted mechanism of action and is designed to address the imbalance of the ANS, which causes HFrEF and other cardiovascular diseases.

- **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 60 peer-reviewed publications, approximately 20 of which relate to the treatment of HF, including, among others, the Journal of the American College of Cardiology.

- **Minimally invasive implant procedure.** Barostim's implantable pulse generator ("IPG") and stimulation lead are implanted during a minimally invasive 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 that 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 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. 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. We continue to develop and expand upon our significant body of published clinical evidence that supports the meaningful benefits of Barostim Therapy. We have also established a U.S. patient registry 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, general cardiologists and vascular surgeons. We are prioritizing our sales and marketing efforts on high volume EP centers that are strategically located and on building long-standing relationships with key physicians. We support these physicians through 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 fully reimbursed by the Centers for Medicare and Medicaid Services ("CMS") across all regions. We offer assistance to patients and providers 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, including tools to simplify the implant procedure for physicians. In 2022, we expect to launch an enhanced IPG that will be approximately 10% smaller in size and improve the battery life by approximately 20% to an average of six years. We are also developing a new implant toolkit called BATwire, which enables an ultrasound-guided implant procedure to implant Barostim and the use of local anesthetics, potentially expanding our annual market opportunity in the U.S. 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.

We generated revenue of $13.0 million, a gross margin of 72% and a net loss of $43.1 million for the year ended December 31, 2021, compared to revenue of $6.1 million, a gross margin of 76% and a net loss of $14.1 million for the year ended December 31, 2020. Revenue for 2020 and 2021 was negatively impacted due to the global pandemic associated with COVID-19. Specifically, in March 2020, healthcare facilities and clinics began restricting in-person access to their clinicians, reducing patient consultations and treatments or temporarily closing their facilities. As a result, beginning in the second week of March 2020, substantially all of our then-scheduled procedures were postponed, and numerous other cases could not be scheduled. During May 2020, the widespread shutdown resulted in key physician-society conferences being moved to a virtual setting, which directly impacted the commercial launch in the U.S. By the beginning of the fourth quarter of 2020, implant centers had resumed procedures in the U.S. and Europe. Procedure volumes were negatively impacted by the Delta and Omicron variants of COVID-19 in the third and fourth quarters of 2021. Our accumulated deficit as of December 31, 2021 and 2020 was $394.8 million and $351.7 million, respectively.

Our success factors

We are focused on transforming the lives of patients suffering from cardiovascular diseases by developing, manufacturing, and commercializing innovative and minimally invasive neuromodulation solutions, which we believe offer a compelling value proposition for large and significantly underpenetrated markets. We believe the continued growth of our company will be driven by the following success factors:

- ***Novel solution offering meaningful clinical benefits to an underserved patient population suffering from HFrEF.*** Barostim is the first and only commercially available neuromodulation device indicated to improve symptoms for HFrEF patients who currently have no viable device-based treatment alternatives. Barostim has demonstrated clinically meaningful symptomatic improvement across industry-standard HF patient-centered outcomes. Our therapy works by sending persistent and imperceptible electrical pulses to baroreceptors located in the wall of the carotid artery, which increases signals to the brain to modulate the cardiovascular function, thereby improving symptoms of HFrEF. Barostim's IPG and stimulation lead are implanted and sutured subcutaneously during a one-hour, minimally invasive procedure with no hardware implanted in the heart or vasculature. Additionally, once implanted, Barostim has an average service life of five years and an implantable battery that does not require recharging. Barostim ensures patient compliance, unlike most commercially available drug treatments, as it requires no device interaction by the patient. With these features, we believe the revolutionary Barostim has the potential to transform the treatment paradigm and become the standard of care for many of the 26 million people worldwide with HFrEF, representing an initial annual market opportunity of $2.9 billion.

- ***Significant body of clinical evidence targeting a widely accepted mechanism of action.*** The benefits of treatment with Barostim were similarly robust and reproducible across our three HFrEF 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. Our HOPE4HF clinical trial results led to CE Mark approval and FDA Breakthrough Device designation for HFrEF, and our BeAT-HF pivotal trial results led to FDA approval on an accelerated basis of only four months from the submission of the clinical trial report. Our trial results have been published in more than 60 peer-reviewed publications, approximately 20 of which relate to the treatment of HF, including, among others, the Journal of the American College of Cardiology. 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, which measure the improvement in the quality of the patients' daily lives. Importantly, the significant benefits of our therapy were observed despite a four-fold uptake of ARNI in the control arm, as compared to the device arm.

- ***Favorable reimbursement paradigm for both outpatient and inpatient settings.*** Barostim is currently indicated for HFrEF patients, 67% of whom are above the age of 65, and therefore are eligible for Medicare or Medicare Advantage. In the U.S.***,*** Barostim is reimbursed for outpatient and inpatient procedures by the CMS, with established coverage policies and Current Procedural Terminology ("CPT") payment codes. Barostim Therapy is eligible for payment across all seven local Medicare administrative contractor ("MAC") regions, representing 38 million covered lives as of July 2020. Of note, CMS awarded Barostim Transitional Pass-Through ("TPT") payment for outpatient procedures that adds the device cost as a pass-through to the calculated procedure cost in the payment code, which took effect in January 2021. In addition, CMS awarded Barostim a New Technology Add-on Payment ("NTAP") for inpatient procedures in the amount of 65% of the device cost that is incremental to reimbursement provided for the implant procedure, which took effect in October 2020. As part of our ongoing reimbursement strategy to broaden payor coverage, we are currently building a dedicated market access team to help patients and providers work with private payors to secure the appropriate prior authorization approvals in advance of initial treatment, which we believe will drive additional positive coverage outcomes for up to approximately 20% of our target-indicated patient population.

- ***Targeted and methodical approach to market development in the U.S.*** We have established a systematic approach to market development that centers on active engagement with physicians and patients. Our direct sales organization is focused on prioritizing high volume EP centers that are strategically located and on building long-standing relationships with key physicians. We support these physicians through all aspects of the patient journey, which includes initial patient diagnosis, surgical support and patient follow-up. Due to the lack of commercially available device-based treatments for our target-indicated patient population, our sales force is keenly focused on increasing awareness by educating referral physicians on the compelling clinical results and strong value proposition of Barostim Therapy. We

build upon this multi-pronged approach with direct-to-consumer marketing initiatives which help to educate patients and frequently results in patient leads. We believe that our approach to engagement across multiple stakeholders will continue to drive increased awareness of, and demand for, our therapy.

- ***Platform technology protected by a comprehensive and broad IP portfolio.*** We developed an integrated platform technology, Barostim, which is designed to leverage the power of the brain and nervous system to address the primary cause of HF and other cardiovascular diseases. Barostim is our second-generation HFrEF product, which is FDA approved and CE Marked, providing access to an initial estimated annual market opportunity of $2.9 billion in the U.S. and EU5. While we are currently focused on the treatment of HFrEF patients with limited viable device-based treatment alternatives, we believe our platform technology has the potential to provide benefits to a broader set of patients suffering from cardiovascular diseases. Our platform technology is supported by our comprehensive portfolio of wholly owned intellectual property, which includes patents, know-how and trade secrets, including therapy regimens, IPGs, leads and electrodes, delivery tools and implant methods. As of December 31, 2021, we owned 54 issued U.S. patents and had three pending U.S. patent applications. Outside of the U.S., we owned seven patents in multiple countries and had one pending application. Our trademark portfolio contains nine trademarks in the U.S. and multiple other countries.

- ***Experienced management team with deep expertise in the HF market and supported by key investors.*** Our senior management team has over 180 years of combined experience in the medical technology industry. Specifically, our team has extensive operating experience in product development, regulatory approval and commercialization activities as well as established relationships with industry specialists in the academic, clinical and commercial HF markets. Members of our management team have served in leadership positions with well-regarded medical technology companies such as Medtronic, Boston Scientific/Guidant, Abbott/St. Jude and General Electric, as well as flag-ship industry societies, including AdvaMed. Since our founding, we have been supported by leading medical technology investors including Johnson & Johnson Development Corp., New Enterprise Associates, Gilde Healthcare Partners, Vensana Capital, Treo Ventures and Action Potential Venture Capital, among others.

Our growth drivers

Our mission is to capitalize upon our first mover advantage to become the global leader in providing clinically proven, innovative and minimally invasive neuromodulation solutions that improve the health of patients with HFrEF and other cardiovascular diseases. Our strategic levers to drive continued growth are as follows:

- ***Continue to build a commercialization infrastructure with a specialized direct sales and marketing team in the U.S.*** We have grown our commercial team in the U.S. to include a direct sales force with substantial applicable medical device sales and clinical experience. Similarly, our marketing team has a significant amount of domain expertise and a strong track record of success. Our Account Managers, along with the support from our Clinical Field Specialists, are responsible for establishing, growing and supporting implant centers and referral physicians. We plan to expand our commercial organization in the U.S. by adding a strategic mix of highly qualified Account Managers and Clinical Field Specialists. Our direct sales force will leverage our existing network of EPs to maximize early commercial traction.

- ***Promote awareness among payors, physicians and patients to accelerate adoption of Barostim.*** We believe Barostim has the potential to become the standard of care for our target-indicated patient population, which currently lacks commercially available device-based treatment options. The vast majority of our indicated patients are well-defined under the purview of an EP and may have already been pre-indicated for an implantable cardiac defibrillator (“ICD”). As a result, we believe that raising awareness among EPs of Barostim Therapy and its clinical benefits will be an effective strategy to accelerate market adoption. We intend to continue to increase engagement with key stakeholders in the decision-making process, including EPs, HF specialists, general cardiologists, vascular surgeons, referring primary care physicians and patients with HF, as well as hospital administrators and third-party payors. In addition, we plan to continue to educate and train physicians as well as continue to publish additional clinical data in peer reviewed publications, online and at various industry conferences. We also plan to continue promoting

patient awareness through our direct-to-consumer marketing initiatives, which includes social media advertising, patient webinars and online videos. We believe this market development strategy will further support adoption of Barostim.

- ***Expand upon our significant body of clinical evidence.*** We will continue to develop and expand upon our growing body of published clinical evidence that endorses the strong value proposition of Barostim Therapy. We also plan to continue enrollment of the U.S. patient registry to evaluate and assess real world patient outcomes, as well as publish additional long-term data to further increase awareness and adoption of Barostim and for inclusion in the medical guidelines.

- ***Continue innovation of Barostim to enhance our value proposition.*** We are committed to driving continuous innovation and technological advancement of Barostim, specifically around simplifying the implant procedure and use of our therapy. For example, we are currently developing a new implant toolkit called BATwire, which enables an ultrasound-guided procedure to implant Barostim and the use of local anesthetics, potentially expanding our addressable patient population to include those who are deemed clinically unfit for the current procedure. In addition, as a result of this simplified implantation process, we believe more physicians, including EPs, would be confident and comfortable implanting Barostim. In 2022, we also expect to launch an enhanced IPG in the U.S. that will be approximately 10% smaller in size and improve the battery life by approximately 20% to an average of six years. We believe our product roadmap coupled with a more simplified procedural process would improve clinical outcomes, optimize patient adoption and comfort, increase access of Barostim to a greater number of patients and allow more physicians to perform the procedure.

- ***Leverage our platform technology to expand into new indications and strategically pursue new international markets.*** HF is a prevalent, devastating and costly condition that affects over 26 million people worldwide. While we are currently focused on the treatment of HFrEF patients, we believe our technology has the potential to provide benefits to a broader set of patients suffering from other cardiovascular diseases. Through additional investment in clinical research and development, our goal is to explore Barostim's potential to expand the indications for use to other areas, while continuing to increase its market adoption and implantation in indicated patients with HFrEF. In addition, we are pursuing a morbidity and mortality indication in HF which would expand our addressable patient population. While our primary commercial focus in the near-term is on the large opportunity within the U.S., we plan to selectively expand our commercial and regulatory efforts in international markets.

Our market and industry

Overview of HF

HF is one of the most prevalent and devastating cardiovascular diseases. It is estimated that HF currently affects approximately 26 million people globally, including approximately 6.2 million people in the U.S. and approximately 8.6 million people in the EU5. Every year, 1.3 million and 1.4 million new patients are diagnosed with HF in the U.S. and the EU5, respectively. HF is associated with a five-fold increase in sudden cardiac death. Despite currently available pharmaceutical and device-based treatments, projections by the American Heart Association's ("AHA") 2020 Heart Disease and Stroke Statistics show that the prevalence of HF is expected to increase approximately 46% from 2012 to 2030 in the U.S. alone due to an aging population and health issues related to diabetes and obesity. 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 usually develops as a result of an

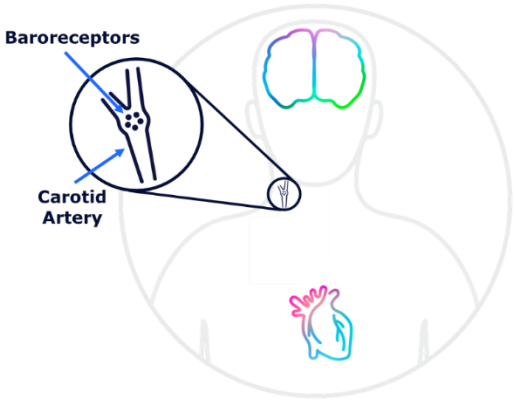
imbalance of the ANS, which is also the primary cause of multiple other cardiovascular diseases, such as hypertension, angina pectoris and arrhythmia.

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. When the body perceives a threat in the environment, the sympathetic system reacts by increasing the heart rate, widening the airways to allow for easier breathing, releasing stored energy, increasing strength in the muscles and slowing 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 certain arterial walls. The baroreceptors regulate the baroreflex, which is one of the body's homeostatic mechanisms that help to maintain blood pressure at nearly constant levels. Baroreceptors provide beat-by-beat regulation of the body's circulatory system by sending electrical signals to the brain.

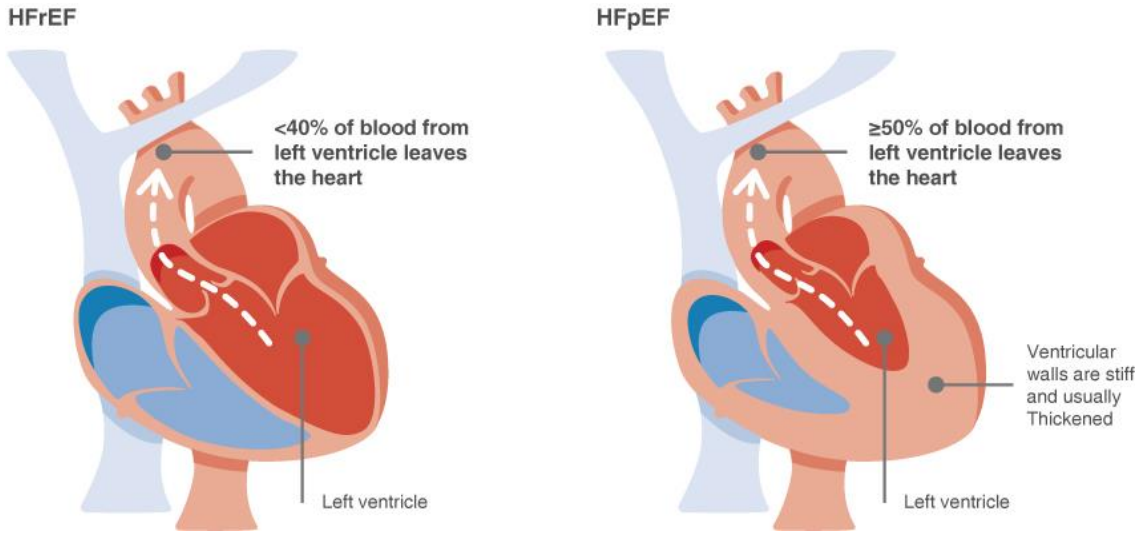
Healthy individuals have balanced sympathetic and parasympathetic activities, promoting the effective function of the heart. However, there are many factors, including a person's diet, lifestyle and underlying conditions such as diabetes and obesity that can cause an imbalance of the ANS. This imbalance, 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 of 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 40% 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. A 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 a 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)

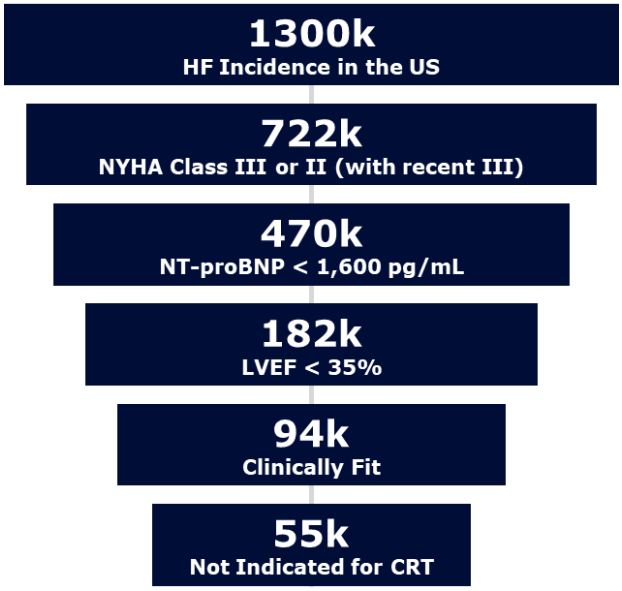
LVAD is an irreversible, invasive surgery generally reserved for critical HFrEF patients with NYHA Class IV. An LVAD is a mechanical pump that is implanted inside a patient's chest and helps pump blood throughout the body. While LVADs do not replace the heart, they do require open chest surgery and often 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 800,000 HF hospitalizations every year in the U.S., representing approximately $39.5 billion in annual spending.

Barostim's market opportunity

We estimate that our initial annual market opportunity for HFrEF is $2.9 billion. This includes a $1.4 billion initial market opportunity based on approximately 55,000 new HFrEF patients in the U.S., and a $1.5 billion initial market opportunity based on approximately 61,000 new HFrEF patients in EU5. The graphic below indicates what we believe would be the stratification of our annual addressable patient population in the U.S. based on our indication for use and excludes patients who are clinically or psychologically unfit or who have severe comorbidities:



The annual market opportunity for Barostim is based on the following HF classifications:

- **NYHA Class III or II (with recent history of III):** Barostim provides symptomatic relief for patients with NYHA Class III or II (with recent history of III), or patients who generally have limits on basic daily activities but are comfortable when resting. We estimate this represents approximately 722,000 of the 1.3 million annual new HF patients in the U.S.

- **NT-proBNP < 1600pg/ml when stable:** Barostim targets patients who have NT-proBNP < 1600pg/ml, which represents approximately 470,000 of the 722,000 of NYHA Class III or II (with recent history of III) annual HF patients in the U.S.

- **Left ventricular ejection fraction (LVEF) ≤ 35%:** Barostim targets patients with a LVEF ≤ 35%, which we estimate represents approximately 182,000 of the 470,000 annual HF patients with NT-proBNP < 1600pg/ml in the U.S.

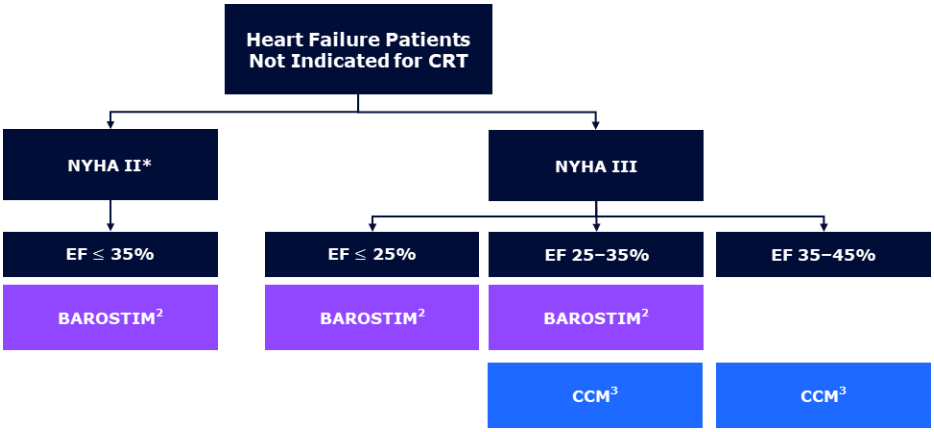
- **Clinically fit:** Barostim is not indicated for HFrEF patients with certain contra-indications, including carotid atherosclerosis and ulcerative plaques, among others. Physicians often exclude patients who are not deemed clinically fit to undergo Barostim procedure. We estimate this represents approximately 94,000 of the 182,000 annual HFrEF patients with LVEF ≤ 35% in the U.S.

- **Not indicated for CRT:** Barostim targets patients who are not indicated for CRT, particularly patients with QRS < 120ms. We estimate this represents approximately 55,000 of the 94,000 annual HFrEF patients in the U.S. who are clinically fit.

Limitations of other commercially available device-based option for indicated HFrEF patients

There is only one other commercially available device-based option, Cardiac Contractility Modulation (CCM), that targets a subset of the same HFrEF patient population indicated for Barostim. CCM is offered by a single privately-held medical technology company and while it has the potential to improve a patient's quality of life and reduce symptoms of HFrEF, it is not designed to address the imbalance of the ANS. We believe CCM is associated with the following drawbacks that have resulted in a remaining significant unmet need for a safe, effective and minimally invasive device-based treatment option for HFrEF patients:

- **Limited overlap in target patient population:** CCM is indicated for a limited population of HF patients with a NYHA Class III, LVEF 25%–45%, narrow QRS and normal sinus rhythm. Within this population, a subset of patients indicated for Barostim are also eligible for CCM, namely those with NYHA Class III and LVEF 25%–35%. As a result, Barostim is the only FDA approved device indicated to improve symptoms for HFrEF patients with NYHA Class III and LVEF <25%, as well as with NYHA Class II (with a recent history of Class III) and LVEF ≤35%.



- **Limited clinical effectiveness in patients with LVEF 25–35%:** Based on published clinical data, CCM demonstrated lower effectiveness in the patients with LVEF 25–35% as compared to the patients with LVEF 35–45% across all three evaluated areas: exercise capacity, quality of life and functional status. Patients with LVEF 25–35% who were implanted with CCM walked only 10 additional meters in six minutes and improved the patients' quality of life by only nine points as compared to the control arm. Furthermore, only 25% of these patients showed an improvement in functional status.

Trial		BeAT-HF (Barostim)[1]		FIX-HF5c (CCM)[2]	
Eligibility Criteria		LVEF<35% • NYHA II** or III (93%) • NT-proBNP<1600 • Not indicated for CRT		LVEF25-45% • NYHA III (91%) or IV* • Normal sinus rhythm • Not indicated for CRT	
EF% Subgroups		LVEF≤25%[1]	LVEF 25%–35%[1]	LVEF 25%–35%[2]	LVEF 35%–45%[2]
Exercise Capacity (6-minute walk distance in meters)	mean	76	**56**	**10 (n/s)**	57
Quality of Life (points)	mean	-15	**-13**	**-9**	-15
NYHA Class Improvement	%	31	**35**	**25**	27

- **Invasive procedure:** CCM requires an invasive procedure that places hardware directly inside the heart, which increases risks to patients. This approach involves a pacemaker-type device to be placed under the skin of the upper chest with two to three electrical leads running through the veins and attached to the heart's ventricle.

- **Requires patient compliance**: CCM devices require patients to charge the battery inside the IPG as often as once per week, which may result in a lack of patient compliance.

Our solution

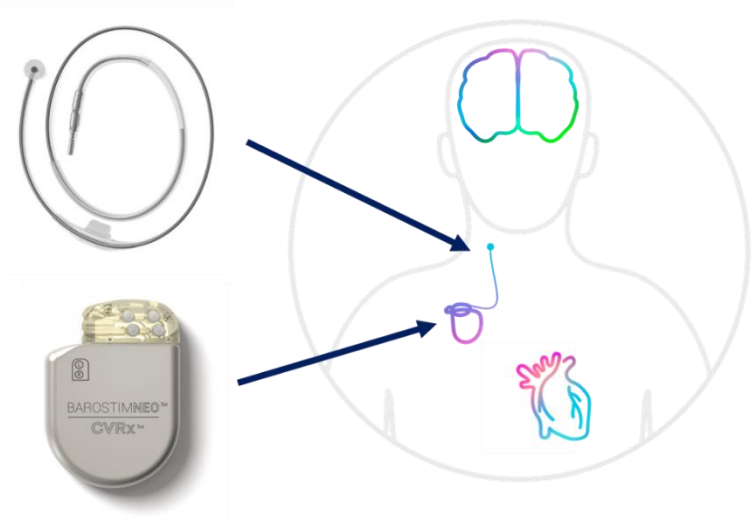
We developed our Barostim platform technology to transform the treatment of HFrEF and other cardiovascular diseases and become the standard of care for this vulnerable and underpenetrated patient population. We believe Barostim offers meaningful benefits for patients, physicians and payors that will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

Overview of Barostim Therapy

Our integrated platform technology, Barostim, leverages the power of the brain and nervous system 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 signal the brain to decrease sympathetic activity and increase parasympathetic activity. This integrated response to rebalancing the ANS 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:



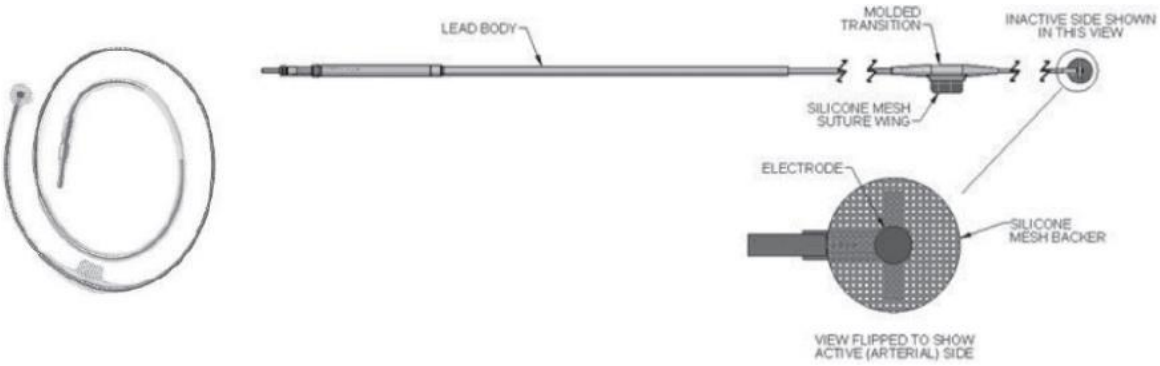
Implantable pulse generator

The current IPG contains the electronics and battery in a hermetic enclosure, has an average service life of five 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:

Parameter	Value
Height	72 mm
Width	50 mm
Thickness	14 mm
Mass	60 grams
Volume	< 40cc

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 the improvement of symptoms of HFrEF — quality of life, 6MHW and functional status — for patients who remain symptomatic despite treatment with GDMT, are NYHA Class III or II (who had a recent history of Class III), have a left ventricular ejection fraction ≤ 35%, a NT-proBNP < 1600 pg/ml and are not indicated for CRT according to the AHA/American College of Cardiology ("ACC")/European Society of Cardiology ("ESC") guidelines.

Once a patient is diagnosed with HFrEF and recommended for an ICD and/or CRT, general cardiologists will usually refer them to EPs. EPs will 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. The vast majority of our indicated patients are well-defined under the purview of an EP and 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 payors

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 payors 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 clinical trial results demonstrated compelling safety and effectiveness data regarding the HFrEF clinical benefits of Barostim. These results showed significant improvement in the following HF patient-centered outcomes:

    - **Quality of life (measured by MLWHF):** Our therapy demonstrated a 14-point improvement in quality of life for patients in the device arm relative to patients in the control arm. A 5-point improvement is considered to be clinically meaningful.

    - **Exercise capacity (measured by the standardized 6MHW distance test):** Our therapy demonstrated that patients in the device arm were able to improve their walking distance in a six-minute period by 60 meters more than that of patients in the control arm. A 25-meter improvement in walking distance is considered to be clinically meaningful.

- **Functional status (determined by NYHA classification):** Our therapy demonstrated that 65% of patients who were in the device arm improved at least one NYHA class as compared to only 31% in the control arm, with 13% of patients improving two NYHA classes in the device arm as compared to only 2% in the control arm.

- **NT-proBNP (Serum biomarker used as indicator of severity of HF):** Our therapy demonstrated that patients in the device arm had a 25% improvement in NT-proBNP relative to that of patients in the control arm. A 10% improvement is considered to be clinically meaningful.

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 address the imbalance of the ANS, which causes HFrEF and other cardiovascular diseases.

- **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 60 peer-reviewed publications, approximately 20 of which relate to the treatment of HF, including, among others, the Journal of the American College of Cardiology.

- **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. In addition, we are currently developing a new implant toolkit called BATwire, which enables an ultrasound-guided procedure to implant Barostim and the use of local anesthetics. As a result of this simplified implantation process, we believe more physicians, including EPs, would be confident and comfortable implanting Barostim, thereby expanding our addressable patient population to include those who are deemed clinically unfit for the current 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 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. 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.

Barostim is indicated for the improvement of symptoms of HFrEF — quality of life, 6MHW and functional status — for patients who remain symptomatic despite treatment with GDMT, are NYHA Class III or Class II (with a recent history of Class III), have a LVEF ≤ 35%, a NT-proBNP < 1,600 pg/ml and excluding patients indicated for CRT according to AHA/ACC/ESC guidelines.

The safety and effectiveness of Barostim Therapy have been published in more than 60 peer-reviewed publications, approximately 20 of which relate to the treatment of HF, including, among others, the publication of the pivotal trial results in the Journal of the American College of Cardiology. The table below summarizes the clinical measurements, results and outcomes from our HF trials, including improvements in HF symptoms, patient-reported quality of life measures and our therapy's favorable safety profile.

	Phase I: BAT in HF	Phase II: HOPE4HF	Pivotal: BeAT-HF
Year published	2014	2015	2020
Study subjects	• n = 11	• n = 146	• n = 467
Objective	• Assess safety • Demonstrate mechanism of action	• Assess safety and effectiveness	• Demonstrate safety and effectiveness • Assess health economics
Key clinical measurements	• Safety • Effectiveness: sympathetic and vagal activity, 6MHW, NYHA class, quality of life, LVEF	• Safety • Effectiveness: 6MHW, NYHA class, quality of life, LVEF, NT-proBNP, HF-related hospitalization days	• Safety • Effectiveness: 6MHW, quality of life, NYHA*, NT-proBNP, morbidity and mortality
Outcomes	• BAROSTIM**NEO** is safe • Mechanism of action demonstrated through muscle sympathetic nerve activity	• BAROSTIM**NEO** is safe and effective in heart failure • CE Mark Approval • EAP** / FDA Breakthrough Device Designation	• BAROSTIM**NEO** is a safe, effective, and an economically attractive solution for heart failure patients • FDA Approval

*Not a primary endpoint
**Expedited Access Pathway

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 is 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 major adverse neurological or cardiovascular system or procedure-related event rate ("MANCE").

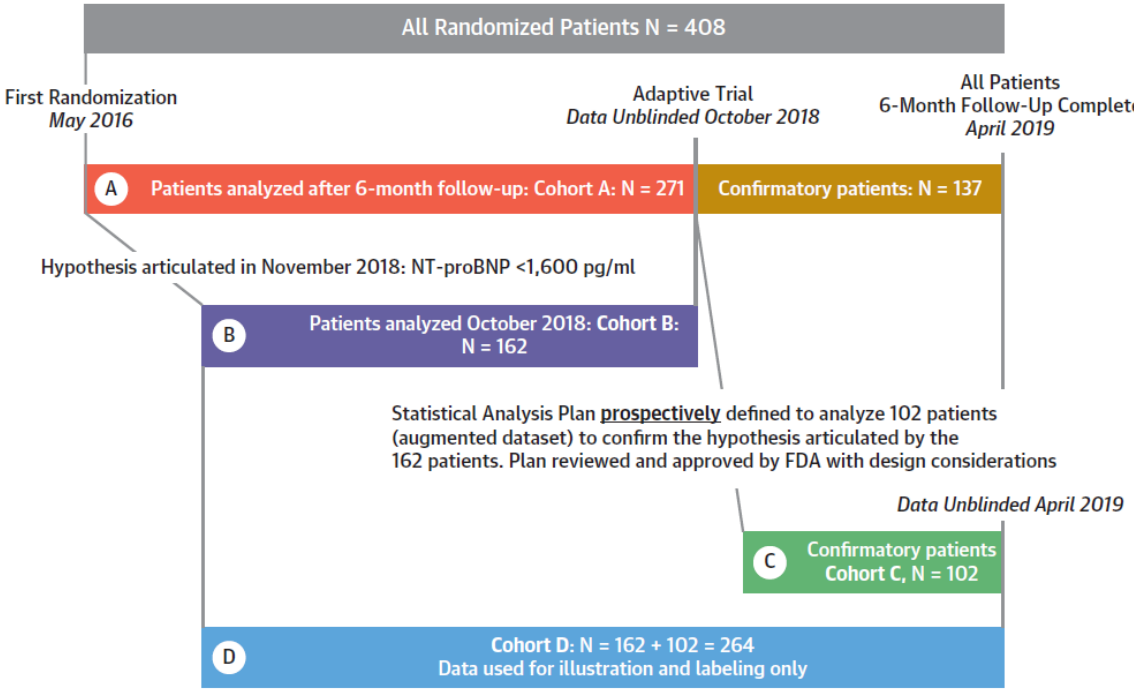
(2) A post-market stage that will examine the effects of BAT on rates of HF hospitalization and cardiovascular mortality and potentially expand the indication for Barostim.

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 AHA/ACC/ESC Class I indication for a CRT were excluded, and there were no restrictions for atrial fibrillation or atrial flutter.

Patients who met all eligibility criteria with complete baseline measurements were randomized 1:1 to receive Barostim Therapy plus GDMT ("BAT+") or GDMT alone ("Control"). BAT+ was delivered by implanting patients with a Barostim Neo System, while keeping the patient on maximally tolerated GDMT. Control was defined as maximally tolerated GDMT.

In the pre-market stage of the BeAT-HF pivotal trial, four patient cohorts were developed in collaboration with the FDA under the Breakthrough Devices Program and shown in the following graphic:



- Cohort A (n=271): In the six-month data available, improvements were seen in two of the three primary effectiveness endpoints, and the safety endpoint MANCE-free rate of 94% exceeded the performance criteria of 85% (p = 0.002). There was no statistically significant reduction in NT-proBNP observed, which contrasted the significant reduction of NT-proBNP seen in the HOPE4HF Phase II trial.

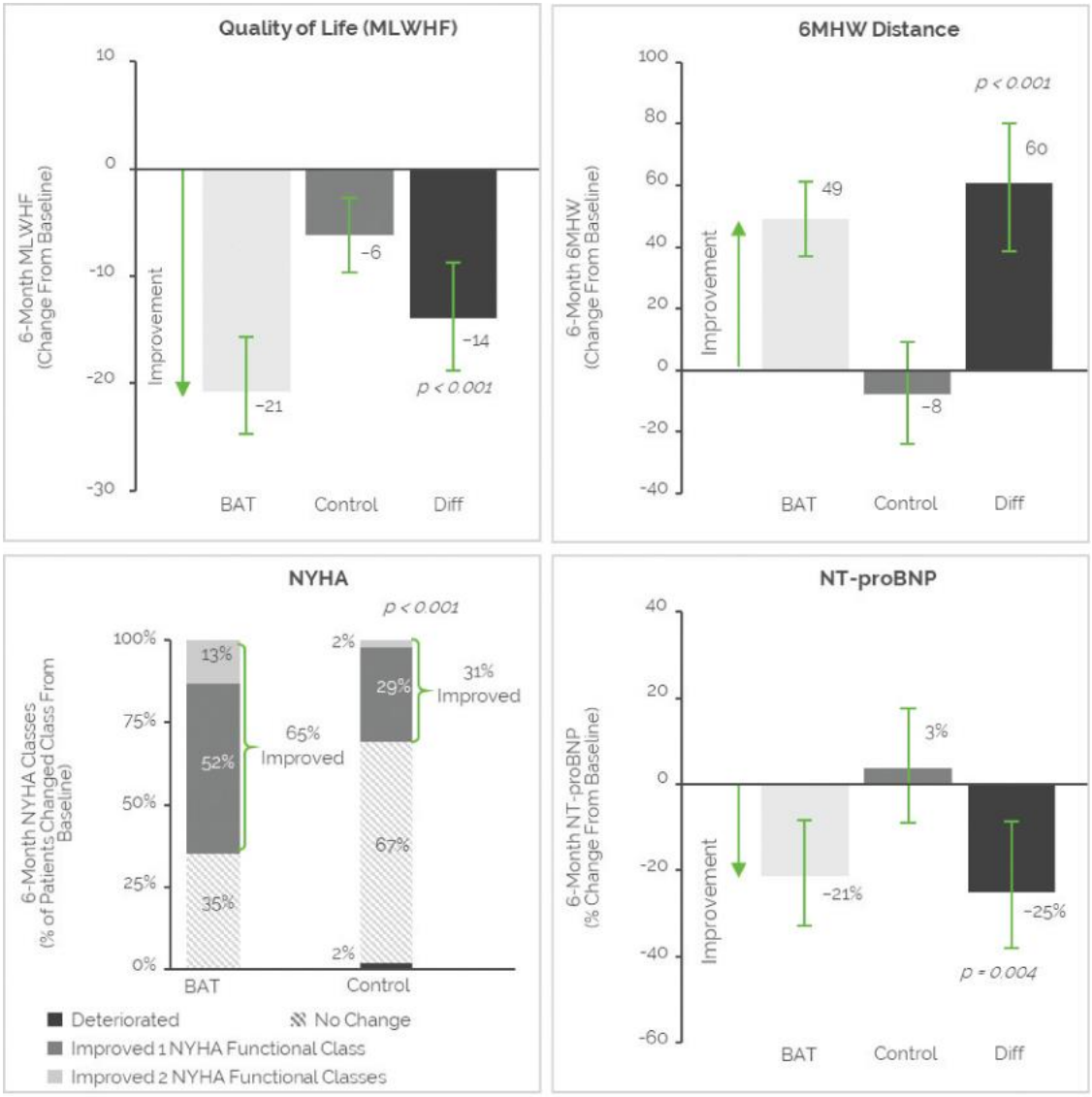
- Cohort B (n=162): Results from cohort A led to the hypothesis-generating cohort B, which included 162 of the 271 patients in cohort A with an NT-proBNP < 1,600 pg/ml. In the six-month data available, improvements were seen in all three primary effectiveness endpoints and resulted in a MANCE-free rate of 97%. A hypothesis was then formally articulated in a revised statistical analysis plan ("SAP"). This SAP was submitted and reviewed with FDA before the cohort C completed its six-month follow-up period.

- Cohort C (n=102): Results from cohort B led to the hypothesis-confirming cohort C, which consisted of 102 patients with NT-proBNP <1,600 pg/ml. In the six-month data available for cohort C, improvements were seen in all three primary effectiveness endpoints. This confirmed the findings in cohort B.

- Cohort D (n=264): Cohort D is a combined cohort, representing the intended use population, and consisted of 264 patients combined from cohorts B and C. Data from cohort D was used to define the indication for use and the labeling of Barostim in the PMA submission.

Trial results

The study consisted of 1,090 enrolled patients across 92 centers, of which 467 met the eligibility criteria and were randomized in the trial. In the pre-market stage, 264 randomized patients who met the intended use criteria were randomized 1:1 with 130 patients in the BAT+ group and 134 patients in the Control group.



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 functional status, as well as the confirmatory nature of the evidence provided by a reduction of NT-proBNP.

- **Quality of life (measured by MLWHF):** BAT resulted in a 14-point reduction (improvement) in quality of life for patients in the BAT+ 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 five-point reduction (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 BAT+ 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 BAT+ 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 BAT+ 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 BAT+ 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 cardiovascular mortality and HF hospitalization.

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%).

Effectiveness results in context

While Barostim is not intended to compete with CRT therapies, it is useful to compare the symptomatic results achieved by CRT devices when they were initially FDA approved. Patients suffering from HFrEF have similar outcomes and symptoms irrespective of whether they are indicated for CRT, and thus provide a good proxy to understand the adoption of these therapies.

Active Heart Failure Therapies vs. Controlled Groups				
Company		**Medtronic**	**Boston Scientific**	**Abbott/ St. Jude**
Name of Trial		Miracle	Contak CD	Rhythm ICD
Eligibility Criteria		NYHA III, LVEF ≤ 35%, QRS ≥ 130ms	NYHA III or IV, LVEF ≤ 35%, QRS ≥ 120ms	NYHA III or IV, LVEF ≤ 35%, QRS > 150ms
Exercise Capacity (6-minute walk distance in meters)	**Mean**		39	28**
	Median	29		
Quality of Life (points)	**Mean***		-11	-11
	Median*	-9		
NYHA Class Improvement	**%**	30	20	
	Diffs*			-0.2

* Negative numbers indicated on improvement in Quality of Life and NYHA Diffs
** Not significant

The results presented in this table have been derived from publicly available reports of clinical trials run independently of the Company or meta-analyses of such clinical results. The Company has not performed any head-to-head trials comparing any of these other HF therapies with Barostim. As such, the results of these other clinical trials may not be comparable to clinical results for Barostim. The design of these other trials vary in material ways from the design of the clinical trials for Barostim. For further information and to understand these material differences, you should read the relevant reports or meta-analyses.

Ancillary analysis

During the initial six-month follow-up period, there was a disproportionately higher number of medications added in the Control group when compared to BAT+ group. Control patients were more likely to have a new class of drugs added (36 [29%] Control vs 21 [18%] in BAT+; difference of 11%, p=0.049; 95% CI: 1% to 22%) and were more likely to have a new ARNI added (20 [16%] Control vs 5 [4%] BAT+; difference of 12%, p=0.003; 95% CI: 4% to 19%). The significant symptomatic improvement in the BAT+ group demonstrated in the trial was observed despite a disproportionate increase in the number of medications in the Control group.

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 BAT+ vs 0.206 Control; nominal p= 0.023; 95% CI: 0.10 to 0.73) and there were no significant differences in blood pressure or heart rate.

The BeAT-HF pivotal trial continued enrolling patients in the post-market stage of the trial in order to determine if Barostim demonstrates a statistically significant improvement in morbidity and mortality in patients with HFrEF. Enrollment was completed and patient follow-up continues to collect morbidity and mortality events until the pre-specified number of events has been accumulated. The patient follow-up data is expected to accrue by the end of 2022. If we successfully obtain FDA approval for a morbidity and mortality indication in HFrEF, we believe our addressable patient population would expand significantly and our therapy could be included at a higher class in the HF medical guidelines.

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 BAT+ 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.

The safety endpoints were system- and procedure-related complications and system- and procedure-related MANCE within six months of implantation. The effectiveness endpoints included changes in functional status, quality of life as measured by the MLWHF, exercise capacity as measured by 6MHW distance, cardiac function as measured by echocardiography and serum biomarkers. Additional hypothesis generating observations were made to assess outcome as measured by HF hospitalizations and HF hospitalization days.

Results

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

Subgroup analysis

The study had a prespecified subgroup analysis of patients who were treated at baseline with CRT versus patients without CRT. Of the 146 patients who were randomized, 140 were active at baseline: 45 patients had a CRT and 95 patients did not have a CRT. The results of this subgroup analysis showed a MANCE-free rate at six months of 100% in the CRT group and a 96% rate in the no-CRT group. At six months, the quality of life as measured by the MLWHF, 6MHW distance, LVEF and NT-pro BNP were significantly improved in the BAT+ group with no-CRT compared to control patients with no-CRT. In the no-CRT BAT+ group, HF hospitalizations were significantly reduced when comparing the periods before and after implant. Patients who received BAT+ showed a symptomatic improvement in the CRT group and the improvements were even more pronounced in the no-CRT group. The results of the substudy were presented in the Late Breaking Clinical Trial session of the Heart Rhythm Society in 2015 and published in the *European Journal of Heart Failure.* The substudy results led to FDA Breakthrough Device designation for HFrEF in June 2015.

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 ($p \leq 0.05$ 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 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 is expected to enroll 180 subjects and follow 71 implanted subjects for one year. If the trial data meets the safety and effectiveness endpoints, we will submit an application for a PMA-supplement approval by FDA.

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, including a randomized, controlled double-blinded 322-patient trial that completed enrollment in 2009. In 2010, we 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). Because of these results, we decided not to pursue PMA approval of the Rheos device, and instead focused our development roadmap on completing our second-generation system, Barostim. 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.

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 CE Mark for the treatment of HFrEF and hypertension in Europe. We market our therapy in the U.S. to hospitals and clinics where EPs, HF specialists, 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, general cardiologists and vascular surgeons. We are 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.

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 these physicians through 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 EP centers that are strategically located and on building long-standing relationships with key 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 active 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 target these patients and make them aware of 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 assist patients and physicians in the process of obtaining prior authorization approval for their procedures.

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 an outpatient setting. Our customers bill various third-party payors, such as government agencies, administrative contractors, commercial payors and integrated managed care organizations, for the cost required to treat each patient.

Third-party payors 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.

Physician reimbursement under Medicare is generally based on a defined fee schedule, the Physician Fee Schedule, through which payment amounts are determined by the relative values of the professional services rendered. Medicare provides reimbursement to hospitals using Barostim under the hospital outpatient prospective system ("HOPPS"), which provides bundled amounts generally intended to reimburse a hospital for all facility costs related to procedures performed in its outpatient setting. Under the HOPPS, the national Medicare payment to a hospital for a new patient implant or an IPG replacement is paid using the Level 5 Neurostimulator payment code APC 5465, which has a national average of $30,063 in 2022. Payment codes such as APC 5465 are indexed to adjust for cost of living and thus vary by location. These payments generally cover the hospital's costs for the device and the implantation procedure. CMS also granted a TPT payment for the implantation of Barostim in an outpatient setting, which took effect in January 2021. The TPT payment is an incremental payment for new and innovative technologies that meet certain qualifications. It allows hospitals to bill for a pass-through of the device cost, which includes up to $35,000, and can be added to the procedure costs.

We anticipate inpatient procedures to continue to represent a small percentage of our sales. For these inpatient procedures, ICD-10-PCS codes 0JH60MZ + 03HL3M are commonly mapped into Diagnosis Related Group ("DRG") 252, which has an established national average Medicare payment of $21,930 in 2022. CMS also granted an NTAP that is added to the DRG for a three-year period starting in October 2020 to cover the implantation of Barostim in an inpatient setting. The NTAP is an incremental inpatient payment for new and innovative technologies that meet certain qualifications. This payment allows hospitals to be reimbursed an additional $22,750 (65% of the total cost of the device), for a total national average Medicare payment of $44,680 in 2022.

The surgeon implanting Barostim is paid an additional physician payment under the Medicare Physician Fee Schedule, which we believe is a reasonable amount for this type of procedure. 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 $140 per visit in 2022.

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

Government program and commercial payor coverage in the United States

A core pillar of our reimbursement strategy involves continuing to broaden our current coverage. Since approximately 67% of our target treatment population includes Medicare-eligible patients, we have prioritized CMS coverage while simultaneously developing processes to engage commercial payors. As of July 2020, all MACs have retired automatic coverage denial policies, thereby allowing hospitals to be paid for our procedure. In November 2021 CMS repealed its proposed rule entitled "Medicare Program; Medicare Coverage of Innovative Technology ("MCIT") and Definition of 'Reasonable and Necessary,'" which would have created an expedited process for Medicare coverage for breakthrough devices, and created greater

clarity around the definition of “reasonable and necessary” for coverage determinations. Although the rule has been repealed, existing mechanisms remain to obtain Medicare coverage for breakthrough devices. 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 payors, if any.

A second pillar of our reimbursement strategy includes leveraging our in-house market access team to assist patients and physicians in obtaining appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist. We believe our market access team is highly effective in working with patients and physicians to obtain prior authorizations for systems similar to Barostim, including handling 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 payors. We intend to have discussions with commercial payors to establish these positive coverage policies by highlighting our compelling and robust clinical 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 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 allowing 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, including tools to simplify the implant procedure for physicians. For example, in 2022 we expect to launch an enhanced IPG that will be approximately 10% smaller in size and improve the battery life by approximately 20% to an average of six years. We are also developing a new implant toolkit called BATwire, which enables an ultrasound-guided procedure to implant Barostim and the use of local anesthetics. This has the potential to expand our annual market opportunity in the U.S. by an estimated $1 billion, or by 39,000 additional patients who are deemed clinically unfit for the current procedure. This simplified procedure would also allow EPs to complete the procedure in an outpatient catheter lab center.

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. If we receive positive mortality and morbidity data from the post-market stage of the BeAT-HF pivotal trial, we plan to request that the FDA limit certain patient exclusions and add the claim “Treatment for Heart Failure” to our current indication. We believe this would increase our annual market

opportunity in the U.S. by an estimated $2.2 billion, or by 88,000 additional patients. 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 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.

For the years ended December 31, 2021 and 2020, we incurred research and development expenses of $7.5 million and $6.4 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 single 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 the imbalance of the ANS; 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 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 competitors.

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, 2021, we owned 54 issued U.S. patents and had three pending U.S. patent applications. Outside of the U.S., we owned seven patents in multiple countries and had one pending application. 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 legal term for patents in 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.

Our pending patent applications may not result in issued patents, and we cannot assure you 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 includes final assembly, testing and packaging of our IPG and stimulation lead, at our 23,890 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 the components they produce for us and test our components and devices 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 Union (“EU”) 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 expect that any revenue we generate could fluctuate from quarter to quarter as a result of timing and seasonality. We anticipate mild seasonality based on national holiday patterns specific to certain nations. These seasonal variations are difficult to predict accurately and may vary amongst different markets. In addition to the above factors, in the U.S. it is possible that we may experience seasonality based on patients' annual deductibility limits under their health insurance coverage. In Europe, we may be required to engage in a contract bidding process in order to sell Barostim, which processes are only open at certain periods of time, and we may not be successful in such bidding processes. In addition, it is possible that we may experience variations in demand for our product in the first fiscal quarter of each year in Europe, following publication of new coverage status and changes in hospital budgets pertaining to allocation of funds to purchase products such as Barostim.

Government regulation

Our products and our 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 European Economic Area ("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 or not we have or are required to obtain FDA clearance or approval for a product, we will be required to obtain authorization before commencing clinical trials and to obtain marketing authorization or approval of our products under 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 into one of three classes—Class I, Class II or 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 are required to 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 prior predicate device or premarket device for comparing substantial equivalence to; however, the FDA believes it is subject to 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, such as life-sustaining, life-supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of an HDE or PMA. Some pre-amendment devices are unclassified but are subject to the FDA's premarket notification and clearance process in order to be commercially distributed.

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, a full description of the methods, facilities and controls used for manufacturing and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete 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. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or 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 for a number of years and to 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 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 FDA.

Clinical trials

Clinical trials are almost always 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, such as animal and laboratory test results, 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, such as monitoring the investigation, ensuring that the investigators obtain informed consent and labeling and record-keeping 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 is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators, informed consent for subjects, financial reporting on investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain subject informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device and comply with all reporting and recordkeeping 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 and pervasive 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 provide 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;

- the federal Physician 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;

- complying with 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 may include applicable post-marketing requirements such as safety surveillance. Our manufacturing processes are required to 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

In the EEA, in order to be placed on the market, 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 issued for Barostim for the treatment of hypertension in 2011 and for the treatment of HFrEF in 2014.

Medical devices regulated under the MDD (as defined below) are 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 Automatic Implantable Medical Device Directive (“AIMDD”) applies to implantable electrical active medical devices that are typically considered to be Class III under MDD and similar controls for the highest risk devices. The classification corresponds to the level of potential hazard inherent in the type of device concerned. Class I includes devices with the lowest risk to the patient. Class IIa and Class IIb devices are higher risk devices and Class III devices are devices with a significant risk, which are subject to more regulatory oversight to ensure the safety and effectiveness of the device, such as performance standards and post-market surveillance. Barostim is classified and regulated under the AIMDD.

EU Legislation: medical devices regulation

On April 5, 2017, the European Parliament passed the MDR (as defined below). The regulations entered into force on May 25, 2017 and progressively replaced the MDD after a transition period. The transition period was extended in April 2020, and the regulation became fully effective on May 26, 2021. Until then, different European countries interpreted and implemented the MDD and AIMDD in different ways. The MDR, among other things, is intended 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. 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.

The regulatory framework governing medical devices underwent a major change when the Medical Devices Regulation (Regulation (EU) 2017/745 — "MDR") became effective. The MDR repealed and replaced the EU Medical Devices Directive (Council Directive 93/42/EEC — "MDD" or Council Directive 90/385/EEC). Unlike directives, which must be implemented into the national laws of the EEA, the regulations are directly applicable, without the need for adoption by EEA member state laws implementing them, in all EEA member states and are intended to eliminate differences in the regulation of medical devices among EEA member states. To avoid market disruption and allow a smooth transition from the MDD/AIMDD to the MDR, several transitional provisions are in place, which include the certificates provided under the MDD/AIMDD remaining valid and devices lawfully placed on the market continuing to be made available on the market or put into service, both under certain prerequisites and until a certain time.

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 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, which requires manufacturers to 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, among other items, submitted for approval of the CE Mark. If the quality management system audit and the technical file review is 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 market.

CE marking in UK

Since January 1, 2021, a medical device with an EEA-issued CE mark will continue to be recognized in the UK (excluding Northern Ireland) until June 30, 2023. Certificates issued by EU-recognized Notified Bodies will continue to be valid for the UK market until June 30, 2023. Since January 1, 2021, all medical devices placed on the UK market need to 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 UK Conformity Assessed ("UKCA") marking must be submitted. However, the data to support an EEA-issued CE mark will probably 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.

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. As an integral part of its quality management system, 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 have to 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 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 regulatory requirements could prevent us from developing, manufacturing and later selling the products in the EU.

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 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 payor, 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 Claim 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 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 $11,181 to $22,363 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 payors, 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 payor, 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 Plan 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 $11,052 per failure up to an

aggregate of $165,786 per year (or up to an aggregate of $1.105 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 $55,910 per violation, not to exceed $1.68 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 for violations of HIPAA, 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.

In the EU, 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 need to 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 a 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 new 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.

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 a number of 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. Where 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 payors 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 payors 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 Biden 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 proposed and adopted since the Affordable Care Act was enacted. 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, due to subsequent legislative amendments to the statute, 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 for the purpose of obtaining or retaining 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, 2021, we had approximately 109 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, available free of charge at our website as soon as reasonably practicable after they have been filed with 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 $43.1 million and $14.1 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021 and 2020, our accumulated deficit was $394.8 million and $351.7 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, expand existing relationships with our customers, 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. In addition, we expect our general and administrative expenses to continue to increase following our initial public offering ("IPO") due to the additional costs associated with being a public company.

Until our IPO, we financed our operations primarily through convertible preferred stock financings and amounts borrowed under our loan and security agreement ("Horizon loan agreement") with Horizon Technology Finance Corporation. We have devoted substantially all of our financial resources to research and development activities as well as general and administrative expenses associated with our operations, including clinical and regulatory initiatives to obtain marketing approval. We will need 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 obtain market acceptance in the U.S. for Barostim would negatively impact our business, liquidity and results of operations.

Since our inception, we have generated minimal revenue as our activities have consisted primarily of developing Barostim Therapy, conducting our BeAT-HF pre-market and post-market pivotal studies in the U.S. and filing for regulatory approvals. 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. Because of its recent commercial introduction in the U.S., Barostim has limited product and brand recognition. In addition, demand for Barostim may decline or may not 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 establish and maintain sales and marketing capabilities, we will be unable to successfully commercialize Barostim or generate sustained and increasing product revenue.

We currently have a limited sales and marketing organization. As a result, we have limited experience marketing and selling Barostim. In order to generate future revenue growth, we plan 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 retain, grow and develop a substantial number of direct sales personnel. We

intend to make a significant investment in recruiting and training sales representatives for our commercialization effort in the U.S. 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 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 provides symptomatic relief for patients with NYHA Class III or II (with recent history of III), have a LVEF ≤ 35% and a NT-proBNP < 1,600 pg/ml. 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.

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

Our success in marketing Barostim depends and will continue to depend in large part on whether U.S. and international government health administrative authorities, private health insurers and other organizations adequately cover and reimburse customers for the cost of our products. In the U.S., we expect to derive nearly all our revenue from sales of Barostim to hospitals that typically bill various third-party payors, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations and other healthcare-related organizations, to cover all or a portion of the costs and fees associated with procedures using Barostim and bill patients for any applicable deductibles or co-payments. Access to adequate coverage and reimbursement for procedures using Barostim by third-party payors is essential to the acceptance of our products by our customers.

Payors in the U.S. generally require hospitals and physicians to identify the proper CPT codes for the service for which they are seeking reimbursement. Procedures using Barostim are currently mapped to CPT code 0266T for the implantation of the device, which is a Category III CPT code. While customers are currently being reimbursed for our procedure, this may not continue in the future, as payors may determine this Category III CPT code to be investigational. This uncertainty could result in some of our target customers being unwilling to adopt Barostim over more established or lower cost therapeutic alternatives. While we intend to request that our codes be promoted to Category I by the American Medical Association, there can be no assurance that such efforts will be successful.

Medicare reimbursement levels are important to increasing adoption of Barostim because nearly two-thirds of the target patient population for Barostim is over the age of 65. Effective January 2021, CMS awarded Barostim a TPT payment for outpatient procedures that adds the device cost as a pass-through payment to the calculated procedure payment. The calculated procedure payment depends on many factors, including the location of the hospitals and their billing practices, and may not adequately cover hospital costs associated with the procedure. In addition, CMS awarded Barostim an NTAP for inpatient procedures, which took effect in October 2020. The NTAP is for 65% of the device cost and is incremental to the standard payment provided for the implant procedure. Hospitals are responsible for billing for the procedures to receive the additional payment, when such increase in payment is necessary and there can be no assurance that hospitals will accurately perform these billing procedures. The TPT payment and the NTAP are only effective for up to three years. While we intend to request that Barostim be reclassified into a higher Medicare reimbursement level, there can be no assurance that such efforts will be successful. 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.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the U.S., no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process for physicians as well as hospitals that often requires us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained. Accordingly, until such time as Barostim gains broader acceptance by third-party payors as a treatment for HFrEF, hospitals and physicians may encounter delays and additional administrative burdens, such as the submission of supporting documentation, in obtaining reimbursement. Such delays and additional burdens may make it less likely for physicians and hospitals to adopt Barostim. Any future decline in the amount third-party payors are 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.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems. If sufficient coverage and reimbursement is not available for our current or future products, in either the U.S. or internationally, the demand for our products and our revenues will be adversely affected.

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. 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 and relationships. 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 LivaNova PLC. 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. 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 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 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, we expect that the hospitals where these physicians treat patients will 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 EU, 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 and price fluctuations, 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 any of our limited suppliers, some of which supply components critical to our products, such as modules, batteries and electrodes. We currently have no plans to enter into any such contracts and 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 efficacy 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 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 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.

If demand for Barostim increases, we will have 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 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.

We take precautions to safeguard this facility, including acquiring insurance, employing back-up generators, adopting health and safety protocols and utilizing off-site storage of computer data. 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.

A pandemic, epidemic or outbreak of an infectious disease in the U.S. or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in the U.S. or worldwide, our business may be adversely affected. In December 2019, a novel strain of coronavirus, SARS-CoV-2, was identified in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease, COVID-19, has spread to most countries and all 50 states within the U.S. The COVID-19 pandemic has negatively impacted our business, financial condition and results of operations by decreasing and delaying the number of procedures performed using Barostim and the pandemic may continue to negatively impact our business, financial condition and results of operations. Similar to the general trend in elective and other surgical procedures, the number of procedures performed using Barostim decreased significantly when healthcare organizations in the U.S. prioritized the treatment of patients with COVID-19 or altered their operations to prepare for and respond to the pandemic. We believe the COVID-19 pandemic has also negatively impacted the number of HFrEF diagnoses as hospitals focus on COVID-19 and as patients postpone healthcare visits and treatments. Specifically, a significant number of procedures using our products were postponed or cancelled beginning in March 2020. By the beginning of the fourth quarter of 2020, implant centers had resumed procedures in the U.S. and Europe; however, procedure volumes were again negatively impacted by the Delta and Omicron variants of COVID-19 in the third and fourth quarters of 2021 and continuing into 2022.

Numerous state and local jurisdictions have 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 COVID-19. Such orders or restrictions have resulted in reduced operations at our headquarters, slowdowns and delays, travel restrictions and cancellation of events and have restricted 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; 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; delays in clinical trials and studies; diversion of or limitations on employee resources that would otherwise be focused on the operations of our business, including because of sickness of employees or their families or the desire of employees to avoid contact with groups of people; delays in growing or reductions in our sales organization, including through delays in hiring, lay-offs, furloughs or other losses of sales representatives; restrictions in our ability to ship our products to customers; business adjustments or disruptions of certain third parties, including suppliers, medical institutions and clinical investigators with whom we conduct business; and additional government requirements or other incremental mitigation efforts that may impact our or our suppliers’ capacity to manufacture our products. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and spread of COVID-19 and its

variants and the durability of immunity offered by vaccines developed to prevent infection, as well as other actions to contain COVID-19 and its variants or treat its impact, among others.

While the potential economic impact brought by and the duration of any pandemic, epidemic or outbreak of an infectious disease, including COVID-19, may be difficult to assess or predict, the widespread COVID-19 pandemic has resulted in and may in the future result in, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of an infectious disease, including COVID-19, could materially affect our business. Such economic recession could have a material adverse effect on our long-term business as hospitals curtail and reduce capital and overall spending. To the extent the COVID-19 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.

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

Sales of Barostim outside the U.S. represented a majority of our revenue from sales as recently as the year ended December 31, 2020. In 2012, we began selling Barostim in the EEA directly to hospitals and through distributors. 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 payors. 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 and 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 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, 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 our revenue.

Future growth will also 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. For example, we are currently pursuing a morbidity and mortality indication for patients with HFrEF, which, if successful, could significantly expand our addressable patient population. However, we cannot assure you that the morbidity and mortality data will be sufficient to allow us to achieve FDA approval for expansion of this indication. In addition, if the morbidity and mortality data is perceived to be negative, such data may

impact the adoption of Barostim, notwithstanding our existing clinical data and FDA approval. Clinical testing takes many years, is expensive and carries uncertain outcomes. The initiation and completion of any of these studies, including the post-market stage of our BeAT-HF pivotal trial, 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 efficacy;
- the study design is inadequate to demonstrate safety and efficacy; or
- the statistical endpoints are not met.

Clinical trials can fail at any stage. Our clinical studies, including the post-market stage of our BeAT-HF pivotal trial related to the morbidity and mortality indication for patients with HFrEF, may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional clinical or non-clinical studies in addition to those we have planned. The impacts of the COVID-19 pandemic, which may have afflicted certain participants in the post-market pivotal trial, are unknown, but they may exacerbate certain of the risks described above. In addition, if the FDA determines for any reason, including safety or their risk-benefit analysis, that the results of the post-market stage of our BeAT-HF pivotal trial or any other future 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 results 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 cash compensation and/or stock options 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. Although we have, and intend to maintain, liability insurance, the coverage limits of our 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.

We may in the future become involved in lawsuits to protect or enforce our intellectual property, 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 are unable to obtain, maintain, protect and enforce our intellectual property, our business will be negatively affected.

The market for medical devices is subject to rapid technological change and frequent litigation regarding patent and other intellectual property rights. It is possible that our patents or licenses may not withstand challenges made by others or protect our rights adequately.

Our success depends in large part on our ability to secure effective patent protection for our products and processes in the U.S. and internationally. We have filed and intend to continue to file patent applications for various aspects of our technology and trademark applications to protect our brand and business. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products or services that misappropriate our technology and/or infringe our intellectual property to compete with our products.

However, we face the risks that:

- We may fail to secure necessary patents, potentially permitting competitors 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.
- Our already-granted patents and any future patents may not survive legal challenges to their scope, validity or enforceability, or provide significant protection for us, and they may be re-examined or invalidated, and/or may be found to be unenforceable or not cover competing products.
- Though an issued patent is presumed valid and enforceable, it may not be drafted or interpreted sufficiently broadly to prevent others from marketing products and services similar to ours or designing around our patents. For example, third parties may be able to make systems or devices that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our commercial technology or the future products and services that we develop. We may not have the

freedom to operate unimpeded by the patent rights of others. Third parties may have dominating, blocking or other patents relevant to our technology of which we are not aware. In addition, because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for our technology or our contemplated technology. Any such patent applications may have priority over our patent applications or issued patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, depending on when the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the U.S. Patent and Trademark Office (the "USPTO"), to determine priority of invention in the U.S. There may be prior public disclosures that could invalidate our inventions or parts of our inventions of which we are not aware. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable.

- Patent law is constantly evolving, can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the U.S. and in many foreign jurisdictions, policies regarding the breadth of claims allowed in patents can be inconsistent. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Any changes may materially affect our patents or patent applications, our ability to obtain patents or the patents and patent applications of our licensors. Future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage, which could adversely affect our financial condition and results of operations.
- Monitoring unauthorized uses of our intellectual property is difficult and costly. From time to time, we seek to analyze our competitors' products and services, and may in the future seek to enforce our patents or other proprietary rights against potential infringement. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Our competitors may also independently develop similar technology. Any inability to meaningfully protect our intellectual property could result in competitors offering products that incorporate our product features, which could reduce demand for our products. In addition, we may need to defend our patents from third-party challenges, or we may need to initiate infringement claims or litigation. In 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. Such an adverse result could place one or more of our patents at risk of being invalidated or interpreted narrowly. Our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us. Further, litigation risks exposure of or compromising our confidential information.
- Any litigation or claim can be costly and time consuming and could place a significant strain on our financial resources, divert the attention of management and harm our reputation, which could have an adverse effect on our financial condition and results of operations.
- We may be forced to enter into cross-license agreements with competitors in order to manufacture, use, sell, import and export products or services that are covered by our competitors' intellectual property rights. If our intellectual property is required to enter such cross-license agreements, it may compromise the value of our intellectual property due to the fact that our competitors may be able to manufacture, use, sell, import and export our patented technology.

For additional information regarding risks related to our intellectual property, see "Risks Related to Intellectual Property."

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 any of our key personnel likely would involve 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.

In addition, many of our employees have become or will soon 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.

Our future success also depends on our ability to retain executive officers and other key employees and attract new key employees. Many executive officers and employees in the medical device industry are subject to strict non-compete or confidentiality agreements with their employers. In addition, some of our existing and future employees are or may be 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 intellectual property 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 global 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 global economy and in the global financial markets. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets and, more recently, the global COVID-19 pandemic caused, and in some cases is continuing to cause, disruptions in the capital and credit markets, severe supply shortages and reduced hospital and clinical visits, including due to temporary shutdowns under federal, state and local mandates. A severe or prolonged economic downturn, such as the global financial crisis and COVID-19 pandemic, has resulted in and could in the future result in a variety of risks to our business, including weakened demand for Barostim, a delayed time to meet clinical endpoints and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy has strained and could in the future 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 payors do not provide adequate coverage and reimbursement for the use of Barostim, our revenue will be negatively impacted.

Medicare reimbursement levels are important to increasing adoption of Barostim because nearly two- thirds of the target patient population for Barostim is over the age of 65. Effective January 2021, CMS awarded Barostim a TPT payment for outpatient procedures that adds the device cost as a pass-through payment to the calculated procedure payment. The calculated procedure payment depends on many factors, including the location of the hospitals and their billing practices, and may not adequately cover hospital costs associated with the procedure. In addition, CMS awarded Barostim an NTAP for inpatient procedures, which took effect in October 2020. The NTAP is for 65% of the device cost and is incremental to the standard payment provided for the implant procedure. Hospitals are responsible for billing for the procedures to receive the additional payment when such increase in payment is necessary and there can be no assurance that hospitals will accurately perform these billing procedures. The TPT payment and the NTAP are only effective for up to three years. While we intend to request that Barostim be reclassified into a higher Medicare reimbursement level, there can be no assurance that such efforts will be successful. Any future decline in the amount Medicare is willing to reimburse our customers for procedures using Barostim could make it difficult for new customers to adopt Barostim and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business. From time to time, physicians and hospitals have in the past experienced, and others may experience, delays in Medicare reimbursement, which have delayed or may delay their willingness to schedule additional Barostim procedures.

Risks related to intellectual property

We may in the future become involved in lawsuits to defend ourselves against intellectual property disputes, which could be expensive, time consuming and ultimately unsuccessful, and could result in the diversion of significant resources, and hinder our ability to commercialize our existing or future products.

Our success depends in part on 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. 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. 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.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business with respect to intellectual property. 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 claims against us 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 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 of 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 build a 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 transition to operating 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, 2021 and 2020, net cash used in operating activities was $27.7 million and $16.1 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 investment in our U.S. commercial infrastructure and sales force;
- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution and hiring a 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 as a public company; 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. 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 will 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 payor 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 payors' 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 expect that any revenue we generate could fluctuate from quarter to quarter as a result of timing and seasonality. We anticipate mild seasonality based on national holiday patterns specific to certain nations. These seasonal variations are difficult to predict accurately, may vary amongst different markets, and at times may be entirely unpredictable. In addition to the above factors, in the U.S. it is possible that we may experience seasonality based on patients' annual deductibility limits under their health insurance coverage. While historically seasonality has been minimal, we anticipate increased seasonality due to our increased focus on sales within the U.S. These seasonal variations are difficult to predict accurately, may vary amongst different markets and at times may be entirely unpredictable, which introduces additional risk into our business as we rely upon forecasts of customer demand to build inventory in advance of anticipated sales. In addition, we believe our limited history commercializing our products has, in part, made our seasonal patterns more difficult to discern and therefore predict.

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. In 2019 and 2020, a majority of our total revenue was denominated in foreign currencies. 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, 2021, we had federal and state NOL carryforwards of approximately $324.8 million and $6.5 million, respectively. The federal NOLs began expiring in 2021 and state NOLs began expiring in 2020. As of December 31, 2021, we had federal and state tax credit carryforwards of approximately $8.9 million and $1.6 million, respectively. The federal and state tax credit carryforwards began expiring in 2021 and 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" (the "TCJA"), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES 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 NOL 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 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 must comply with the Essential Requirements laid down in Annex I to the EU Active Implantable Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the CE mark to Barostim, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE Mark to Barostim, we must undergo a conformity assessment procedure, which varies 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 can 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 requires 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 and examine the Technical File and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles 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 maintain our CE Mark and continue to comply with certain EU Directives and in the future EU MDR. Our failure 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 bring Barostim to market 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.

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 action, 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, health information privacy and security laws and transparency 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 may also be 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 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 physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;
- state and foreign law equivalents 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 payor, 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 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 in the current environment of healthcare reform, 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 payors 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 Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be 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 current 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 became fully effective in May 2021 and, among other things:

- strengthened the rules on placing devices on the market and reinforced surveillance once they are available;
- established explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improved 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
- strengthened 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. In December 2021 we began the process of filing the Barostim device under the EU MDR and must go through a successful technical file conformity assessment and quality system audit before being certified for CE mark under the EU MDR.

Risks related to our common stock

We are incurring and will incur significantly increased costs as a result of being a public company, and our management is required to devote substantial time to compliance with our public company responsibilities, which may adversely affect our business, financial condition and results of operations.

As a public company, we have incurred and expect to continue to incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we are now subject to the reporting requirements of the Exchange Act and must comply with the applicable requirements of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC and The Nasdaq Stock Market LLC ("Nasdaq"), including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Compliance with these requirements has and will continue to increase our legal and financial compliance costs and make some activities more time consuming and costly, which may adversely affect our business, financial condition and results of operations.

In addition, our management and other personnel must now divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we have incurred and expect to continue to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act, which will increase when we are no longer an emerging growth company, as defined by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and are not a non-accelerated filer. We have hired, and will need to continue to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and have established an internal audit function. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs. Additional compensation costs and any future equity awards will increase our compensation expense, which would increase our general and administrative expense and could adversely affect our profitability. As a public company, it is more difficult and expensive for us to obtain director and officer liability insurance on reasonable terms. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees, or as executive officers.

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;
- manufacture, 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.

We have broad discretion to determine how to use the funds raised in the IPO and may use them in ways that may not enhance our operating results or the price of our common stock.

Our management has broad discretion over the use of proceeds from the IPO, and we could spend them in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We currently expect to use the net proceeds from the IPO to continue funding the expansion of our direct sales force and commercial organization related to Barostim in the U.S., research and development activities related to Barostim Therapy and working capital and general corporate purposes. If we do not invest or apply the proceeds of the IPO in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

An active trading market for our shares of common stock may not be sustained.

Our common stock began trading on June 30, 2021 and has a limited trading history upon which to assess whether an active public market for our shares may be sustained. The lack of an active market may impair the value of your shares or your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies or in-license new product candidates using our shares as consideration. Furthermore, there can be no guarantee that we will continue to satisfy the continued listing standards of Nasdaq. If we fail to satisfy these listing standards, we could be de-listed, which would have a negative effect on the price of our common stock.

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 will 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 $1.07 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 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, beginning with our second annual report following the IPO, which will be for our fiscal year ending December 31, 2022, 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.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

Our principal stockholders, management and directors (four of whom are affiliated with our principal stockholders) own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2021, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 59% of our outstanding voting stock. Four of our non-employee directors are also affiliated with certain 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 2. Properties

We lease 23,890 square feet of office space in Minneapolis, Minnesota, which houses our principal executive offices and our manufacturing facility. We lease this space under an operating lease agreement that commenced December 1, 2008 and expires July 31, 2024. We intend to add new facilities as we grow and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

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 14, 2022, there were approximately 110 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.

Use of Proceeds from the IPO

On July 2, 2021, we completed our IPO and issued 8,050,000 shares of our common stock at a public offering price of $18.00 per share, which includes 1,050,000 shares of common stock issued upon the exercise in full by the underwriters of their option to purchase additional shares, for total gross proceeds from the offering, before deducting the underwriting discount and other offering expenses, of approximately $144.9 million. After deducting the underwriting discount of $10.1 million and offering expenses of $1.6 million, we received net proceeds of approximately $133.2 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates. J.P. Morgan Securities LLC, Piper Sandler & Co. and William Blair & Company, L.L.C. acted as joint book-running managers of the IPO and Canaccord Genuity LLC acted as a lead manager for the IPO. Shares of our common stock began trading on the Nasdaq Global Select Market on June 30, 2021. The offer and sale of the shares were registered under the Securities Act on a Registration Statement on Form S-1 (File No. 333-256800), which was declared effective on June 29, 2021.

There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus, dated June 29, 2021, filed with the SEC on July 1, 2021 pursuant to Rule 424(b) of the Securities Act.

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 Baroreflex Activation Therapy by sending imperceptible and persistent electrical pulses to baroreceptors located in the wall of the carotid artery to signal the brain to modulate cardiovascular function. Barostim is currently approved by the FDA to improve the symptoms of patients with HFrEF and is CE Marked for HFrEF and resistant hypertension.

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

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

The costs for the device and implantation procedure are reimbursed through various third-party payors, such as government agencies and commercial payors. In the U.S., we estimate that 67% of our target patient population is Medicare-eligible based on the age demographic of the HFrEF patient population indicated for Barostim. As a result, we have prioritized coverage by the CMS while simultaneously developing processes to engage commercial payors. As of July 2020, all Medicare Administrative Contractors have retired automatic coverage denial policies for our Current Procedural Terminology codes, thereby allowing hospitals to be paid for the Barostim procedure. Our reimbursement strategy involves continuing to broaden our current coverage and build our in-house market access team to assist patients and physicians in obtaining appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist. Outside the U.S., reimbursement levels vary by country and within some countries by region. Barostim is eligible for reimbursement in certain countries in the European Union, such as Germany, where annual healthcare budgets for the hospital generally determine the number of patients to be treated and the prices to be paid for the related devices that may be purchased.

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

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

We intend to use a portion of the IPO proceeds to continue funding the expansion of our direct sales force and commercial organization related to Barostim in the U.S. We also intend to continue investing in research and development in the near term to improve clinical outcomes, optimize patient adoption and comfort, increase patient access and enhance the physician and patient experience. Longer term, we plan to explore Barostim’s potential to expand its indications for use to other cardiovascular diseases. As a result of these investments and our commercialization efforts, we expect to continue to incur net losses for the next several years, which may require additional funding and could include future equity and debt financings.

Recent developments

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

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

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

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

Our hospital customers in the U.S. and Europe began to gradually perform elective procedures again during the fourth quarter of 2020. We believe the recovery of our business in the fourth quarter of 2020 and through most of fiscal year 2021 is an encouraging sign for when remaining shelter-in-place and hospital limitations are lifted. As the pandemic eased throughout 2021, we experienced the following positive trends:

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

However, procedure volumes were again negatively impacted by the Delta and Omicron variants of COVID-19 in the third and fourth quarters of 2021. We believe the challenges resulting from COVID-19 will likely continue for the duration of the pandemic. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new

information that may emerge concerning the severity and spread of COVID-19 and its variants and the actions to contain the spread of COVID-19 and its variants or treat its impact.

Factors affecting our performance

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

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

Components of results of operations

Revenue

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

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

Cost of goods sold and gross margin

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

We calculate gross margin as revenue less cost of goods sold divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, but is primarily driven by the average sale price of our product, the percentage of products sold that include a full system (i.e., an IPG and a stimulation lead), as compared to individual IPG sales, and the allocated manufacturing overhead. Although we sell the majority of our devices directly to hospitals, the impact of the average selling price on gross margin is driven by the percentage of products we sold to distributors as compared to those sold directly to hospitals as our average selling price is typically higher on products we sell directly. The full system sales typically have a lower gross margin as they include the cost of an IPG and a stimulation lead whereas individual IPG sales only include the cost of an IPG. The manufacturing overhead costs of Barostim are directly aligned to our production volume and therefore the cost per product is reduced if production levels increase. While we expect our gross margin to be positively affected over time to the extent we are successful in selling more product through our direct sales force and by increasing our production volumes, it will likely fluctuate from

period to period as we continue to introduce new products and adopt new manufacturing processes and technologies.

Research and development expenses

Research and development ("R&D") expenses consist primarily of personnel costs, including salaries, bonuses, employee benefits and stock-based compensation expenses for our R&D employees. R&D expenses also include costs associated with product design efforts, development prototypes, testing, clinical trial programs and regulatory activities, contractors and consultants, equipment and software to support our development, facilities and information technology. We expense research and development costs as they are incurred. We expect R&D expenses to increase in absolute dollars as we continue to develop enhancements to Barostim. Our R&D expenses may fluctuate from period to period due to the timing and extent of our product development and clinical trial expenses related to Barostim in HFrEF.

Selling, general and administrative expenses

Selling, general and administrative ("SG&A") expenses consist primarily of personnel costs, including base salaries, bonuses, employee benefits and stock-based compensation expense for our sales and marketing personnel, including sales commissions, and for administrative personnel that support our general operations such as executive management, financial accounting, information technology and human resources personnel. SG&A expenses also include costs attributable to marketing, as well as travel, legal fees, financial audit fees, insurance, fees for other consulting services, depreciation and facilities. We expense commissions at the time of the sale.

We expect SG&A expenses to increase in absolute dollars as we continue to expand our direct sales force and commercial organization in the U.S. In addition, we will continue to increase our international presence and to develop and assist our channel partners. We also expect our administrative expenses will increase as we increase our headcount and information technology to support our operations as a public company. Additionally, we anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company. However, we expect our SG&A expenses to decrease as a percentage of revenue as our revenue grows.

Interest expense

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

Other expense, net

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

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, 2021, compared to the year ended December 31, 2020

(in thousands)	Year ended December 31, 2021	2020	Change $	Change %
Revenue	$ 13,036	$ 6,053	$ 6,983	115 %
Cost of goods sold	3,640	1,440	2,200	153 %
Gross profit	9,396	4,613	4,783	104 %
Gross margin	72 %	76 %		
Operating Expenses:				
Research and development	7,501	6,410	1,091	17 %
Selling, general and administrative	27,863	9,717	18,146	187 %
Total operating expenses	35,364	16,127	19,237	119 %
Loss from operations	(25,968)	(11,514)	(14,454)	126 %
Interest expense	(2,219)	(2,470)	251	(10)%
Other expense, net	(14,800)	(40)	(14,760)	NM
Loss before income taxes	(42,987)	(14,024)	(28,963)	207 %
Provision for income taxes	(91)	(85)	(6)	7 %
Net loss	$ (43,078)	$ (14,109)	$ (28,969)	205 %

NM – Not meaningful

Revenue

(in thousands)	Revenue by Geography Year ended December 31, 2021	2020	Change $	Change %
United States	$ 9,147	$ 1,733	$ 7,414	428 %
Europe	3,889	4,320	(431)	(10)%
Total Revenue	$ 13,036	$ 6,053	$ 6,983	115 %

Revenue was $13.0 million for the year ended December 31, 2021, an increase of $7.0 million, or 115%, over the year ended December 31, 2020.

Revenue generated in the U.S. was $9.1 million for the year ended December 31, 2021, an increase of $7.4 million, or 428%, over the year ended December 31, 2020. Total HF revenue units in the U.S. totaled 290 and 32 for the years ended December 31, 2021 and 2020, respectively.

HF revenue in the U.S. totaled $8.4 million and $1.0 million for the years ended December 31, 2021 and 2020, respectively. The increase was primarily driven by the continued growth following the commercial launch in 2020, which resulted in the expansion into new sales territories and increased physician and patient awareness of Barostim.

As of December 31, 2021, the Company had a total of 46 active implanting centers, as compared to 11 as of December 31, 2020. Active implanting centers are customers that have completed at least one commercial HF implant in the last 12 months. The number of sales territories in the U.S. increased by eight to a total of 14 during the year ended December 31, 2021. A sales territory is an established regional area held by an account manager, typically after six months of employment.

Legacy hypertension revenue in the U.S. totaled $0.7 million for each of the years ended December 31, 2021 and 2020.

Revenue generated in Europe was $3.9 million for the year ended December 31, 2021, a decrease of $0.4 million, or 10%, over the year ended December 31, 2020. Total revenue units in Europe decreased to 176 for the year ended December 31, 2021, from 193 for the prior year period. The decrease is due to reduced procedure volumes resulting from the Delta and Omicron variants of COVID-19 in 2021. The number of sales territories in Europe remained consistent at six during the year ended December 31, 2021.

Cost of goods sold and gross margin

Cost of goods sold increased $2.2 million, or 153%, to $3.6 million for the year ended December 31, 2021, compared to the year ended December 31, 2020. This increase was primarily due to higher sales of Barostim.

Gross profit was $9.4 million for the year ended December 31, 2021, an increase of $4.8 million, or 104%, over the year ended December 31, 2020. Gross margin decreased to 72% for the year ended December 31, 2021, compared to 76% for the year ended December 31, 2020. Gross margin for the year ended December 31, 2021 was lower due to a larger percentage of our revenue units coming from full systems versus battery replacements for existing patients. This was partially offset by an increase in the average selling price.

Research and development expenses

R&D expenses increased $1.1 million, or 17%, to $7.5 million for the year ended December 31, 2021, compared to the year ended December 31, 2020. This change was primarily driven by a $0.4 million increase in clinical study expenses, a $0.4 million increase in compensation expenses as a result of increased headcount, and a $0.4 million increase in non-cash stock-based compensation expense.

Selling, general and administrative expenses

SG&A expenses increased $18.1 million, or 187%, to $27.9 million for the year ended December 31, 2021, compared to the year ended December 31, 2020. This change was driven by an increase of $9.0 million in compensation expenses, including salaries and commissions, and other employee-related expenses, mainly as a result of increased headcount, a $3.1 million increase in marketing and advertising expenses, primarily related to the commercialization of Barostim in the U.S., a $1.4 million increase in non-cash stock-based compensation expense, a $1.3 million increase related to D&O insurance costs incurred as a result of becoming a public company, a $1.2 million increase in travel expenses and a $1.0 million increase in consulting expenses.

Interest expense

Interest expense decreased $0.3 million, or 10%, to $2.2 million for the year ended December 31, 2021, compared to the year ended December 31, 2020. This was driven by the repayment of the outstanding debt in November 2021 under the Horizon loan agreement.

Other expense, net

Other expense, net was $14.8 million for the year ended December 31, 2021, compared to other expense, net of $40,000 for the year ended December 31, 2020. The expense in 2021 was primarily driven by a $13.7 million increase in expense related to the increase in fair value of our convertible preferred stock warrants due to the change in the value of our common stock from December 31, 2020 to July 2, 2021, which is the date the warrants converted to common stock warrants. The expense in 2021 was also due to a $1.3 million loss on debt extinguishment in connection with the November 2021, repayment of the outstanding debt under the Horizon loan agreement.

Provision for income taxes

Provision for income taxes was nominal for the years ended December 31, 2021 and 2020.

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, 2021 and 2020, we had cash and cash equivalents of $142.1 million and $59.1 million, respectively. For the years ended December 31, 2021 and 2020, our net losses were $43.1 million and $14.1 million, respectively. Our net cash used in operating activities for the years ended December 31, 2021 and 2020, was $27.7 million and $16.1 million, respectively.

Prior to the IPO, our operations were financed primarily by aggregate net proceeds from the sale of our convertible preferred stock of $383.1 million, as well as debt financings. In September 2019, we entered into the Horizon loan agreement to borrow $20.0 million, which was fully repaid on November 3, 2021. In July 2020, we completed an equity financing pursuant to which we issued 62,500,000 shares of Series G Preferred Shares at a price of $0.80 per share, for net proceeds of $49.8 million after deducting offering expenses. On July 2, 2021, we closed our IPO for net proceeds from the offering, after deducting the underwriting discount and other offering expenses payable by us, of $133.2 million.

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 revenue will be sufficient to meet our forecasted requirements for operating liquidity, capital expenditures and debt services for at least the next three years. If these sources are insufficient to satisfy our liquidity requirements, however, we may seek to sell additional equity or enter into a loan agreement. If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Debt financing, if available, may involve covenants further restricting our operations or our ability to incur additional debt. Any 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:

(in thousands)	Year ended December 31 2021	2020
Net cash (used in) provided by:		
Operating activities	$ (27,732)	$ (16,096)
Investing activities	(1,183)	(311)
Financing activities	111,883	49,783
Effect of exchange rate changes on cash and cash equivalents	(8)	(5)
Net change in cash and cash equivalents	$ 82,960	$ 33,371

Cash used in operating activities

Net cash used in operating activities for the year ended December 31, 2021 was $27.7 million and consisted primarily of a net loss of $43.1 million and a decrease in net operating assets of $1.6 million, partially offset by non-cash charges of $13.3 million related to the fair value adjustment to our convertible preferred stock warrants, $1.9 million from non-cash stock-based compensation expense and $1.3 million from the loss on debt extinguishment. Net operating assets consisted primarily of inventory, accounts receivable and accrued expenses to support the growth of our operations.

Net cash used in operating activities for the year ended December 31, 2020 was $16.1 million and consisted primarily of a net loss of $14.1 million and a decrease in net operating assets of $2.9 million. Net operating assets consisted primarily of inventory, accounts receivable, accounts payable and accrued expenses to support the growth of our operations.

Cash used in investing activities:

Cash used in investing activities was $1.2 million and $0.3 million for the years ended December 31, 2021 and 2020, 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, 2021 was $111.9 million and consisted primarily of proceeds from the issuance of common stock of $133.2 million, partially offset by the repayment of the outstanding debt balance and related fees of $21.3 million.

Net cash provided by financing activities for the year ended December 31, 2020 was $49.8 million and consisted entirely of proceeds from the issuance of Series G convertible preferred stock.

Indebtedness

In September 2019, we entered into the Horizon loan agreement under which we borrowed $20.0 million, which is the maximum borrowing under the Horizon loan agreement. Amounts outstanding under the Horizon loan agreement bore interest at a floating per annum rate equal to 10% plus the amount by which the 30-day U.S. dollar LIBOR rate on the first business day of the month exceeded 2.2%. The Horizon loan agreement initially required interest only payments through October 2021 and then 36 monthly principal and interest payments beginning in November 2021. In August 2020, we entered into an amended agreement with Horizon to extend the interest only period through April 2022, followed by 30 monthly principal and interest payments beginning May 2022. A final payment of $0.7 million, equal to 3.5% of the original principal, was due to be paid in October 2024. On November 3, 2021, we fully repaid our outstanding principal balance of $20.0 million and incurred an additional $1.3 million related to a loss on debt extinguishment in connection

with the Horizon loan agreement. We were in compliance with all covenants at the time the principal balance was fully repaid.

Critical accounting policies and estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP 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 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 nonemployee directors, including grants of restricted shares and stock options, to be recognized as expense in the statements of operations and comprehensive loss based on their grant date fair values. We estimate the grant date fair value of stock options using the Black-Scholes option pricing model. We use an estimate of the value of our common stock, with the assistance of an independent appraiser, to determine the fair value of options.

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

- Fair value of common stock — Given the absence of a public trading market for our common stock prior to the IPO, the fair value of our common stock was determined by our Board of Directors with the assistance of an unrelated third-party valuation firm. The valuation was determined in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held Company Equity Securities Issued as Compensation. For the valuation as of the date of pricing of the IPO, the fair value of our common stock was determined by our Board of Directors to be the public offering price of the shares of common stock issued in the IPO. For valuations after the completion of the IPO, our Board of Directors will determine the fair value of each share of common stock based on the closing price of our common stock as reported on the date of grant. Future expense amounts for any particular period could be affected by changes in our assumptions or market conditions.

- Expected share price volatility — Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar (guideline) companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The group of guideline companies have characteristics similar to us, including stage of product development and focus on the life science industry.

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

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

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

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

JOBS Act accounting election

The 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, which are carried at quoted market prices. We do not currently use or plan to use financial derivatives in our investment portfolio.

Foreign currency exchange rate risk

Portions of our revenue and our operating expenses are incurred outside the U.S. and thus 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, 2021 and 2020, our cash and cash equivalents were maintained with one financial institution in the U.S., and our current deposits are likely in excess of insured limits. We believe this institution has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
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, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), 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, 2021 and 2020, 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 financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 22, 2022

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 142,072	$ 59,112
Accounts receivable, net	2,560	1,281
Inventory	3,880	3,343
Prepaid expenses and other current assets	2,585	605
Total current assets	151,097	64,341
Property and equipment, net	1,425	410
Other non-current assets	26	26
Total assets	$ 152,548	$ 64,777
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 510	$ 483
Accrued expenses	5,398	3,583
Warrant liability	—	3,911
Total current liabilities	5,908	7,977
Long-term debt	—	19,278
Other long-term liabilities	681	777
Total liabilities	6,589	28,032
Commitments and contingencies (Note 10)		
Convertible preferred stock, $0.01 par value, 10,000,000 and 237,370,645 authorized as of December 31, 2021 and December 31, 2020, respectively; 0 and 223,541,754 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	—	329,983
Stockholders' equity (deficit):		
Common stock, $0.01 par value, 200,000,000 and 625,217,795 authorized as of December 31, 2021 and December 31, 2020, respectively; 20,399,337 and 360,412 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	204	4
Additional paid-in capital	540,707	58,624
Accumulated deficit	(394,754)	(351,676)
Accumulated other comprehensive loss	(198)	(190)
Total stockholders' equity (deficit)	145,959	(293,238)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 152,548	$ 64,777

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,	
	2021	2020
Revenue	$ 13,036	$ 6,053
Cost of goods sold	3,640	1,440
Gross profit	9,396	4,613
Operating expenses:		
Research and development	7,501	6,410
Selling, general and administrative	27,863	9,717
Total operating expenses	35,364	16,127
Loss from operations	(25,968)	(11,514)
Interest expense	(2,219)	(2,470)
Other expense, net	(14,800)	(40)
Loss before income taxes	(42,987)	(14,024)
Provision for income taxes	(91)	(85)
Net loss	(43,078)	(14,109)
Cumulative translation adjustment	(8)	(1)
Comprehensive loss	$ (43,086)	$ (14,110)
Net loss per share, basic and diluted	$ (4.16)	$ (37.01)
Weighted-average common shares used to compute net loss per share, basic and diluted	10,360,054	387,083

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

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

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' (deficit) equity
	Shares	Amount	Shares	Amount				
Balances as of December 31, 2019	161,041,754	$ 279,983	483,931	$ 5	$ 58,708	$ (337,567)	$ (189)	$ (279,043)
Exercise of stock options	—	—	175	—	—	—	—	—
Repurchase of common stock	—	—	(123,694)	(1)	1	—	—	—
Employee stock compensation	—	—	—	—	132	—	—	132
Issuance of Series G preferred stock, net of costs	62,500,000	49,783	—	—	—	—	—	—
Accretion of Series G issuance costs	—	217	—	—	(217)	—	—	(217)
Net loss for the year ended December 31, 2020	—	—	—	—	—	(14,109)	—	(14,109)
Cumulative translation adjustment	—	—	—	—	—	—	(1)	(1)
Balances as of December 31, 2020	**223,541,754**	**$ 329,983**	**360,412**	**$ 4**	**$ 58,624**	**$ (351,676)**	**$ (190)**	**$ (293,238)**
Exercise of stock options	—	—	59,341		23	—	—	23
Employee stock compensation	—	—	—	—	1,912	—	—	1,912
Issuance of common stock, net of offering costs	—	—	8,050,000	81	133,080	—	—	133,161
Reverse stock split	—	—	—	—	(1)	—	—	(1)
Conversion of Series G preferred stock	(223,541,754)	(329,983)	11,929,584	119	347,069	—	—	347,188
Net loss for the year ended December 31, 2021	—	—	—	—	—	(43,078)	—	(43,078)
Cumulative translation adjustment	—	—	—	—	—	—	(8)	(8)
Balances as of December 31, 2021	**—**	**$ —**	**20,399,337**	**$ 204**	**$ 540,707**	**$ (394,754)**	**$ (198)**	**$ 145,959**

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,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (43,078)	$ (14,109)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,912	132
Depreciation of property and equipment	168	75
Amortization of deferred financing costs and loan discount	229	286
Loss on debt extinguishment	1,325	—
Changes in fair value of convertible preferred stock warrants	13,294	371
Changes in operating assets and liabilities:		
Accounts receivable	(1,279)	(562)
Inventory	(537)	(1,271)
Prepaid expenses and other current assets	(1,980)	(226)
Accounts payable	27	46
Accrued expenses	2,187	(838)
Net cash used in operating activities	(27,732)	(16,096)
Cash flows from investing activities:		
Purchase of property and equipment	(1,183)	(311)
Net cash used in investing activities	(1,183)	(311)
Cash flows from financing activities:		
Proceeds from the exercise of common stock options	23	—
Proceeds from issuance of Series G Preferred Stock, net of fees	—	49,783
Payments related to reverse stock split	(1)	—
Proceeds from the issuance of common stock, net of offering costs	133,161	—
Repayment on debt financing	(21,300)	—
Net cash provided by financing activities	111,883	49,783
Effect of currency exchange on cash and cash equivalents	(8)	(5)
Net change in cash and cash equivalents	82,960	33,371
Cash and cash equivalents at beginning of year	59,112	25,741
Cash and cash equivalents at end of period	$ 142,072	$ 59,112
Supplemental Information:		
Cash paid for interest	$ 1,706	$ 2,033
Cash paid for income taxes	2	10

The accompanying notes are an integral part of these 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. All intercompany balances and transactions have been eliminated in consolidation.

JOBS Act accounting election

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

Use of estimates

Preparation of the 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, 2021 and 2020, cash equivalents consisted of money market funds, which are stated at cost and approximate fair value.

Accounts Receivable

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

Inventory

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

Revenue recognition

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

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

Stock-Based Compensation

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

Recently accounting pronouncements

In February 2016, the Financial Accounting Standards Board issued Accounting Standards Update 2016-02, Leases ("Topic 842"). The purpose of Topic 842 is to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet, including those previously classified as operating leases under current U.S. GAAP and disclosing key information about leasing arrangements. Topic 842 is effective for private companies and smaller reporting companies for annual periods beginning after December 15, 2021 and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted, and the Company must elect whether the date of initial application is the beginning of the earliest comparative period presented in the financial statements, or the beginning of the period of adoption. Under the alternative modified retrospective transition approach, the reported results for 2022 reflect the application of Topic 842 guidance, whereas comparative periods and their respective disclosures prior to the adoption of Topic 842 are presented using the legacy guidance of Accounting Standards Classification ("ASC") 840. As a result of adopting the new standard, the Company will recognize right-of-use assets of $579,000 and lease liabilities of $561,000 million as of January 1, 2022. The

difference between the amount of right-of-use assets and lease liabilities recognized includes adjustments to prepaid rent. There will be no change to net deferred tax balances as a result of the Company's adoption of Topic 842. The adoption of Topic 842 did not impact the Company's results of operations or cash flows.

3. Selected balance sheet information

Inventory consists of the following at:

(in thousands)	December 31, 2021	December 31, 2020
Raw material	$ 1,593	$ 1,361
Work-in-process	482	321
Finished goods	1,805	1,661
	$ 3,880	$ 3,343

Property and equipment, net consists of the following at:

(in thousands)	December 31, 2021	December 31, 2020
Office furniture and equipment	$ 271	$ 189
Lab equipment	1,565	1,272
Computer equipment and software	556	516
Leasehold improvements	88	44
Capital equipment in process	813	89
	3,293	2,110
Less: Accumulated depreciation and amortization	1,868	1,700
	$ 1,425	$ 410

Depreciation expense was $0.2 million and $0.1 million for the years ended December 31, 2021 and 2020, respectively.

Accrued expenses consist of the following at:

(in thousands)	December 31, 2021	December 31, 2020
Clinical trial and other professional fees	$ 1,607	$ 1,690
Bonuses	2,028	794
Paid time off	699	552
Customer rebates	380	—
Taxes	351	42
Interest payable	—	356
Other	333	149
	$ 5,398	$ 3,583

4. Fair value measurements

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

- Level 1 — Inputs are quoted prices in active markets for identical assets or liabilities.

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

- Level 3 — Inputs are unobservable for the asset or liability.

The following table sets forth the Company's liabilities that were measured at fair value on a recurring basis by level within the fair value hierarchy. There was no convertible preferred stock warrant liability as of December 31, 2021.

(in thousands) Balance as of December 31, 2020	Level 1	Level 2	Level 3	Total
Liabilities:				
Convertible preferred stock warrant liability	$ —	$ —	$ 3,911	$ 3,911
Total liabilities	$ —	$ —	$ 3,911	$ 3,911

The convertible preferred stock warrant liability related to warrants issued in connection with loan and security agreements entered into in September 2014, as amended in July 2015, in May 2016 and in September 2019. These warrants were originally issued to purchase shares of Series F-2 convertible preferred stock and Series G convertible preferred stock ("Series G Preferred Shares"). In connection with the closing of the initial public offering ("IPO"), these convertible preferred stock warrants became warrants to purchase 108,406 shares of common stock and were reclassified to equity.

The convertible preferred stock warrant liability also related to a warrant issued to Biosense Webster, Inc. ("BWI"), an affiliate of Johnson & Johnson Innovation — JJDC, Inc., to purchase Series G Preferred Shares with an exercise price of $0.01 per share. In connection with the closing of the IPO, the BWI warrant to purchase Series G Preferred Shares became exercisable to purchase 607,725 shares of common stock at an exercise price of $0.16 per share.

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

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

(in thousands)	December 31, 2021	2020
Beginning of the period	$ 3,911	$ 3,540
Change in fair value	13,294	371
Conversion to common stock warrants	(17,205)	—
End of the period	$ —	$ 3,911

There were no transfers in or out of Level 1, Level 2 or Level 3 fair value measurements during the periods ended December 31, 2021 and 2020.

5. Debt

Horizon loan agreement

In September 2019, the Company entered into a loan and security agreement ("Horizon loan agreement") with Horizon Technology Finance Corporation ("Horizon") under which it could borrow up to a total of $20.0 million at a floating per annum rate equal to 10% plus the amount by which the 30-day U.S. dollar LIBOR rate on the first business day of the month exceeds 2.2%. The Horizon loan agreement initially required interest only payments through October 2021 and then 36 monthly principal and interest payments beginning in November 2021. A final payment of $0.7 million, equal to 3.5% of the original principal, was due in October 2024. The Horizon loan agreement initially required the Company to maintain cash on deposit of not less than $5.0 million in accounts over which Horizon maintained an account control agreement. This minimum cash on deposit requirement was released in July 2020, following the satisfaction of a financing milestone. The borrowings were collateralized by all or substantially all of the assets of the Company. The Horizon loan agreement required the payment of certain penalties if the loan was paid off prior to maturity for any reason, including pursuant to a subjective acceleration clause, and included various restrictive covenants, including a restriction on the payment of dividends.

In August 2020, the Company entered into an amended agreement with Horizon to extend the interest only period through April 2022, followed by 30 monthly principal and interest payments beginning in May 2022.

In connection with the Horizon loan agreement, the Company recorded $1.1 million of debt issuance costs and discounts as a reduction of long-term debt. Of this total, $0.5 million related to legal fees and an investment bank fee and $0.6 million related to the warrants to purchase Series G Preferred Shares issued by the Company. These warrants were exercisable on the grant date at a price of $0.80 per share and expire in September 2029. The Company used the Black-Scholes option pricing model to determine the grant date fair value of these warrants.

On November 3, 2021 the Company fully repaid all amounts outstanding under the Horizon loan agreement. The total repayment amount was $21.3 million, inclusive of $1.3 million of prepayment and other fees, which represent a loss on extinguishment of debt and are included in Other expense, net on the consolidated statements of operations. The Company was in compliance with all related covenants at the time the principal balance was fully repaid. There was no debt outstanding in relation to the Horizon loan agreement as of December 31, 2021.

6. Stockholders' equity

Initial Public Offering

During 2016, the Company issued 72,125,000 shares of Series G Preferred Shares at a price of $0.80 per share, for net proceeds to the Company of approximately $57.4 million after deducting offering expenses payable by the Company. The same Series G investors agreed to purchase an additional $35.3 million of Series G Preferred Shares upon the Company's achievement of a certain operational milestone, subject to limited closing conditions. In January 2019, May 2019 and August 2019, the Series G investors purchased additional Series G Preferred Shares, resulting in net proceeds to the Company of $24.7 million.

In July of 2020, the Company issued 62,500,000 additional Series G Preferred Shares, at a price of $0.80 per share, for net proceeds to the Company of $49.8 million after deducting offering expenses payable by the Company.

On May 31, 2016, holders of the requisite number of the Company's then-outstanding convertible preferred stock approved the conversion of all preferred stock into shares of the Company's common stock in connection with a new equity financing. Accordingly, all of the Company's then-outstanding preferred stock was converted on a one-for-one basis into shares of the Company's common stock. Under the terms of the equity financing, each prior holder of preferred stock who purchased a required amount of securities in the new financing was entitled to exchange certain of the shares of common stock received in the conversion described above into new prime series of preferred stock corresponding to the series of preferred stock from which the common stock was previously converted. All of the previously held Series A-1, B-1, C-1, D-1, E-1 and F preferred stock had similar features as the Series A-2 preferred stock ("Series A-2 Preferred Shares"), Series B-2 preferred stock ("Series B-2 Preferred Shares"), Series C-2 preferred stock ("Series C-2 Preferred Shares"), Series D-2 preferred stock ("Series D-2 Preferred Shares"), Series E-2 preferred stock ("Series E-2 Preferred Shares") and Series F-2 preferred stock ("Series F-2 Preferred Shares") described below. The Series A-2, Series B-2, Series C-2, Series D-2, Series E-2, Series F-2 and Series G Preferred Shares are referred to collectively as the "Preferred Shares."

As of December 31, 2020, convertible preferred stock consisted of the following:

	Authorized	Issued and Outstanding	Carrying Value *(in thousands)*	Aggregate Liquidation Preference *(in thousands)*
Series A-2	2,454,686	2,454,686	$ 4,909	$ 4,909
Series B-2	2,963,069	2,963,069	7,526	7,526
Series C-2	4,308,394	4,308,394	13,141	13,141
Series D-2	8,631,967	8,631,967	53,518	53,518
Series E-2	12,114,211	10,135,320	76,826	91,806
Series F-2	29,773,318	29,548,318	41,663	104,783
Series G	177,125,000	165,500,000	132,400	494,550
	237,370,645	223,541,754	$ 329,983	$ 770,233

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

Upon the closing of the IPO, all shares of convertible preferred stock were automatically converted into common stock. Series G Preferred Shares were converted into common stock on a 15.819-for-1 basis, and all other shares of convertible preferred stock were automatically converted into common stock on a 39.548-for-1 basis. The conversion of the outstanding preferred stock resulted in an aggregate of 11,929,584 shares of common stock. As of December 31, 2021, no preferred stock is outstanding.

Reverse Stock Split

In connection with the IPO, the Company's Board of Directors and stockholders approved a 1-for-39.548 reverse stock split of the Company's common stock. The reverse stock split became effective on June 22, 2021. The par value of the common stock was not adjusted as a result of the reverse stock split. Adjustments corresponding to the reverse stock split were made to the ratio at which the convertible preferred stock will convert into common stock in connection with the closing of the IPO. Accordingly, all share and per-share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse stock split and the adjustment of the conversion ratio of the convertible preferred stock.

Preferred Stock Warrants and Common Stock Warrants

In connection with the loan and security agreement entered into by the Company in September 2014 and the amendment in July 2015, the Company issued a warrant to purchase shares of Series F-2 convertible preferred stock.

In connection with the loan and security agreement entered into in May 2016, the Company issued a warrant to purchase Series G Preferred Shares.

The Company issued to BWI a warrant to purchase shares of Series E-2 convertible preferred stock that only would have become exercisable in the event of an acquisition or asset transfer involving the Company and it expired upon our IPO.

In September of 2018, the Company also issued to BWI a warrant to purchase up to 10,000,000 Series G Preferred Shares with an exercise price of $0.01 per share. The warrant to purchase Series G Preferred Shares became exercisable upon our IPO and would have expired on the earlier of (i) an acquisition or asset transfer involving the Company or (ii) 180 days after receipt of the data from the post-market stage of the BeAT-HF pivotal trial.

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

Warrants to purchase shares of our common stock are summarized below:

	Common Stock Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2020	—	$ —
Preferred stock warrants converted to common stock warrants at IPO	716,131	2.39
Exercised	—	—
Outstanding at December 31, 2021	716,131	$ 2.39

7. Stock-Based compensation

Summary of plans and activity

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

In connection with the IPO in 2021, the Company's Board of Directors and stockholders established the 2021 Equity Incentive Plan ("2021 Plan"). The number of shares of common stock initially reserved for issuance under the 2021 Plan was 1,854,490 newly reserved shares in addition to the 600,373 shares that remained available for issuance under the 2001 Plan. The shares available for issuance under the 2021 Plan will automatically increase on the first day of each year, commencing January 1, 2022 and ending on (and including) January 1, 2031, in an amount equal to 5% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of each automatic increase, or such lesser number of shares as determined by the Board of Directors. The 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, 2021, there were 1,789,453 shares available for future issuance under the 2021 Plan.

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

During the years 2008 through December 31, 2021, the Board of Directors authorized the grant of stock options for the purchase of shares of common stock to the employers of certain nonemployee directors. The options were not granted under the 2001 Plan or the 2021 Plan, but terms are substantially the same as the Company's standard form of option agreement for nonemployee 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, 2019	966,146	$ 1.58	$ 2,256
Granted	517,566	$ 4.35	
Cancelled / Forfeited	(10,178)	$ 4.35	
Exercised	(175)	$ 0.40	
Balance as of December 31, 2020	1,473,359	$ 2.77	$ 3,745
Granted	1,411,717	$ 13.31	
Cancelled / Forfeited	(76,294)	$ 11.25	
Exercised	(59,341)	$ 0.39	
Balance as of December 31, 2021	2,749,441	$ 7.93	$ 16,262
Options exercisable as of December 31, 2021	1,060,820	$ 2.53	$ 10,303

As of December 31, 2021, stock options outstanding included 9,993 options that were not granted under the 2001 Plan or the 2021 Plan. For options outstanding as of December 31, 2021, the weighted average remaining contractual life was 8.1 years. For options exercisable as of December 31, 2021, the weighted average remaining contractual life was 6.6 years.

In connection with the IPO, the Company's Board of Directors and stockholders also established an Employee Stock Purchase Plan (the "ESPP"). The number of shares of common stock initially reserved for issuance under the ESPP was 278,170. The shares available for issuance under the ESPP will automatically increase on the first day of each year, commencing January 1, 2022 and ending on (and including) January 1, 2031, in an amount equal to 1% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of each automatic increase, or such lesser number of shares as determined by the Board of Directors. The ESPP will permit certain of the Company's U.S. employees to purchase shares of the Company's common stock at a price per share not less than 85% of the lower of (i) the closing market price per share of the Company's common stock on the first day of the applicable purchase period or (ii) the closing market price per share of the Company's common stock on the purchase date at the end of the applicable six-month purchase period. The first purchase period commenced January 1, 2022. Accordingly, as of December 31, 2021, no shares of common stock have been purchased under the ESPP.

Stock-based compensation expense

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

The following table provides the weighted average fair value of options granted to employees and the related assumptions used in the Black-Scholes option pricing model for the years ended December 31, 2021 and 2020.

	Year ended December 31, 2021	2020
Weighted average fair value of options granted	$ 5.64	$ 1.98
Expected term (in years) — non-officer employees	2.7 to 6.1	2.7
Expected term (in years) — officer employees	3.0	3.0
Expected volatility	56.1% to 63.4 %	62.6 %
Expected dividend yield	— %	— %
Risk-free interest rate	0.17% to 1.44 %	0.16% to 0.18 %

The Company reviews these assumptions on a periodic basis and adjusts them, as necessary. The expected term of an award was determined based on the Company's 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. The expected volatility is based upon observed volatility of comparable public companies. The expected dividend yield is assumed to be zero, as the Company has never paid dividends and has no current plans to do so. The risk-free interest rate is based on the yield on U.S. Treasury securities for a period approximating the expected term of the options being valued.

For the years ended December 31, 2021 and 2020, the Company recognized stock-based compensation expense as follows:

(in thousands)	Year Ended December 31, 2021	2020
Selling, general & administrative	$ 1,468	$ 88
Research & development	420	43
Cost of goods sold	24	1
	$ 1,912	$ 132

As of December 31, 2021, unrecognized compensation expense related to unvested stock-based compensation arrangements was $6.9 million. As of December 31, 2021, the related weighted average period over which it is expected to be recognized is approximately 3.3 years.

Early exercise of stock options

Under the 2001 Plan, the Company has issued options to certain executive officers with early-exercise provisions. The options may be exercised by the holder any time after they are granted. The Company has the right to repurchase, at the original option exercise price, shares issued pursuant to such early-exercise provisions, upon the termination of employment or death of the stockholder. This repurchase right expires based upon the original option vesting schedule. As of December 31, 2021 and 2020, there have been no early exercises and therefore there is no liability recorded for the early exercise of stock options.

8. Income taxes

As of December 31, 2021 and 2020, a valuation allowance was recorded against all deferred tax assets due to the Company's cumulative net loss position.

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

(in thousands)	Year Ended December 31, 2021	2020
Current		
Federal and state	$ —	$ —
Foreign	91	85
Total current	91	85
Total provision for income taxes	$ 91	$ 85

Provision for income taxes for the years ended December 31, 2021 and 2020 was $91,000 and $85,000, respectively.

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

	Year Ended December 31, 2021	2020
Tax at federal statutory rate	21.0 %	21.0 %
Permanent differences	(9.0)	(0.5)
Research and development ("R&D") tax credit	0.9	2.6
Uncertain tax position	(0.2)	(0.5)
State, net of federal benefit	(0.7)	0.3
Deferred rate change	2.5	(0.3)
Change in valuation allowance	(14.7)	(23.2)
Total	(0.2)%	(0.6)%

Significant components of net deferred tax assets were as follows:

(in thousands)	Year Ended December 31, 2021	2020
Deferred tax assets		
Net operating loss carryforwards	$ 74,716	$ 68,957
R&D tax credits	8,711	8,318
IRC Section 59e election	8,577	7,955
Start-up costs	1,104	1,198
Non-qualified stock options	350	136
Property and equipment	91	90
Accrued vacation	151	106
Preferred stock warrants	-	607
Other	59	67
Total deferred tax assets	93,759	87,434
Valuation allowance	(93,759)	(87,434)
Net deferred tax assets	$ —	$ —

As of December 31, 2021, the Company had federal and state net operating loss carryforwards ("NOLs") of approximately $324.8 million and $6.5 million, respectively. The federal NOLs began expiring in 2021 and the state NOLs began expiring in 2020. As of December 31, 2021, the Company had federal and state tax credit carryforwards of approximately $8.9 million and $1.6 million, respectively. The federal tax credit carryforwards began expiring in 2021 and the state tax credits began 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. The Company has not performed a detailed analysis to determine whether an ownership change has occurred. Such a change of ownership would limit the Company's utilization of the NOLs and could be triggered by subsequent sales of securities by the Company or its stockholders.

The changes to our gross unrecognized tax benefits were as follows:

(in thousands)	Year Ended December 31, 2021	2020
Gross unrecognized tax benefits at beginning of year	$ 1,840	$ 1,757
Gross increases:		
Prior year tax positions	10	—
Current year tax positions	91	83
Gross decreases:		
Prior year tax positions	(2)	—
Gross unrecognized tax benefits at end of year	$ 1,939	$ 1,840

All of these unrecognized tax benefits, if recognized, would impact the effective tax rate before taking consideration of the valuation allowance. The Company recognized approximately $61,000 and $56,000 of interest or penalties for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021 and 2020, total accrued interest and penalties are $0.3 million and $0.3 million, respectively. The Company recognizes accrued interest and penalties related to unrecognized tax positions as a component of income tax expense. The Company does not expect a significant change in the amount of unrecognized tax benefits in the next year.

The Company is subject to U.S. federal income tax as well as income tax of multiple state and foreign jurisdictions. Tax years from 2001 through present remain open for audit under the applicable statute of limitations due to the carryover of the unused NOLs and tax credit carryforwards. The Company does not have any tax audits or other proceedings pending.

9. (Loss) Earnings Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

(in thousands)	Year Ended December 31, 2021	2020
Numerator:		
Net loss	$ (43,078)	$ (14,109)
Accretion of preferred stock to redemption value	—	(217)
Net loss attributable to common stockholders	$ (43,078)	$ (14,326)
Denominator:		
Weighted average common shares outstanding — basic and diluted	10,360,054	387,083
Net loss per share attributable to common stockholders — basic and diluted	$ (4.16)	$ (37.01)

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

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

	Year Ended December 31, 2021	2020
Options to purchase common stock	2,749,441	1,473,359
Warrants to purchase redeemable convertible preferred stock (as converted to common stock)	—	108,406
Warrants to purchase common stock	716,131	—
Redeemable convertible preferred stock (as converted to common stock)	—	11,929,584
	3,465,572	13,511,349

10. Commitments and contingencies

Commitments

Operating Leases

The Company has entered into an operating lease agreement for its office, manufacturing and research facility, which expires in 2024. Rent expense for the years ended December 31, 2021 and 2020 was $0.4 million and $0.4 million, respectively.

Future minimum lease payments under all operating leases as of December 31, 2021 are as follows for the years ending:

(in thousands)	
December 31, 2022	$ 227
December 31, 2023	234
December 31, 2024	138
	$ 599

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual or disclosure as of December 31, 2021 or December 31, 2020.

11. Employee benefit plans

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

12. Segment, geographic information and revenue disaggregation

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

and its Chief Executive Officer evaluate performance based primarily on revenue in the geographic locations in which the Company operates.

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

(in thousands)	Year ended December 31, 2021	2020
U.S.	$ 9,147	$ 1,733
Germany	3,250	3,790
Other countries	639	530
	$ 13,036	$ 6,053

As of December 31, 2021 and 2020, 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, 2021, 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

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

In addition, for so long as we qualify as an "emerging growth company" as defined under the JOBS Act or remain a non-accelerated filer, our independent registered accounting firm is not required to issue an attestation report on our internal control over financial reporting.

Item 9B. Other Information

None.

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 2022 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

Item 11. Executive Compensation

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2022 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

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 2022 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

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 2022 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

Item 14. Principal Accountant Fees and Services

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2022 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

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, 2021 and 2020

Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2021 and 2020

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) for the years ended December 31, 2021 and 2020

Consolidated Statements of Cash Flows for the years ended December 31, 2021 and 2020

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	Amended and Restated Certificate of Incorporation of CVRx, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 7, 2021)
3.2	Amended and Restated By-Laws of CVRx, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on July 7, 2021)
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 September 12, 2014, issued by the Company to Life Science Loans, LLC (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)
4.3*	Warrant to Purchase Stock, dated as of September 12, 2014, issued by the Company to Silicon Valley Bank (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)

4.4*	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)
4.5*	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)
4.6*	Warrant to Purchase Stock, dated as of May 31, 2016, issued by the Company to Oxford Finance LLC (incorporated by reference to Exhibit 4.7 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 4.8 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)
4.8*	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)
4.9*	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)
4.10	Warrant to Purchase Series E-2 Convertible Preferred Stock, dated as of September 28, 2018, issued by the Company to Biosense Webster, Inc. (incorporated by reference to Exhibit 4.11 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)
4.11	Warrant to Purchase Series G Convertible Preferred Stock, dated as of September 28, 2018, issued by the Company to Biosense Webster, Inc. (incorporated by reference to Exhibit 4.12 to the Company's Registration Statement on Form S-1 filed on June 4, 2021)
4.12	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)
4.13	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)
4.14	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)
4.15	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)
4.16†	Description of the Company's Common Stock

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	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)
10.7#	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)
10.8#	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)
10.9#	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)
10.10#	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)
10.11#	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)
10.12#	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)
10.13#	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)
10.14†	Employee Stock Purchase Plan
10.15*	Venture Loan and Security Agreement, dated as of September 30, 2019, by and among Horizon Technology Finance Corporation, as a lender and collateral agent, and the Company, as borrower (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A filed on June 23, 2021)

10.16#	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)
10.17	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)
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
21.1†	List of Subsidiaries
23.1†	Consent of Grant Thornton LLP, independent registered public accounting firm
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 behalf by the undersigned, thereunto duly authorized.

Date: February 22, 2022

CVRX, INC.

By: /s/ Nadim Yared
Name: Nadim Yared
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 22, 2022

Signature	Title	Date
/s/ Nadim Yared **Nadim Yared**	President and Chief Executive Officer (Principal Executive Officer)	February 22, 2022
/s/ Jared Oasheim **Jared Oasheim**	Chief Financial Officer (Principal Financial and Accounting Officer)	February 22, 2022
/s/ Ali Behbahani **Ali Behbahani**	Director	February 22, 2022
/s/ John Nehra **John Nehra**	Director	February 22, 2022
/s/ Geoff Pardo **Geoff Pardo**	Director	February 22, 2022
/s/ Joseph Slattery **Joseph Slattery**	Director	February 22, 2022
/s/ Mudit Jain **Mudit Jain**	Director	February 22, 2022
/s/ Kirk Nielsen **Kirk Nielsen**	Director	February 22, 2022
/s/ Martha Shadan **Martha Shadan**	Director	February 22, 2022

XBRL-Only Content Section

Element	Value
EntityCentralIndexKey#	0001235912
CurrentFiscalYearEndDate	--12-31
DocumentFiscalYearFocus	2021
DocumentFiscalPeriodFocus	FY
AmendmentFlag	true/false