As confidentially submitted to the Securities and Exchange Commission on April 9, 2021.
This draft registration statement has not been publicly filed with
the Securities and Exchange Commission and all information herein remains strictly confidential.
Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

CVRx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**41-1983744**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification No.)**

9201 West Broadway Avenue, Suite 650
Minneapolis, MN 55445
763-416-2840
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Nadim Yared
President and Chief Executive Officer
CVRx, Inc.
9201 West Broadway Avenue, Suite 650
Minneapolis, MN 55445
763-416-2840
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Amy C. Seidel, Esq. **Ben A. Stacke, Esq.** **Faegre Drinker Biddle & Reath LLP** **2200 Wells Fargo Center** **Minneapolis, MN 55402-1425** **Telephone: (612) 766-7000**	**Ilir Mujalovic, Esq.** **Shearman & Sterling LLP** **599 Lexington Avenue** **New York, NY 10022** **(212) 848-4000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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 ☐ Smaller reporting company ☒ Emerging growth company ☒

Non-accelerated filer ☒

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 to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Proposed maximum aggregate offering price(1)(2)**	**Amount of registration fee**
Common stock, par value $0.01 per share	$	$

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) of the Securities Act of 1933, as amended.

(2) Includes the aggregate offering price of additional shares that the underwriters have the option to purchase, if any.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED , 2021

PRELIMINARY PROSPECTUS

Shares

Common Stock

This is CVRx, Inc.'s initial public offering. We are selling shares of our common stock.

We expect the public offering price to be between $ and $ per share. Currently, no public market exists for the shares. After pricing of the offering, we expect that the shares will trade on the under the symbol "CVRX."

We are an emerging growth company under the federal securities laws and are subject to reduced public company disclosure standards. See "Prospectus Summary — Implications of Being an Emerging Growth Company."

Investing in the common stock involves risks that are described in the "Risk Factors" section beginning on page 13 of this prospectus.

	Per share	Total
Public offering price	$	$
Underwriting discount(1)	$	$
Proceeds, before expenses, to us	$	$

(1) See "Underwriting" of this prospectus for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on or about , 2021.

J.P. Morgan **Piper Sandler** **William Blair**

Canaccord Genuity

The date of this prospectus is , 2021.

Table of contents

In this prospectus, the "Company," "CVRx," "we," "us" and "our" and similar terms refer to CVRx, Inc. and its consolidated subsidiaries. References to our "common stock" refer to the common stock of CVRx, Inc.

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell shares of common stock and seeking offers to buy shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

BAROSTIM®, BAROSTIM NEO®, BAROSTIM THERAPY®, BAT®, CVRX® and NEO®, which are our property and are protected under applicable intellectual property laws, are some of our trademarks used in this prospectus. This prospectus also includes trademarks, trade names and service marks that are the property of other organizations. Solely for convenience, our trademarks and trade names referred to in this prospectus appear without the ® and ™ symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor, to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Prospectus summary

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our common stock, you should read this entire prospectus carefully, including the sections of this prospectus entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes contained elsewhere in this prospectus.

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 NEO, 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 NEO 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 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 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 an 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 the BAROSTIM NEO as a safe, effective and minimally invasive device-based treatment option for HFrEF.

We believe BAROSTIM NEO 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 NEO 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 our BAROSTIM NEO 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 NEO for HFrEF. These results showed significant improvement in the following patient-centered outcomes:
  - **Quality of Life (measured by Minnesota Living with Heart Failure ("MLWHF") standardized questionnaire).** 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 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 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 NEO 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 NEO'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 cost-impact analysis published in 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 NEO 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.

Our BAROSTIM NEO is a minimally invasive neuromodulation device that consists of two implantable components, an IPG and a stimulation lead, and is managed remotely 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") of BAROSTIM NEO 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 NEO.

We primarily sell our BAROSTIM NEO 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, which included 13 Account Managers and five Clinical Field Specialists in the U.S. as of March 31, 2021, 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 as well as a qualification process to aid in the identification of the appropriate patients for our therapy. In the U.S., BAROSTIM NEO is fully reimbursed by the Center of Medicare and Medicaid Services ("CMS") across all regions. We offer assistance to patients and providers with reimbursement approvals, if required. We plan to continue to expand 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 our BAROSTIM NEO, 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 of BAROSTIM NEO and the use of local anesthetics, potentially expanding our annual market opportunity in the U.S. In the future, we plan to explore BAROSTIM NEO's potential to expand its indications for use to other cardiovascular diseases, including different forms of HF, hypertension, and arrhythmias.

We generated revenue of $6.1 million, a gross margin of 76.2% and a net loss of $14.1 million for the year ended December 31, 2020, compared to revenue of $6.3 million, a gross margin of 73.1% and a net loss of $14.6 million for the year ended December 31, 2019. Revenue for 2020 was negatively impacted by 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 our 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. Our accumulated deficit as of December 31, 2020 was $351.7 million.

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;***
- ***Significant body of clinical evidence targeting a widely accepted mechanism of action;***

- ***Favorable reimbursement paradigm for both outpatient and inpatient settings;***
- ***Targeted and methodical approach to market development in the U.S.;***
- ***Platform technology protected by a comprehensive and broad IP portfolio; and***
- ***Experienced management team with deep expertise in the HF market and supported by key investors.***

Our market and industry

BAROSTIM NEO's market opportunity

We estimate that our initial annual market opportunity for HFrEF is $2.9 billion, representing $1.4 billion, or 55,000 new patients in the U.S., and $1.5 billion, or 61,000 new patients in EU5. The annual market opportunity for BAROSTIM NEO is based on our indication for use and excludes patients who are clinically or psychologically unfit or who have severe comorbidities:

- **NYHA Class III and II (recent history of III):** The NYHA classification guidelines are the most common measure of HF severity and allow physicians to classify patients into four classes 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).
- **N-terminal pro-B-type natriuretic peptide ("NT-proBNP") < 1600pg/ml when stable:** 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") ≤35%:** LVEF 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.
- **Clinically fit:** Our BAROSTIM NEO is not indicated for HFrEF patients with certain contra-indications, including carotid atherosclerosis and ulcerative plaques, among others.
- **Not indicated for Cardiac Resynchronization Therapy ("CRT"):** Our BAROSTIM NEO targets patients who are not indicated for CRT.

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 HFrEF patients indicated for BAROSTIM NEO, namely those with NYHA Class III and LVEF 25%–35%. 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:

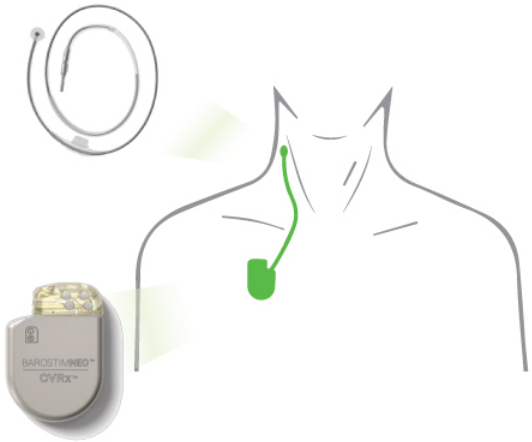
- **Narrow indication:** CCM is indicated for a limited population of HF patients with a NYHA Class III, LVEF 25%–45%, narrow QRS and normal sinus rhythm.
- **Limited clinical effectiveness in patients with LVEF 25–35%:** Based on published clinical data, CCM demonstrated lower effectiveness in patients with LVEF 25–35% as compared to 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.
- **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 underserved patient population. We believe BAROSTIM NEO offers meaningful benefits for patients, physicians and payors that will continue to drive adoption of our therapy.

Our BAROSTIM Therapy utilizes a widely accepted mechanism of action and works by sending imperceptible and persistent electrical pulses to baroreceptors on the carotid artery to signal the brain to decrease sympathetic activity (“fight or flight”) and increase parasympathetic activity (“rest and digest”). 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.

BAROSTIM NEO consists of an IPG and stimulation lead and is managed by a wireless programmer that communicates with the IPG. The IPG controls and delivers the electrical pulses to baroreceptors on the carotid artery through the stimulation lead, which is attached to the exterior wall of the carotid artery. The programmer can be used to verify the desired location of the stimulation electrode 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.



Once a patient is diagnosed with HFrEF and recommended for an implantable cardiac defibrillator ("ICD"), or CRT, general cardiologists will usually refer them to EPs who 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 recommended for an ICD.

BAROSTIM NEO is implanted during a one-hour, minimally invasive procedure that is typically performed on an outpatient basis by a vascular surgeon or, less commonly, by 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. Patients typically recover quickly and are discharged from the hospital within 24 hours of the procedure.

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 growth are as follows:

- ***Continue to build a commercialization infrastructure with a specialized direct sales and marketing team in the U.S.;***
- ***Promote awareness among payors, physicians and patients to accelerate adoption of BAROSTIM NEO;***
- ***Expand upon our significant body of clinical evidence;***
- ***Continue innovation of BAROSTIM NEO to enhance our value proposition; and***
- ***Leverage our platform technology to expand into new indications and strategically pursue new international markets.***

Summary risk factors

Our business is subject to a number of risks that you should be aware of before making an investment decision. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth under “Risk Factors” in deciding whether to invest in our common stock. Among these important risks are 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;
- we have a limited history operating as a commercial company and are highly dependent on a single product, BAROSTIM NEO, and the failure to obtain market acceptance in the U.S. for BAROSTIM NEO would negatively impact our business, liquidity and results of operations;
- we have limited commercial sales experience marketing and selling our BAROSTIM NEO, and if we are unable to establish and maintain sales and marketing capabilities, we will be unable to successfully commercialize our BAROSTIM NEO or generate sustained and increasing product revenue;
- we must demonstrate to physicians and patients the merits of our BAROSTIM NEO;
- if third-party payors do not provide adequate coverage and reimbursement for the use of BAROSTIM NEO, 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 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 NEO, 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 single source or 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.

Corporate information

We were incorporated in August 2000 in Delaware under the name CVRx, Inc. Our principal executive offices are located at 9201 West Broadway, Suite 650, Minneapolis, Minnesota 55445, and our telephone number is (763)416-2840. Our website address is www.cvrx.com. The information on, or that can be accessed through, our website is not part of this prospectus. We have included our website address as an inactive textual reference only.

Implications of being an emerging growth company

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). As such, we may take advantage of certain exemptions from various reporting requirements that are applicable to other publicly traded entities that are not emerging growth companies. These exemptions include, but are not limited to:

- the option to present only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);
- not being required to submit certain executive compensation matters to stockholder advisory votes, such as “say-on-pay,” “say-on-frequency,” and “say-on-golden parachutes;” and
- not being required to disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation.

As a result of our reliance on these exemptions, we do not know if some investors will find our common stock less attractive. The result may be a less active trading market for our common stock, and the price of our common stock may become more volatile.

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 13(a) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, 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. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable.

We will remain an emerging growth company until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion; (ii) the last day of 2026; (iii) the date that we become a “large

accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common equity held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during any three-year period.

The Offering

Common stock we are offering .	shares.
Common stock to be outstanding after the offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
Option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to additional shares of our common stock at the public offering price less the estimated underwriting discount.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $ million (or approximately $ million if the underwriters exercise their option to purchase additional shares in full), based on an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discount and estimated offering expenses payable by us. We currently expect to use the net proceeds from this offering to continue funding the expansion of our direct sales force and commercial organization related to BAROSTIM NEO in the U.S., research and development activities related to BAROSTIM Therapy and working capital and general corporate purposes. See “Use of Proceeds” for a more complete description of the intended use of proceeds from this offering.
Risk factors	Investing in our common stock involves a high degree of risk. See “Risk Factors” and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in our common stock.
Proposed trading symbol	“CVRX”

The number of shares of common stock to be outstanding after this offering is based on 486,252,139 shares of common stock outstanding as of March 31, 2021, and excludes the following:

- 80,280,513 shares of common stock issuable upon the exercise of outstanding stock options as of March 31, 2021 having a weighted-average exercise price of $0.09 per share;
- 225,000 shares of common stock underlying warrants currently exercisable for shares of Series F-2 convertible preferred stock at an exercise price of $1.41 per share (“Series F-2 Warrants”), 4,062,500 shares of common stock underlying warrants currently exercisable for Series G convertible preferred stock at an exercise price of $0.80 per share (“Series G Warrants”) and 24,034,345 shares of common stock (which may increase up to 25,000,000 shares of common stock if Johnson & Johnson Innovation — JJDC, Inc. (“JJDC”) purchases shares of our common stock in this offering) underlying warrants exercisable upon the closing of our initial public offering for Series G convertible preferred stock at an exercise price of $0.01 per share (“JJDC Warrants,” and together with the Series F-2 Warrants and the Series G Warrants, “Warrants”), which Warrants all will be exercisable for common stock upon the closing of this offering;
- 23,188,772 shares of common stock reserved for issuance pursuant to future awards under our 2001 Stock Incentive Plan (the “2001 Plan”);

- shares of common stock reserved for issuance pursuant to future awards under our 2021 Equity Incentive Plan (the "2021 Plan"), which will become effective upon the closing of this offering; and
- shares of common stock reserved for future issuance under our Employee Stock Purchase Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan.

Unless otherwise indicated, the number of shares of our common stock described above reflects and assumes the following:

- a 1-for- reverse stock split of our common stock effected on , 2021;
- the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 471,791,754 shares of common stock upon the closing of this offering;
- the effectiveness of our amended and restated certificate of incorporation, which will occur upon the closing of this offering; and
- no exercise of the underwriters' option to purchase additional shares.

We refer to our Series A-2, Series B-2, Series C-2, Series D-2, Series E-2, Series F-2 and Series G convertible preferred stock collectively as "convertible preferred stock" in this prospectus.

Summary consolidated financial data

The following tables present summary consolidated financial data for our business for the periods and as of the dates indicated. We derived the following consolidated statements of operations data for the years ended December 31, 2020 and 2019 from our audited consolidated financial statements included elsewhere in this prospectus. We derived the following statements of operations data for the three months ended March 31, 2021 and 2020 and the balance sheet data as of March 31, 2021 from our unaudited interim consolidated financial statements included elsewhere in this prospectus. We have prepared the unaudited information on the same basis as the audited consolidated financial statements and have included all adjustments, consisting of normal recurring adjustments, that we consider necessary for a fair statement of our financial position and operating results for such period. Our historical results are not necessarily indicative of the results that may be expected or may actually occur in the future, and our interim results are not necessarily indicative of the expected results for future interim periods or the full year. You should read this data together with our consolidated financial statements and related notes appearing elsewhere in this prospectus and the information under the captions “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	Years ended December 31,		Three months ended March 31,	
	2020	2019	2021	2020
	(in thousands, except share and per share data)		*(unaudited)*	
Consolidated Statements of Operations Data:				
Revenue:	$ 6,053	$ 6,257	$	$
Cost of goods sold	1,440	1,683		
Gross profit	4,613	4,574		
Operating expenses:				
Research and development	6,410	8,662		
Selling, general, and administrative	9,717	6,106		
Total operating expenses	16,127	14,768		
Loss from operations	(11,514)	(10,194)		
Interest expense	(2,470)	(1,720)		
Other expense, net	(40)	(2,646)		
Loss before income taxes	(14,024)	(14,560)		
Provision for income taxes	(85)	(73)		
Net loss	$ (14,109)	$ (14,633)	$	$
Cumulative translation adjustment	(1)	(6)		
Comprehensive loss	$ (14,110)	$ (14,639)		
Net loss per share attributable to common stockholders, basic and diluted(1)	$ (0.94)	$ (0.77)	$	$
Weighted-average common shares used to compute net loss per share, basic and diluted(1)	15,308,364	19,085,104		
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(1)	$		$	
Pro forma weighted-average common shares used to compute net loss per share, basic and diluted (unaudited)(1)				

(1) See Notes 2 and 9 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate our basic and diluted net loss per share, pro forma net loss per share and the weighted-average number of shares used in the computation of the per share amounts.

The table below presents our balance sheet data as of March 31, 2021:

- on an actual basis;
- on a pro forma basis to give effect to:
  - the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 471,791,754 shares of common stock upon the closing of this offering; and
  - the effectiveness of our amended and restated certificate of incorporation, which will occur upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, after deducting the underwriting discount and estimated offering expenses payable by us.

	As of March 31, 2021		
	Actual	Pro forma	Pro forma as adjusted[1]
	(unaudited, in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$	$	$
Working capital(2)			
Total assets			
Long-term debt			
Convertible preferred stock warrant liability			
Redeemable convertible preferred stock			
Total stockholders' deficit			

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, respectively, the amount of cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discount and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase or decrease of 1,000,000 in the number of shares we are offering would increase or decrease, respectively, the amount of cash and cash equivalents, working capital, total assets and stockholders' equity (deficit) by approximately $ million, assuming the assumed initial public offering price per share, as set forth on the cover page of this prospectus, remains the same.

(2) We define working capital as current assets less current liabilities.

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 prospectus, 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 $14.1 million and $14.6 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, our accumulated deficit was $351.7 million. 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 our BAROSTIM NEO, expand existing relationships with our customers, add new features to our BAROSTIM NEO, 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 increase following this offering due to the additional costs associated with being a public company.

To date, we have financed our operations primarily through convertible preferred stock financings and amounts borrowed under the Horizon loan agreement (as defined below). 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 NEO. The failure to obtain market acceptance in the U.S. for BAROSTIM NEO 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 our 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 our BAROSTIM NEO in the European Economic Area ("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 NEO 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., our BAROSTIM NEO has limited product and brand recognition. In addition, demand for our BAROSTIM NEO 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 NEO, 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 NEO or are unable to market BAROSTIM NEO as a result of a quality problem, failure to maintain regulatory approvals, unexpected or serious complications or other unforeseen negative effects related to BAROSTIM NEO 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 our BAROSTIM NEO, and if we are unable to establish and maintain sales and marketing capabilities, we will be unable to successfully commercialize our BAROSTIM NEO 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 our BAROSTIM NEO. 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 our BAROSTIM NEO.

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 NEO to physicians. In order for us to sell BAROSTIM NEO, we must successfully demonstrate to physicians and patients the merits of BAROSTIM Therapy for use in treating patients with HFrEF. Specifically, BAROSTIM NEO provides symptomatic relief for patients with NYHA Class III or II (with recent history of III), have a LVEF $\leq$ 35% and a NT-proBNP < 1,600 pg/ml. Acceptance of BAROSTIM NEO depends on educating physicians as to the distinctive characteristics, perceived benefits, safety, ease of use and cost-effectiveness of BAROSTIM NEO, and communicating to physicians the proper application of our BAROSTIM Therapy for patients who meet BAROSTIM NEO's eligibility criteria. If we are not successful in convincing physicians of the merits of our BAROSTIM Therapy, they may not use BAROSTIM NEO 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 NEO. 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 NEO, 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 NEO, physicians may not use or advocate for our BAROSTIM NEO. In such circumstances, our results of operations would be materially adversely affected.

Patients may not choose or be able to receive our BAROSTIM NEO 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 our BAROSTIM NEO, 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 NEO, our revenue will be negatively impacted.

Our success in marketing BAROSTIM NEO 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 NEO 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 NEO and bill patients for any applicable deductibles or co-payments. Access to adequate coverage and reimbursement for procedures using BAROSTIM NEO 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 Current Procedural Terminology ("CPT") codes for the service for which they are seeking reimbursement. Procedures using BAROSTIM NEO 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 NEO 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 NEO because nearly two-thirds of the target patient population for BAROSTIM NEO is over the age of 65. Effective January 2021, CMS awarded BAROSTIM NEO a Transitional Pass-Through ("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 NEO a New Technology Add-on Payment ("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 NEO 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 NEO could make it difficult for new customers to adopt BAROSTIM NEO 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 NEO 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 NEO. Any future decline in the amount third-party payors are willing to reimburse our customers for procedures using BAROSTIM NEO could make it difficult for new customers to adopt BAROSTIM NEO 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 NEO, 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 our BAROSTIM Therapy and BAROSTIM NEO for the treatment of HFrEF. Any product we develop that achieves regulatory clearance or approval, including BAROSTIM NEO, 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 (“Medtronic”), 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 NEO, 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 European Union ("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 single source or 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 our BAROSTIM NEO from single source, or a limited number of, suppliers. Our ability to supply BAROSTIM NEO 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 all of our single source or limited suppliers, some of which supply components critical to our products. We cannot guarantee that our single source suppliers will be able to meet our demand for their products and services, either because of the nature of our agreements 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 NEO 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 sole or limited source suppliers may be unwilling or unable to supply components of BAROSTIM NEO;

- 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 NEO, 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 single and 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 single source suppliers, we are especially susceptible to supply shortages because we do not have 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 NEO 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 NEO, 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 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 our BAROSTIM NEO, 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 our BAROSTIM NEO 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.

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 the durability of immunity offered by vaccines developed to prevent infection, as well as other actions to contain COVID-19 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 NEO outside the U.S. represented a majority of our revenue from sales in the year ended December 31, 2020. In 2012, we began selling BAROSTIM NEO in the EEA directly to hospitals and through distributors. The sale and shipment of BAROSTIM NEO 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 U.S. Foreign Corrupt Practices Act (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 NEO 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 NEO.

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 NEO, 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, institutional review boards ("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. 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 NEO. Moreover, a negative perception of clinical results for one indication for use could impact the use of BAROSTIM NEO 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 NEO, and clinical testing of our 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 affords 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 financial 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. Further, our employees' ability to exercise those options and sell their stock in a public market after the closing of this offering and the expiration of any applicable lock-up agreements may result in a higher than normal turnover rate.

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.

Our Horizon loan agreement contains restrictions that limit our flexibility in operating our business.

In September 2019, we entered into a loan and security agreement with Horizon Technology Finance Corporation, as amended ("Horizon loan agreement"), under which we borrowed $20 million, which is the maximum borrowing under the Horizon loan agreement.

In order to service this indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This will place us at a competitive disadvantage compared to our competitors that have less indebtedness.

The Horizon loan agreement also contains various covenants that limit our ability to engage in specified types of transactions and take certain actions. Subject to limited exceptions, these covenants limit our ability to, among other things:

- convey, sell, lease, or otherwise dispose of our assets;
- create, incur, assume or permit to exist additional indebtedness or liens;
- pay dividends on, repurchase or make distributions with respect to our capital stock;
- make specified investments (including loans and advances);
- merge, consolidate or liquidate; and
- enter into certain transactions with our affiliates.

In addition, the Horizon loan agreement contains certain financial covenants, including a minimum U.S. revenue requirement of approximately $5.9 million during the year ended December 31, 2021, approximately $14.6 million during the year ended December 31, 2022 and $5.0 million during each calendar quarter thereafter, as well as certain negative covenants, including a requirement that we not receive a final disapproval letter from the FDA for use of BAROSTIM NEO in certain other HF patients upon our request for additional labeling based upon the results of the post-market stage of our BeAT-HF pivotal trial. The covenants in the Horizon loan agreement may limit our ability to take certain actions and, in the event that we breach one or more covenants, our lender may choose to declare an event of default and require that we immediately repay all amounts outstanding, terminate

the commitment to extend further credit and foreclose on the collateral granted to it to secure such indebtedness. The borrowings under the Horizon loan agreement are collateralized by substantially all of our assets, including our intellectual property portfolio.

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. Despite the precautionary measures we have taken to prevent breakdowns in our information technology and telephone systems, 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 NEO as compared to other common HF devices will continue to drive growth in the market for BAROSTIM NEO. 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 BAROSTIM NEO 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 NEO is 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 our BAROSTIM NEO 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, in addition to disruptions in the capital and credit markets, severe supply shortages and reduced hospital and clinical visits 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 continue to result in a variety of risks to our business, including weakened demand for BAROSTIM NEO, 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 continue to strain our manufacturers or suppliers, resulting in supply disruption, or causing our customers to delay making payments for our services. Any of the foregoing could has 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.

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.

Recent 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 recently 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. Accordingly, 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 NEO 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 ("R&D") efforts. We believe that the net proceeds from this offering, together with 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 12 months. 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 year ended December 31, 2020, our net cash used in operating activities was $16.1 million as compared to $12.8 million for the year ended December 31, 2019. 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 NEO;
- the R&D 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 NEO and our 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 consist of a substantial number of individual components. In order to market and sell BAROSTIM NEO 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 in 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 ("NOL") and tax credit carryforwards. 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. It is uncertain how various states will respond to the TCJA and the CARES Act.

In addition, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or 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 initial public offering. 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.

We may not be able to generate sufficient cash to service our Horizon loan agreement.

As of December 31, 2020, the aggregate principal amount outstanding under our Horizon loan agreement was $20.0 million. Our ability to make scheduled payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to numerous risks, including the risks in this section, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot be certain that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. In addition, in the event of our breach of our Horizon loan agreement, we may be required to repay any outstanding amounts earlier than anticipated.

Risks related to regulation of our industry

BAROSTIM NEO 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 NEO 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 NEO 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 NEO, 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 NEO, 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 EC 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 EC 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 NEO in Europe, we must maintain our CE Mark and continue to comply with certain EU Directives. 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 British Standards Institution, or BSI), 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 NEO 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 Federal Food, Drug, and Cosmetic Act 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 NEO has been indicated for the improvement of symptoms of HFrEF by the FDA and EEA. We may only promote or market BAROSTIM NEO 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 States laws implementing Directive 93/42/EEC concerning Medical Devices, or the EU Medical Devices Directive, 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 NEO, or a recall of BAROSTIM NEO 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 NEO 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 Quality System Regulation ("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 EU Medical Devices Directive (Directive 93/42/EEC), 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 Health Insurance Portability and Accountability Act of 1996 ("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 the Health Information Technology for Economic and Clinical Health Act of 2009 ("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 Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, (collectively, the "ACA"), which require certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services 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 the Department of Health and Human Services 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 March 2010, the ACA was signed into law, which incorporates, among other things, comparative effectiveness research, an independent payment advisory board and payment system reforms, including shared savings pilots and other provisions, may significantly affect the payment for, and the availability of, healthcare services and result in fundamental changes to federal healthcare reimbursement programs, any of which may materially affect numerous aspects of our business.

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, which could result in reduced demand for our product candidates or additional pricing pressures.

Additionally, on April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive 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 Medical Devices Regulation, 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 Medical Devices Regulation became applicable in May 2020 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.

Risks related to our Common Stock and this Offering

We will incur significantly increased costs and devote substantial management time as a result of operating as a public company, which may adversely affect our business, financial condition and results of operations.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we will be subject to the reporting requirements of the Exchange Act and will be required to 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 , including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly, which may adversely affect our business, financial condition and results of operations.

In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect 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 JOBS Act, and are not a non-accelerated filer. We will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and will need to establish 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. We also expect that operating as a public company will make it 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.

We and the representatives of the underwriters will determine the initial public offering price of our common stock through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. The trading price of our common stock following this offering is likely to be highly volatile and be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section of this prospectus and others, such as:

- 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 NEO;
- 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 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 this offering and may use them in ways that may not enhance our operating results or the price of our common stock.

Our management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering 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 this offering to continue funding the expansion of our direct sales force and commercial organization related to BAROSTIM NEO in the U.S., research and development activities related to BAROSTIM Therapy and working capital and general corporate purposes. Investors in this offering have only limited information concerning management's specific intentions and will need to rely upon the judgment of our management with respect to the use of proceeds. If we do not invest or apply the proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

There has been no prior public market for our common stock and an active trading market may never develop or be sustained.

Prior to this offering, there has been no public market for shares of our common stock, and an active public market for our shares may not develop or be sustained after this offering. An active trading market may not develop following the consummation of this offering or, if it is developed, may not be sustained. Further, certain of our existing institutional investors, including investors affiliated with certain of our directors, have indicated an interest in purchasing up to approximately $ million in this offering and, to the extent these affiliated investors purchase shares in this offering, fewer shares may be actively traded in the public market because these stockholders will be restricted from selling the shares by restrictions under applicable securities laws and the lock-up agreements described in the "Shares Eligible for Future Sale" and "Underwriting" sections of this prospectus, which would reduce the liquidity of the market for our common stock. 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, although we have been approved to list our common stock on , there can be no guarantee that we will continue to satisfy the continued listing standards of . 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.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, 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 this offering, (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 implement and 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 will need 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 are continuing to develop and 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 this offering, 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 are in the process of designing and implementing 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 are 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.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price of our common stock is substantially higher than the pro forma net tangible book value per share of our common stock before giving effect to this offering. Accordingly, if you purchase our common stock in this offering, you will incur immediate substantial dilution of approximately $ per share, based on an assumed initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus), and our net tangible book value as of December 31, 2020. Furthermore, if the underwriters exercise their option to purchase additional shares, or outstanding options are exercised, you could experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section titled "Dilution."

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.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that these sales may occur, could result in a decrease in the market price of our common stock.

Based upon the number of shares outstanding as of December 31, 2020, upon the closing of this offering, we will have outstanding a total of approximately million shares of common stock, assuming no exercise of the underwriters' option to purchase additional shares. Of these shares, shares of our common stock, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable, without restriction, in the public market immediately following this offering, unless purchased by our affiliates or existing stockholders.

The lock-up agreements pertaining to this offering will expire 180 days from the date of the underwriting agreement executed in connection with this offering. After the lock-up agreements expire, up to an additional approximately million shares of common stock will be eligible for sale in the public market, approximately million of which shares are held by current directors, executive officers and other affiliates and may be subject to volume limitations under Rule 144 under the Securities Act. The representatives of the underwriters, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to lock-up agreements to sell shares prior to the expiration of the lock-up agreements. See "Shares Eligible for Future Sale."

In addition, as of March 31, 2021, approximately million shares of common stock that are subject to outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of approximately million shares of our outstanding common stock as of March 31, 2021, including shares of our common stock issuable upon the conversion of the shares of our convertible preferred stock immediately prior to the closing of this offering and shares issuable upon exercise of outstanding options, will be entitled to rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other

stockholders as described in the section of this prospectus entitled “Description of Capital Stock —Registration Rights.”. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market, subject to volume limitations applicable to affiliates and the lock-up agreements referred to above and described in the section of this prospectus entitled “Underwriting.”

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of March 31, 2021, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately % of our outstanding voting stock and, upon the closing of this offering, that same group will beneficially own approximately % of our outstanding voting stock (assuming no exercise of the underwriters’ option to purchase additional shares and no exercise of outstanding options). Certain of our existing institutional investors, including investors affiliated with certain of our directors, have indicated an interest in purchasing an aggregate of up to approximately $ million in shares of our common stock in this offering at the initial public offering price. Any such purchases, if completed, would be made on the same terms as the shares that are sold to the public generally and not pursuant to any pre-existing contractual rights or obligations. If such investors purchase all shares they have indicated interests in purchasing, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates will beneficially own approximately % of our outstanding voting stock upon the closing of this offering (based on the assumed initial public offering price of $ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, and assuming no exercise of the underwriters’ option to purchase additional shares and no exercise of outstanding options). Therefore, even after this offering these stockholders, if they act together, 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.

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. Additionally, the terms of our Horizon loan agreement prohibit us from paying cash dividends on our capital stock. 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.

Special note regarding forward-looking statements

This prospectus contains forward-looking statements. Forward-looking statements convey our current expectations or forecasts of future events and are not guarantees of future performance. They are based on numerous assumptions that we believe are reasonable, but they are open to a wide range of uncertainties and business risks. Our ability to predict results or the actual effect of future plans or strategies is inherently uncertain.

Any statements contained in the prospectus that are not statements of historical fact may be forward-looking statements. When we use the words “intends,” “estimates,” “predicts,” “potential,” “continues,” “anticipates,” “plans,” “expects,” “believes,” “should,” “could,” “may,” “will,” “seeks” or the negative of these terms or other comparable terminology, we are identifying forward-looking statements.

Forward-looking statements involve risks and uncertainties, which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. Key factors that could cause actual results to be different than expected or anticipated include, but are not limited to:

- our history of significant losses, which we expect to continue;
- our limited history operating as a commercial company and our dependence on a single product, BAROSTIM NEO;
- our ability to establish and maintain sales and marketing capabilities;
- our ability to demonstrate to physicians and patients the merits of our BAROSTIM NEO;
- any failure by third-party payors to provide adequate coverage and reimbursement for the use of BAROSTIM NEO;
- our competitors’ success in developing and marketing products that are safer, more effective, less costly, easier to use or otherwise more attractive than BAROSTIM NEO;
- any failure to receive access to hospitals;
- our dependence upon third-party manufacturers and suppliers, and in some cases a single source or limited number of suppliers;
- a pandemic, epidemic or outbreak of an infectious disease in the U.S. or worldwide, including the outbreak of the novel strain of coronavirus, COVID-19;
- any failure of clinical studies for future indications to produce results necessary to support regulatory clearance or approval in the U.S. or elsewhere;
- product liability claims;
- future lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and ultimately unsuccessful; and
- any failure to retain our key executives or recruit and hire new employees.

In light of these risks, uncertainties and assumptions, you are cautioned not to place undue reliance on forward-looking statements, which are inherently unreliable and speak only as of the date of this prospectus. When considering forward-looking statements, you should keep in mind the cautionary statements in this prospectus. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry

into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all our forward-looking statements by these cautionary statements.

Market, industry and other data

This prospectus contains estimates, projections and other information concerning our industry, our business and the market for our BAROSTIM NEO, including data regarding the estimated patient population in the HF market, their projected growth rates, the perceptions and preferences of patients and physicians regarding HF, as well as data regarding market research, estimates and forecasts prepared by our management. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. Although we believe these sources are reliable, neither we nor the underwriters have independently verified the accuracy or completeness of any third-party information. The content of these third-party sources, except to the extent specifically set forth in this prospectus, does not constitute a portion of this prospectus and is not incorporated herein. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable.

All of the market data used in this prospectus involves a number of assumptions and limitations. While we believe that the information from these industry publications, surveys and studies is reliable, the industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section entitled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

Use of proceeds

We estimate that the net proceeds from the sale of shares of common stock in this offering will be approximately $ million at an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discount and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that net proceeds will be approximately $ million after deducting the underwriting discount and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discount and estimated offering expenses payable by us, by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discount and estimated offering expenses payable by us, by approximately $ million, assuming the assumed initial public offering price stays the same. We do not expect that a change in the offering price or the number of shares by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

We currently expect to use the net proceeds from this offering as follows:

- approximately $ to $ million to continue funding the expansion of our direct sales force and commercial organization related to BAROSTIM NEO in the U.S.;
- approximately $ to $ million to fund research and development activities related to BAROSTIM Therapy; and
- the remainder for working capital and general corporate purposes.

However, due to the uncertainties inherent in the development and regulatory approval process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. As such, our management will retain discretion over the use of the net proceeds from this offering. The amounts and timing of our expenditures will depend upon numerous factors, including the timing and success of our commercialization efforts for our BAROSTIM NEO, the size, scope and timing of any additional research and development efforts and clinical trials that we may decide to pursue for our BAROSTIM NEO for HF or other potential future indications and the amount of revenue received from our existing sales in the U.S. and Europe. In the future, we may need to raise additional capital to support our commercialization and research and development efforts in the U.S. and Europe. For additional information regarding our potential capital requirements, see “*We may be required to obtain additional funds in the future, and these funds may not be available on acceptable terms or at all*” under the heading “Risk Factors.”

Pending the use of the proceeds from this offering described above, we intend to invest the net proceeds in interest-bearing, investment-grade securities, certificates of deposit or government securities.

Dividend policy

We have never declared or paid cash dividends on our capital stock. In addition, the terms of the Horizon loan agreement prohibit us from paying any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, tax considerations, legal or contractual restrictions, business prospects, the requirements of current or then-existing debt instruments, general economic conditions and other factors our board of directors may deem relevant.

Capitalization

The following table sets forth our cash and cash equivalents, short-term investments and capitalization as of March 31, 2021:

- on an actual basis;
- on a pro forma basis to give effect to:
  - the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 471,791,754 shares of common stock upon the closing of this offering;
  - the effectiveness of our amended and restated certificate of incorporation, which will occur upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, after deducting the underwriting discount and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our capitalization following the completion of this offering is subject to adjustment based on the initial public offering price of our common stock and other terms of this offering determined at pricing. You should read this information together with other financial information contained in this prospectus, including our consolidated financial statements and related notes included elsewhere in this prospectus and the information set forth under the headings “Use of Proceeds,” “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of March 31, 2021		
	Actual	Pro forma	Pro forma as adjusted(1)
	(unaudited, in thousands, except share and per share data)		
Cash and cash equivalents	$	$	$
Long-term debt			
Convertible preferred stock, no par value; shares authorized, shares issued and outstanding, actual; no shares authorized or issued and outstanding, pro forma and pro forma as adjusted			
Stockholders’ (deficit) equity:			
Common stock, $0.01 par value; shares authorized, shares issued and outstanding, actual; shares authorized, pro forma and pro forma as adjusted; shares issued and outstanding, pro forma; shares issued and outstanding, pro forma as adjusted			
Additional paid-in capital, common stock			
Accumulated deficit			
Accumulated other comprehensive loss			
Total stockholders’ deficit			
Total capitalization	$	$	$

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase or decrease, respectively, the amount of cash and cash equivalents, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discount, and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase or decrease of 1,000,000 in the number of shares we are offering would increase or decrease, respectively, the amount of cash and cash equivalents and short-term investments, working capital, total assets and stockholders’ equity by approximately $ million, assuming the assumed initial public offering price per share, as set forth on the cover page of this prospectus, remains the same. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

The number of shares of common stock shown as issued and outstanding in the table above excludes, as of March 31, 2021, the following:

- 80,280,513 shares of common stock issuable upon the exercise of outstanding stock options as of March 31, 2021 having a weighted-average exercise price of $0.09 per share;
- 225,000 shares of common stock underlying Series F-2 Warrants, 4,062,500 shares of common stock underlying Series G Warrants and 24,034,345 shares of common stock (which may increase up to 25,000,000 shares of common stock if JJDC purchases shares of our common stock in this offering) underlying JJDC Warrants, which Warrants all will be exercisable for common stock upon the closing of this offering;
- 23,188,772 shares of common stock reserved for issuance pursuant to future awards under our 2001 Plan;
- shares of common stock reserved for issuance pursuant to future awards under our 2021 Plan, which will become effective upon the closing of this offering; and
- shares of common stock reserved for future issuance under our Employee Stock Purchase Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan.

Dilution

If you invest in our common stock in this offering, your interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock in this offering and the net tangible book value per share of our common stock after this offering.

As of March 31, 2021, we had a historical net tangible book value of $ million, or $ per share of common stock. Our net tangible book value represents total tangible assets less total liabilities and convertible preferred stock, all divided by the number of shares of common stock outstanding on March 31, 2021. Our pro forma net tangible book value at March 31, 2021, before giving effect to this offering, was $ million, or $ per share of our common stock. Pro forma net tangible book value, before the issuance and sale of shares in this offering, gives effect to:

- the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 471,791,754 shares of common stock upon the closing of this offering; and
- the effectiveness of our amended and restated certificate of incorporation, which will occur upon the closing of this offering.

After giving effect to the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus) and after deducting the underwriting discount and estimated offering expenses, our pro forma as adjusted net tangible book value at March 31, 2021 would have been approximately $ million, or $ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to existing stockholders and an immediate dilution of $ per share to new investors. The following table illustrates this per share dilution:

Assumed initial public offering price per share		$
Historical net tangible book value per share as of March 31, 2021	$	
Pro forma increase in net tangible book value per share		
Pro forma net tangible book value per share as of March 31, 2021		
Increase in pro forma net tangible book value per share attributable to new investors		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors participating in this offering		$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value as of March 31, 2021 after this offering by approximately $ million, or approximately $ per share, and would increase (decrease) dilution to investors in this offering by approximately $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the underwriting discount and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares we are offering would increase (decrease) our pro forma as adjusted net tangible book value as of March 31, 2021 after this offering by approximately $ million, or approximately $ per share, and would decrease (increase) dilution to investors in this offering by approximately $ per share, assuming the assumed initial public offering price per share remains the same, after deducting the underwriting discount and estimated offering expenses payable by us. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters fully exercise their option to purchase additional shares, pro forma as adjusted net tangible book value after this offering would increase to approximately $ per share, and there would be an immediate dilution of approximately $ per share to new investors.

To the extent that outstanding options with an exercise price per share that is less than the pro forma as adjusted net tangible book value per share, before giving effect to the issuance and sale of shares in this offering, are exercised, new investors will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

The following table shows as of March 31, 2021, on a pro forma as adjusted basis, after giving effect to the pro forma adjustments described above, the number of shares of common stock purchased from us, the total consideration paid to us and the average price paid per share by existing stockholders and by new investors purchasing common stock in this offering at an assumed initial public offering price of $ per share, before deducting the underwriting discount and estimated offering expenses payable by us (in thousands, except share and per share amounts and percentages):

	Shares purchased		Total consideration		
	Number	Percent	Amount	Percent	Average price per share
Existing stockholders					$
Investors participating in this offering					$
Total					

The foregoing tables are based on the number of shares of common stock to be outstanding after this offering, as based on 486,252,139 shares of common stock outstanding as of March 31, 2021 and excludes the following:

- 80,280,513 shares of common stock issuable upon the exercise of outstanding stock options as of March 31, 2021 having a weighted-average exercise price of $0.09 per share;
- 225,000 shares of common stock underlying Series F-2 Warrants, 4,062,500 shares of common stock underlying Series G Warrants and 24,034,345 shares of common stock (which may increase up to 25,000,000 shares of common stock if JJDC purchases shares of our common stock in this offering) underlying JJDC Warrants, which Warrants all will be exercisable for common stock upon the closing of this offering;
- 23,188,772 shares of common stock reserved for issuance pursuant to future awards under our 2001 Plan;
- shares of common stock reserved for issuance pursuant to future awards under our 2021 Plan, which will become effective upon the closing of this offering; and
- shares of common stock reserved for future issuance under our Employee Stock Purchase Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan.

Certain of our existing stockholders, including entities affiliated with certain of our directors, have agreed to purchase an aggregate of approximately $ million in shares of our common stock in this offering at the initial public offering price. The foregoing discussion does not give effect to any potential purchases by these stockholders in this offering.

Selected consolidated financial data

The following tables contain selected portions of our financial data. We derived the following selected consolidated statements of operations data for the years ended December 31, 2020 and 2019, and our selected consolidated balance sheet data as of December 31, 2020 and 2019, from our audited consolidated financial statements included elsewhere in this prospectus. We derived the following selected consolidated statements of operations data for the three months ended March 31, 2021 and 2020 and the balance sheet data as of March 31, 2021 from our unaudited interim consolidated financial statements included elsewhere in this prospectus. We have prepared this unaudited information on the same basis as the audited consolidated financial statements and have included all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair statement of our financial position and operating results for such period.

Our historical results are not necessarily indicative of the results that may be expected or may actually occur in the future, and our interim results are not necessarily indicative of the expected results for future interim periods or the full year. You should read this selected financial data together with our consolidated financial statements and related notes included elsewhere in this prospectus and the information under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results are not necessarily indicative of our future results.

	Years ended December 31,		Three months ended March 31,	
	2020	2019	2021	2020
	(in thousands, except share and per share data)			
Consolidated statements of operations data:			*(unaudited)*	
Revenue:	$ 6,053	$ 6,257	$	$
Cost of goods sold	1,440	1,683		
Gross profit	4,613	4,574		
Operating expenses:				
Research and development	6,410	8,662		
Selling, general, and administrative	9,717	6,106		
Total operating expenses	16,127	14,768		
Loss from operations	(11,514)	(10,194)		
Interest expense	(2,470)	(1,720)		
Other expense, net	(40)	(2,646)		
Loss before income taxes	(14,024)	(14,560)		
Provision for income taxes	(85)	(73)		
Net loss	$ (14,109)	$ (14,633)	$	$
Cumulative translation adjustment	(1)	(6)		
Comprehensive loss	$ (14,110)	$ (14,639)	$	$
Net loss per share attributable to common stockholders, basic and diluted(1)	$ (0.94)	$ (0.77)	$	$
Weighted-average common shares used to compute net loss per share, basic and diluted(1)	15,308,364	19,085,104		
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(1)	$	$	$	$
Pro forma weighted-average common shares used to compute net loss per share, basic and diluted (unaudited)(1)				

(1) See Notes 2 and 9 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate our basic and diluted net loss per share, pro forma net loss per share and the weighted-average number of shares used in the computation of the per share amounts.

	As of December 31,		As of March 31, 2021
	2020	2019	
	(in thousands)		*(unaudited)*
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 59,112	$ 25,741	$
Working capital(1)	56,364	20,293	
Total assets	64,777	29,107	
Long-term debt	19,278	18,992	
Convertible preferred stock warrant liability	3,911	3,540	
Redeemable convertible preferred stock	329,983	279,983	
Total stockholders' deficit	(293,238)	(279,043)	

(1) We define working capital as current assets less current liabilities.

Management's discussion and analysis of financial condition and results of operations

You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Selected Consolidated Financial Data" and our consolidated financial statements and related notes to those statements included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the sections entitled "Risk Factors" and "Special Note Regarding Forward-Looking Statements" included elsewhere in this prospectus. Some of the numbers included herein have been rounded for the convenience of presentation.

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 ANS which causes HFrEF and other cardiovascular diseases. Our second-generation product, BAROSTIM NEO, is the first and only commercially available neuromodulation device indicated to improve symptoms for patients with HFrEF. BAROSTIM NEO provides BAT by sending imperceptible and persistent electrical pulses to baroreceptors located in the wall of the carotid artery to signal the brain to modulate cardiovascular function. BAROSTIM NEO 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 our 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 NEO 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 our BAROSTIM NEO 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 the hospitals, where the procedures are performed primarily in an outpatient setting, to be our customers, as they are the purchasing entities of our BAROSTIM NEO 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 which consisted of 13 Account Managers and 6 Clinical Field Specialists as of March 31, 2021. We have dedicated significant resources to educate physicians who treat HFrEF about the advantages of BAROSTIM NEO and train them on the implant procedure.

The cost 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 NEO. As a result, we have prioritized CMS coverage while simultaneously developing processes to engage commercial payors. As of July 2020, all Medicare Administrative Contractors have retired automatic coverage denial policies for our CPT 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 NEO is eligible for reimbursement in certain countries in the EU, such as Germany, where annual healthcare budgets for the hospital generally determine the number of patients to be treated and the prices to be paid for the related devices that may be purchased.

We manage all aspects of manufacturing operations and product supply of our BAROSTIM NEO, which includes final assembly, testing and packaging of our IPG and stimulation lead, at our headquarters in Minneapolis, Minnesota. We utilize components or various subassemblies manufactured by third-party suppliers, some of which have significant lead times. Many of these components are from a single source or 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 our BAROSTIM NEO 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.

Since our inception we have 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 our BAROSTIM Therapy, including clinical and regulatory initiatives to obtain marketing approval, and sales and marketing activities.

We 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 NEO'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 our BAROSTIM NEO, 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 the 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 issuance of shares of Series G Preferred Stock for net proceeds of $49.8 million in July 2020.

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 the first quarter of 2021 is an encouraging sign for when shelter-in-place and hospital limitations are lifted. As the pandemic has eased, we are experiencing 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.

Despite the encouraging signs of recovery of our business, 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 the actions to contain the spread of COVID-19 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 our BAROSTIM NEO;
- Raising awareness among payors to build upon reimbursement for BAROSTIM NEO;
- Investing in research and development to foster innovation and further simplify our BAROSTIM NEO procedure; and
- Leveraging our manufacturing capacity to further improve our gross margins.

Components of results of operations

Revenue

We have derived primarily all of our historical revenue from the sale of our BAROSTIM NEO to hospitals in Germany and other select countries in Europe. Revenue from sales of our BAROSTIM NEO in Europe fluctuates based on the average selling price of our BAROSTIM NEO 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.

Our U.S. sales have increased since the pre-market approval of our BAROSTIM NEO 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 NEO 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 account for the majority of our revenue going forward.

Cost of goods sold and gross margin

Cost of goods sold consists primarily of acquisition costs of the components and subassemblies of BAROSTIM NEO, 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 NEO 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

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 NEO. 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 NEO 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 expenses 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 U.S. Securities and Exchange Commission (“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 outstanding convertible preferred stock warrants, which are accounted for as a liability and marked-to-market at each reporting period. The final fair value adjustment of the warrant liability will be recorded upon the closing of this offering as the warrants will convert to common stock warrants. Other items include gains (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.

Income tax expense

Income tax expense consists primarily of income taxes in foreign jurisdictions in which we conduct business. We maintain a full valuation allowance for deferred tax assets including net operating loss carryforwards, research and development credits and other tax credits.

Results of operations

Consolidated results of operations for the year ended December 31, 2020 compared to the year ended December 31, 2019

	Year ended December 31,		Change	
(in thousands)	**2020**	**2019**	**$**	**%**
Revenue	$ 6,053	$ 6,257	$ (204)	(3)%
Cost of goods sold	1,440	1,683	(243)	(14)%
Gross profit	4,613	4,574	39	1%
Gross margin	76%	73%		
Operating Expenses:				
Research and development	6,410	8,662	(2,252)	(26)%
Selling, general and administrative	9,717	6,106	3,611	59%
Total operating expenses	16,127	14,768	1,359	9%
Loss from operations	(11,514)	(10,194)	(1,320)	13%
Interest expense	(2,470)	(1,720)	(750)	44%
Other expense, net	(40)	(2,646)	2,606	(98)%
Loss before income taxes	(14,024)	(14,560)	536	(4)%
Provision for income taxes	(85)	(73)	(12)	16%
Net loss	$ (14,109)	$ (14,633)	$ 524	(4)%

Revenue

Revenue decreased by $0.2 million, or 3%, to $6.1 million for the year ended December 31, 2020 compared to the year ended December 31, 2019. This decrease was attributable to a decrease of $0.9 million, or 18%, in Europe, primarily in Germany, which was partially offset by an increase of $0.7 million, or 73%, in the U.S.

Revenue generated in the U.S. was $1.7 million for the year ended December 31, 2020, an increase of $0.7 million, or 73%, over the year ended December 31, 2019. Total HFrEF revenue units in the U.S. totaled 32 and 0 for the years ended December 31, 2020 and 2019, respectively. HFrEF revenue in the U.S. totaled $1.0 million and $0 for the years ended December 31, 2020 and 2019, respectively. The increase was driven by the commercial launch in the U.S. of our BAROSTIM NEO for HFrEF in 2020, which resulted in the expansion into new sales territories, increased physician and patient awareness of our BAROSTIM NEO and an increase in our average selling price. As noted above, growth in U.S. revenue was slowed for the year ended December 31, 2020 as a result of the COVID-19 pandemic. The number of sales territories in the U.S. increased from zero to six from December 31, 2019 to 2020. The increase in HFrEF revenue was partially offset by a decrease in legacy hypertension revenue in the U.S., which totaled $0.7 million and $1.0 million for the years ended December 31, 2020 and 2019, respectively.

Revenue generated in Europe was $4.3 million for the year ended December 31, 2020, a decrease of $0.9 million, or 18%, over the year ended December 31, 2019. Total revenue units in Europe decreased from 242 to 193 for the years ended December 31, 2019 and 2020, respectively. The revenue decrease was primarily due to the impact of the COVID-19 pandemic, which was partially offset by an increase due to favorable exchange rates and an increase in our average selling price. The number of sales territories in Europe remained consistent from 2019 to 2020 at six.

Cost of goods sold and gross margin

Cost of goods sold decreased $0.2 million, or 14%, to $1.4 million for the year ended December 31, 2020 compared to the year ended December 31, 2019. This decrease was primarily due to lower sales of our BAROSTIM NEO.

Gross margin increased to 76% for the year ended December 31, 2020 compared to 73% for the year ended December 31, 2019. Gross margin for the year ended December 31, 2020 was higher as a result of improved operating leverage and an increase in our average selling price.

Research and development expenses

R&D expenses decreased $2.3 million, or 26%, to $6.4 million for the year ended December 31, 2020 compared to the year ended December 31, 2019. This change was due to a $3.8 million decline in clinical study expenses primarily related to the completion of the enrollment of the post-market stage of the BeAT-HF pivotal trial in the first half of 2020 and the reduction in travel expenses due to the COVID-19 pandemic. This decrease was partially offset by an increase of $2.0 million of R&D costs associated with the development of the next generation IPG, a new and simplified programmer and a new implant toolkit called BATwire.

Selling, general and administrative expenses

SG&A expenses increased $3.6 million, or 59%, to $9.7 million for the year ended December 31, 2020 compared to the year ended December 31, 2019. The primary driver of this increase was an increase of $2.0 million in compensation, including salaries and commissions, and other employee-related expenses, mainly as a result of increased headcount. In addition, consulting and marketing expenses increased $1.2 million primarily related to the commercial launch of our BAROSTIM NEO in the U.S.

Interest expense

Interest expense increased $0.8 million, or 44%, to $2.5 million for the year ended December 31, 2020 compared to the year ended December 31, 2019. This change was driven by an increase in the average long-term debt balance in the year ended December 31, 2020 as a result of a new $20 million loan and security agreement, which we entered into in September 2019.

Other expense, net

Other expense, net decreased $2.6 million, or 98%, to $40,000 for the year ended December 31, 2020 compared to the year ended December 31, 2019. This change was driven by a $2.2 million reduction in expense related to the fair value adjustments to our convertible preferred stock warrants and $0.3 million less expenses in 2020 as a result of expense recognized in 2019 related to the extinguishment of a previous loan and security agreement.

Income tax expense

Income tax expense increased $12,000, or 15%, to $85,000 for the year ended December 31, 2020 compared to the year ended December 31, 2019.

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 our BAROSTIM NEO, 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 our BAROSTIM NEO.

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, 2020, we had cash and cash equivalents of $59.1 million compared to $25.7 million as of December 31, 2019. For the years ended December 31, 2020 and 2019, our net losses were $14.1 million and $14.6 million, respectively, and our net cash used in operating activities was $16.1 million and $12.8 million, respectively.

Prior to this offering, our operations have been financed primarily by aggregate net proceeds from the sale of our convertible preferred stock of $383 million, as well as debt financings. In July 2020, we completed an equity financing pursuant to which we issued 62,500,000 shares of Series G Preferred Stock at a price of $0.80 per share, for net proceeds of $49.8 million after deducting offering expenses. In September 2019, we entered into a loan and security agreement with Horizon Technology Finance Corporation to borrow $20 million. In January, May and August of 2019, we completed equity financings pursuant to which we issued shares of Series G Preferred Stock at a price of $0.80 per share, for net proceeds of $24.7 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 NEO 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 12 months. If these sources are insufficient to satisfy our liquidity requirements, however, we may seek to sell additional equity, increase the availability under the Horizon loan agreement or enter into an additional 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 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 our BAROSTIM NEO.

Cash flows

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

	Year ended December 31,	
(in thousands)	**2020**	**2019**
Net cash (used in) provided by:		
Operating activities	$ (16,096)	$ (12,785)
Investing activities	(311)	(106)
Financing activities	49,783	29,549
Effect of exchange rate changes on cash and cash equivalents	(5)	(5)
Net increase in cash	$ 33,371	$ 16,653

Cash used in operating activities

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 that were partially offset by non-cash charges of $0.9 million. Net operating assets consisted primarily of inventory, accounts receivable and accrued expenses to support the growth of our operations. Non-cash charges consisted primarily of changes in the fair value of convertible preferred stock warrants, amortization of deferred financing costs, stock-based compensation and depreciation.

Net cash used in operating activities for the year ended December 31, 2019 was $12.8 million and consisted primarily of a net loss of $14.6 million and a decrease in net operating assets of $1.3 million that were partially offset by non-cash charges of $3.2 million. Net operating assets consisted primarily of inventory, accounts receivable, accounts payable and accrued expenses to support the growth of our operations. Non-cash charges consisted primarily of changes in the fair value of convertible preferred stock warrants, amortization of deferred financing costs, losses on the extinguishment of debt, stock-based compensation and depreciation.

Cash used in investing activities:

Cash used in investing activities was $0.3 million and $0.1 million for the years ended December 31, 2020 and 2019, respectively, and consisted of purchases of property and equipment.

Cash provided by financing activities:

Net cash provided by financing activities was $49.8 million for the year ended December 31, 2020 and was primarily related to the $49.8 million of net proceeds from the issuance of our Series G Preferred Stock.

Net cash provided by financing activities was $29.5 million for the year ended December 31, 2019 and was primarily related to the $24.7 million of net proceeds from the issuance of our Series G Preferred Stock and $4.9 million of net proceeds from long-term borrowing activity.

Indebtedness

In September 2019, we entered into the Horizon loan agreement under which we borrowed $20 million, which is the maximum borrowing under the Horizon loan agreement. Amounts outstanding under the Horizon loan agreement bear 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 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. 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 May 2022. A final payment of $0.7 million, equal to 3.5% of the original principal, is due to be paid in October 2024. The Horizon loan agreement initially required us to maintain cash on deposit in accounts in which Horizon maintains an account control agreement of not less than $5.0 million. This minimum cash on deposit

requirement was released in July 2020 following the satisfaction of a financing milestone. The borrowings are collateralized by all or substantially all of the assets of the Company, including our intellectual property portfolio. The Horizon loan agreement contains certain financial covenants, including a minimum U.S. revenue requirement of approximately $5.9 million during the year ended December 31, 2021, approximately $14.6 million during the year ended December 31, 2022 and $5.0 million during each calendar quarter thereafter; certain negative covenants, including a requirement that we not receive a final disapproval letter from the FDA for use of BAROSTIM NEO in certain other HF patients upon our request for additional labeling based upon the results of the post-market stage of our BeAT-HF pivotal trial; and various restrictive covenants, including a restriction on the payment of dividends. We were in compliance with these covenants as of December 31, 2020. The amount outstanding under the Horizon loan agreement as of December 31, 2020 was $20.0 million.

Contractual obligations and commitments

Our contractual obligations and commitments as of December 31, 2020 are summarized in the table below:

	Payments due by period				
(in thousands)	**Total**	**Less than 1 year**	**1 to 3 years**	**4 to 5 years**	**After 5 years**
Long-term debt(1)	$20,000	$ —	$13,333	$6,667	$—
Operating lease(2)	830	231	460	139	
Total	$20,830	$ 231	$13,793	$6,806	$—

(1) The amount includes prin cipal payments under the Horizon loan agreement. As of December 31, 2020, the total amount outstanding under the Horizon loan agreement was $20.0 million.

(2) We currently lease approximately 26,379 square feet for our headquarters in Minneapolis, Minnesota under a lease that expires in July 2024.

Off-balance sheet arrangements

We do not have any off-balance sheet arrangements, as defined by applicable regulations of the SEC, that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Related party transactions

Information concerning related party transactions is set forth in the section captioned “Certain Relationships and Related Party Transactions.”

Critical accounting policies and estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S., or 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 prospectus. 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 prospectus, 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 this offering, we intend to adopt a new equity incentive plan under which we may grant equity incentive awards to eligible employees (including our named executive officers), non-employee directors and consultants in order to enable us to obtain and retain services of these individuals, which we deem as essential to our long-term success.

We recognize equity-based compensation expense for awards of equity instruments to employees and non-employees based on the grant date fair value of those awards in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, 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) 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 this offering, 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 valuations after the completion of this offering, 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.
- 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 estimate pre-vesting forfeitures at the time of grant by analyzing historical data and revise those estimates in subsequent periods if actual forfeitures differ from those estimates or if they are likely to change. 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.

Freestanding preferred stock warrants

Warrants to purchase our preferred stock are classified as a liability on our consolidated balance sheets. These warrants are subject to remeasurement at each balance sheet date and any change in fair value is recognized in

other (expense) income, net. We will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants or when the warrants become exercisable to purchase our common stock at which time the liability will be reclassified to stockholders' equity (deficit).

The valuation of our warrants requires the input of certain subjective assumptions, including (i) IPO probability, (ii) the future fair value of common stock, (iii) the expected share price volatility, (iv) the expected term, (v) the risk-free interest rate and (vi) the expected dividend yield.

- IPO probability — Management, along with the assistance of an unrelated third-party valuation firm, evaluated the likelihood and timing of an IPO and applied these assumptions to the determination of the future fair value of the common stock as well as the expected term assumption.
- Future fair value of common stock — Given the absence of a public trading market for our common stock prior this offering, 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.
- 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 — The expected term of the warrant is driven by the probability and timing of an IPO.
- 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.

JOBS Act

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company," as defined in the JOBS Act. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include:

- being permitted to present only two years of audited financial statements and the related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- 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 this prospectus and in our periodic reports, proxy statements and registration 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 may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenue exceeds $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this registration statement and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the

information that we provide to our stockholders may be different from what you might receive from other public reporting companies in which you hold equity interests.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, 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. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable.

Recent accounting pronouncements

A discussion of recent accounting pronouncements is included in Note 2 to our audited financial statements included elsewhere in this prospectus.

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. Additionally, the interest rate for our outstanding debt is variable. If overall interest rates had increased by 100 basis points during the periods presented our interest expense would not have been materially affected.

Foreign currency exchange rate risk

To date, a majority of our revenue and a portion of our operating expenses are incurred outside the U.S. and are denominated in foreign currencies and are 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 statement of operations. 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, 2020 and 2019, 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.

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 ANS which causes HF and other cardiovascular diseases. Our second-generation product, BAROSTIM NEO, is the first and only commercially available neuromodulation device indicated to improve symptoms for patients with HFrEF, or systolic HF. BAROSTIM NEO provides BAT by sending imperceptible and persistent electrical pulses to baroreceptors located in the wall of the carotid artery to signal the brain to modulate 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 HF. We estimate that our initial annual market opportunity for HFrEF is $1.4 billion in the U.S. and $1.5 billion in 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 Germany, France, Italy, Spain and the United Kingdom. Every year, 1.3 million and 1.4 million new patients are diagnosed with HF in the U.S. and select European markets, 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 an 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 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 LVADs or heart transplants. These other implantable devices mostly target different HF 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 NEO 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 NEO 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 our BAROSTIM NEO 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 NEO for HFrEF. These results showed significant improvement in the following 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 clinically meaningful.

  - **Exercise capacity (measured by the standardized 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 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 NEO 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 NEO's 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 HF 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 cost-impact analysis published in 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 NEO 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.

Our BAROSTIM NEO is a minimally invasive neuromodulation device that consists of two implantable components, an IPG and a stimulation lead, and is managed remotely 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 NEO 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 NEO.

We primarily sell our BAROSTIM NEO 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, which included 13 Account Managers and five Clinical Field Specialists in the U.S. as of March 31, 2021, engages in sales efforts and promotional activities focused on 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 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 NEO is fully reimbursed by 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 our BAROSTIM NEO, 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 NEO and the use of local anesthetics, potentially expanding our annual market opportunity in the U.S. In the future, we plan to explore BAROSTIM NEO's potential to expand its indications for use to other cardiovascular diseases, including different forms of HF, hypertension, and arrhythmias.

We generated revenue of $6.1 million, a gross margin of 76.2% and a net loss of $14.1 million for the year ended December 31, 2020, compared to revenue of $6.3 million, a gross margin of 73.1% and a net loss of $14.6 million for the year ended December 31, 2019. Revenue for 2020 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. Our accumulated deficit as of December 31, 2020 was $351.7 million.

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 NEO 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 NEO 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 NEO'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 NEO has an average service life of five years and an implantable battery that does not require recharging. BAROSTIM NEO 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 NEO 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 NEO 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 NEO 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 NEO is reimbursed for outpatient and inpatient procedures by the CMS, with established coverage policies and 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 NEO 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 NEO a 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 NEO 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 March 31, 2021, we owned 103 issued patents globally (with 56 issued U.S. patents), had five pending patent applications (with three U.S. pending patent applications), and our trademark portfolio contained 46 trademark registrations (with six U.S. trademark registrations) and seven pending trademark applications (with three U.S. pending trademark applications).

- ***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 which, as of March 31, 2021, consisted of 13 Account Managers and five Clinical Field Specialists 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 NEO.*** We believe BAROSTIM NEO 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 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 NEO.
- ***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 NEO and for inclusion in the medical guidelines.
- ***Continue innovation of BAROSTIM NEO to enhance our value proposition.*** We are committed to driving continuous innovation and technological advancement of BAROSTIM NEO, 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 NEO 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 NEO. 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 NEO 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 NEO'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 significantly 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.

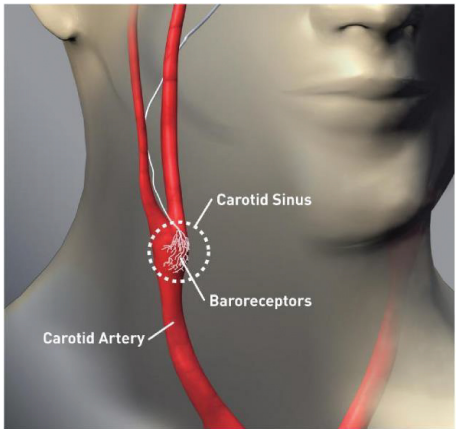
The role of the imbalance of ANS in HF

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.



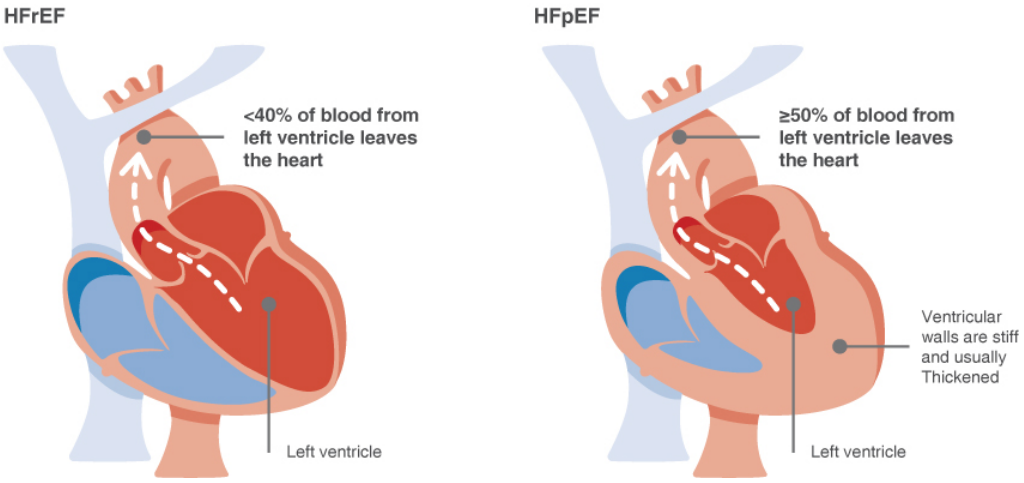
These two systems are strongly influenced by baroreceptors that are located in certain arterial walls. The baroreceptors regulate the baroreflex, which is one of the body’s homeostatic mechanisms that help to maintain blood pressure at nearly constant levels. Baroreceptors provide beat-by-beat regulation 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, or 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)

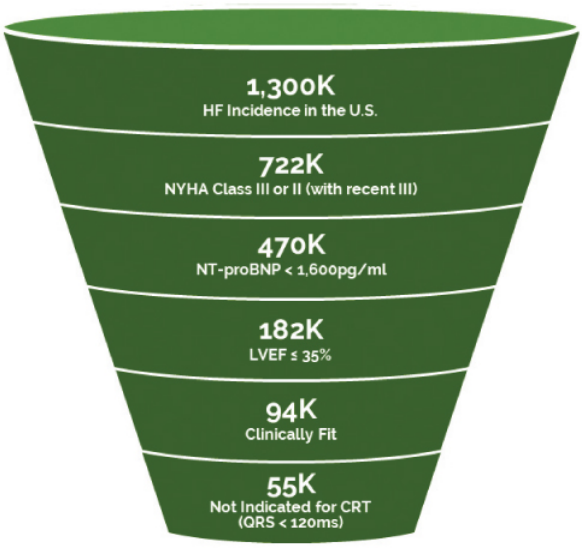
LVAD is an irreversible, invasive surgery generally reserved for critical HFrEF patients with NYHA Class IV. An LVAD is a mechanical pump that is implanted inside a patient's chest and helps pump blood throughout the body. While LVADs do not replace the heart, they do require open chest surgery and often 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 NEO'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, or approximately 55,000 new HFrEF patients in the U.S. and a $1.5 billion, or 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 excluding patients who are clinically or psychologically unfit or who have severe comorbidities:



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

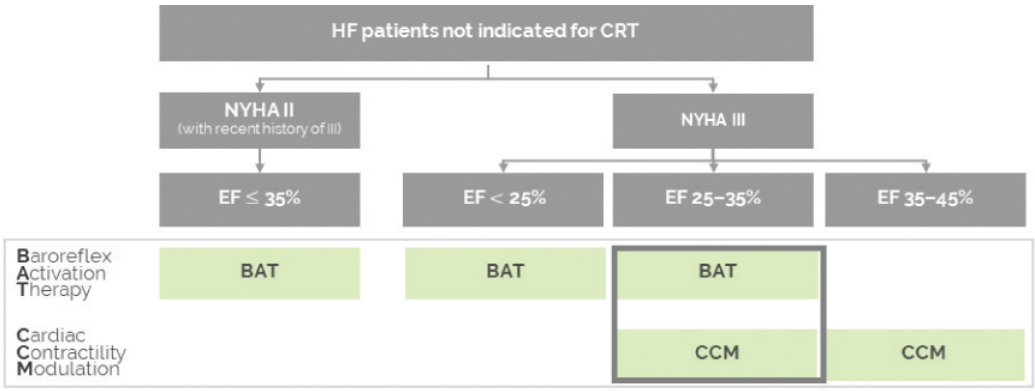
- **NYHA Class III or II (with recent history of III):** Our BAROSTIM NEO provides symptomatic relief for patients with NYHA Class III or II (with recent history of III), or patients who generally have limits on basic daily activities but are comfortable when resting. We estimate this represents approximately 722,000 of the 1.3 million annual HF patients in the U.S.
- **NT-proBNP < 1600pg/ml when stable:** Our BAROSTIM NEO 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%:** Our BAROSTIM NEO 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:** Our BAROSTIM NEO 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 our 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:** Our BAROSTIM NEO 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 NEO. 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 NEO are also eligible for CCM, namely those with NYHA Class III and LVEF 25%–35%. As a result, BAROSTIM NEO 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		FIX-HF5c (CCM)	
Eligibility Criteria		LVEF25-45% • NYHA III (91%) or IV* • Normal sinus rhythm • Not indicated for CRT	
EF% Subgroups		LVEF 25%–35%	LVEF 35%–45%
Exercise Capacity (6-minute walk distance in meters)	mean	10 (n/s)	57
Quality of Life (points)	mean	-9	-15
NYHA Class Improvement	%	25	27

* Labeled indication for CCM is NYHA III only

- **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

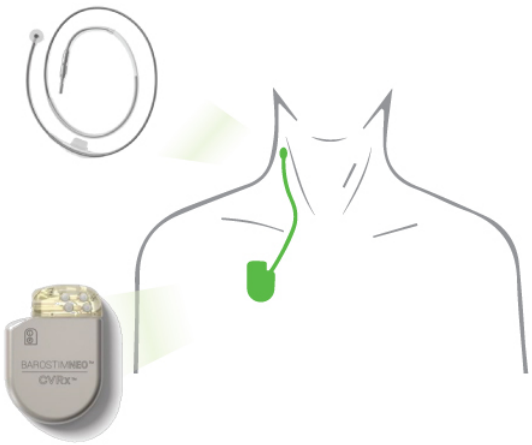
We developed our BAROSTIM platform technology to transform the treatment of HF and other cardiovascular diseases and become the standard of care for this vulnerable and underpenetrated patient population. We believe BAROSTIM NEO offers meaningful benefits for patients, physicians and payors that will 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 second-generation product, BAROSTIM NEO, is the first and only commercially available neuromodulation device indicated to improve symptoms for patients with HFrEF. Our 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 NEO has demonstrated its ability to meaningfully improve the quality of daily life, both physically and emotionally, for patients suffering from HFrEF.

BAROSTIM NEO

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



Implantable pulse generator

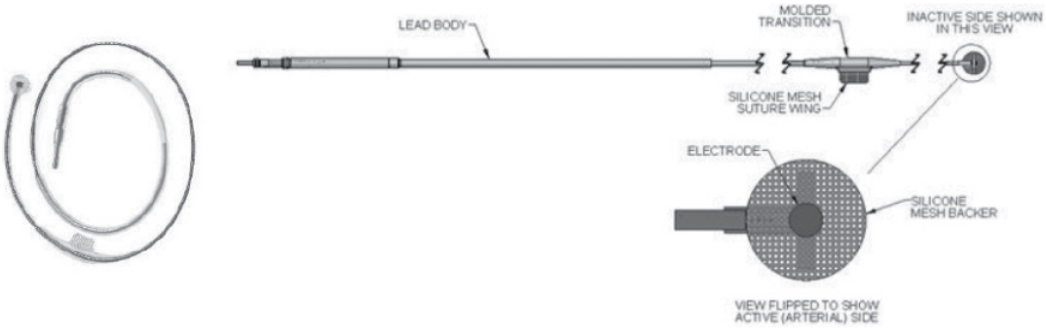
The IPG contains the electronics and battery in a hermetic enclosure, has an average service life of five years and includes a battery that does not require any recharging. The IPG provides control and delivery of electrical pulses to baroreceptors located in the wall of the carotid artery through the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

Programmer

Once implanted, BAROSTIM NEO 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 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 NEO

Patient selection

BAROSTIM NEO 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/ACC/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 NEO 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 NEO 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 frequency 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 NEO 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 NEO 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 NEO 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 our BAROSTIM NEO 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 NEO. 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 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 NEO 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 NEO'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 NEO 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 NEO, 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 NEO has the potential to result in cost savings to healthcare systems. A Company-sponsored cost-impact analysis published in 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 NEO 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 NEO 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 NEO in August 2019 on an accelerated basis of only four months from the submission of the clinical trial report.

BAROSTIM NEO 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
** Expanded Access Programs

We have established a U.S. patient registry to evaluate and assess real world patient outcomes from patients who have been implanted with BAROSTIM NEO. 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 NEO. 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").

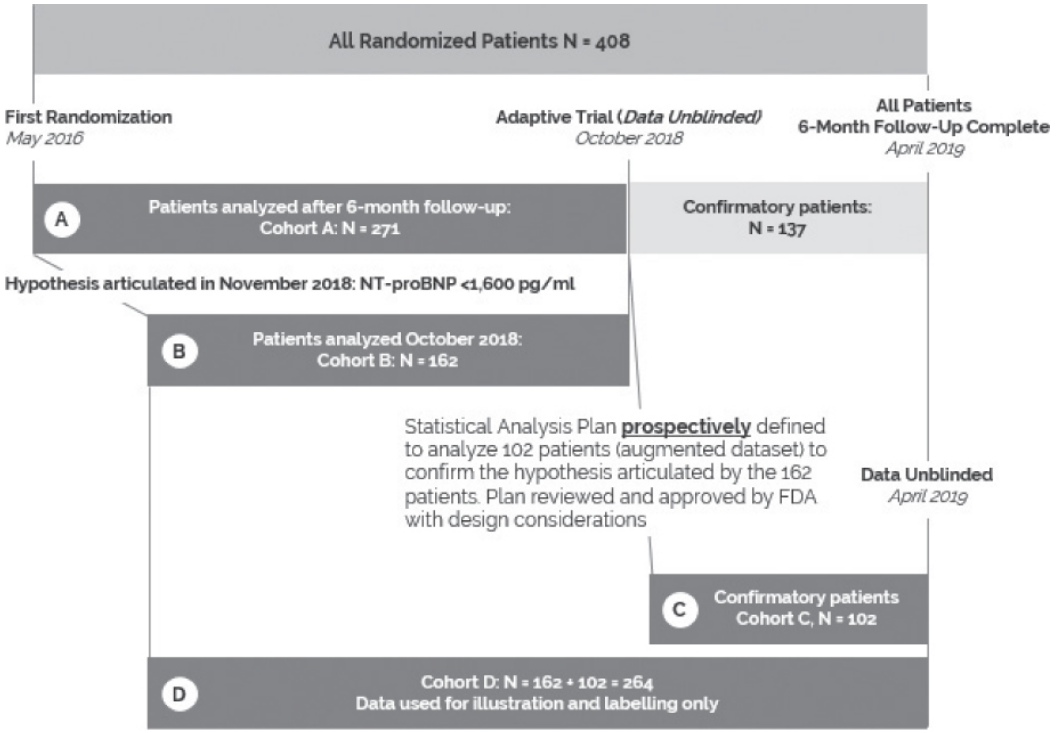
(2) A post-market stage that will examine the effects of BAT on rates of HFrEF hospitalization and cardiovascular mortality and potentially expand the indication for BAROSTIM NEO.

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, while keeping the patient on maximally tolerated GDMT. Control was defined as maximally tolerated GDMT.

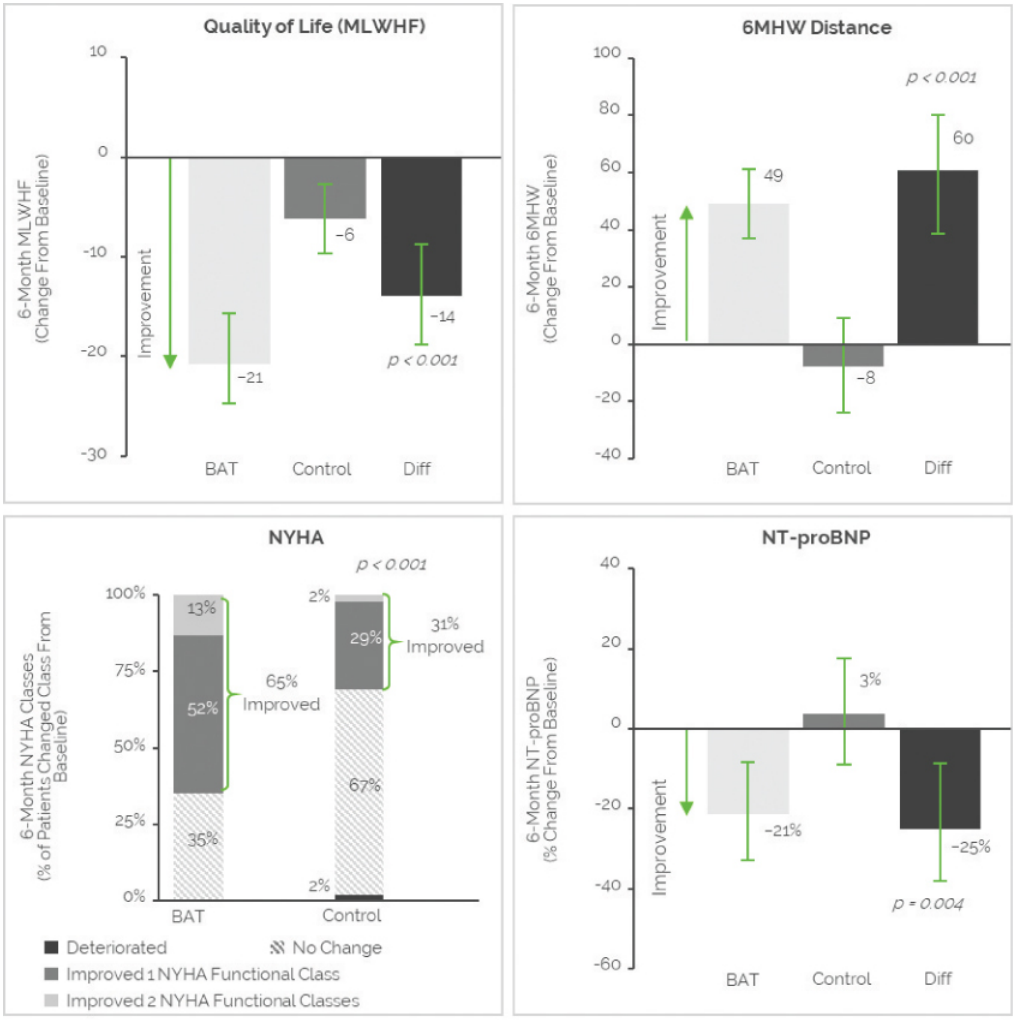
In the pre-market stage of the BeAT-HF pivotal trial, four patient cohorts were developed in collaboration with the FDA under the Breakthrough Devices Program and shown in the following graphic:



- 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 NEO 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 NEO. 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 NEO 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 NEO. As such, the results of these other clinical trials may

not be comparable to clinical results for BAROSTIM NEO. The design of these other trials vary in material ways from the design of the clinical trials for BAROSTIM NEO. 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 NEO 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 in the second half of 2022 or first half of 2023. 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 NEO. 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 $\leq$ 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 $\leq$ 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 NEO. 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 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 NEO. 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 the second-generation BAROSTIM NEO ("*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 NEO 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 NEO 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 NEO 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.

Our BAROSTIM NEO 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 our BAROSTIM NEO 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, which included 13 Account Managers and five Clinical Field Specialists in the U.S. as of March 31, 2021, 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 NEO 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 our BAROSTIM NEO. 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 NEO 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 NEO 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 NEO 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 $29,445 in 2021. 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 NEO 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 DRG 252, which has an established national average Medicare payment of $21,343 in 2021. 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 NEO 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 $44,093 in 2021.

The surgeon implanting BAROSTIM NEO 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 $139 per visit in 2021.

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. We are also continuing to monitor the proposed rule "Medicare Program; Medicare Coverage of Innovative Technology ("MCIT") and Definition of 'Reasonable and Necessary,'" which would create national Medicare coverage for breakthrough devices, the services necessary to implant and maintain the devices, and any reasonable and necessary treatments due to complications from the devices. As the rule is currently written, breakthrough devices market authorized within two years prior to the date the final MCIT rule becomes effective will be eligible for coverage, but that coverage will not exceed four years from the date of market authorization. Claims will not be retroactively payable prior to the effective date of the rule. CMS is currently in the process of collecting public comments on the proposed MCIT rule. Whether and to what extent the proposed MCIT rule impacts coverage for BAROSTIM NEO will depend upon the rule becoming effective, the actual terms of the rule when it becomes effective, and how the rule applies to previously approved breakthrough devices.

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 NEO, 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 NEO 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 NEO for the treatment of HFrEF. It can also be combined with G-DRG ICD I10.10 to cover reimbursement of BAROSTIM NEO 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 NEO 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 our BAROSTIM NEO 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 our BAROSTIM NEO, 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 NEO 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 NEO’s potential to expand the indications for use to other cardiovascular diseases, including different forms of HF, hypertension, and arrhythmias.

For the years ended December 31, 2020 and 2019, we incurred research and development expenses of $6.4 million and $8.7 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 NEO. 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 our BAROSTIM NEO. However, because our BAROSTIM NEO 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 March 31, 2021, we owned 103 issued patents globally (with 56 issued U.S. patents), had five pending patent applications (with three U.S. pending patent applications), and our trademark portfolio contained 46 trademark registrations (with six U.S. trademark registrations) and seven pending trademark applications (with three U.S. pending trademark applications). 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. 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 our BAROSTIM NEO, 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 our BAROSTIM NEO from a single source or 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 our BAROSTIM NEO 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, 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.

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 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 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 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 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 to 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 a 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 marketed BAROSTIM NEO is a Class III device which has received PMA approval.

PMA approval pathway

Class III devices require PMA 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.

Clinical trials

Clinical trials are almost always required to support a PMA and are sometimes required to support a 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 patient 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 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 patients, 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 patient 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 claim includes items or services resulting from a violation of the federal Anti-Kickback Statute 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 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 organisation 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 NEO 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 NEO 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 will progressively replace the existing MDD after a transition period. The transition period was extended in April 2020, and the regulation will become fully effective on May 26, 2021. Until now, different European countries have 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. Once fully effective, the new regulations will:

- 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 will undergo a major change when the Medical Devices Regulation (Regulation (EU) 2017/745 — "MDR") becomes effective. The MDR repeals and replaces 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.

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 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. We do not yet know the full impact that the Affordable Care Act will have on our business. 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, removes 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 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.

Facilities

Our principal executive offices are located at 9201 West Broadway Avenue, Suite 650, Minneapolis, Minnesota 55445, where we lease approximately 23,890 square feet of office, manufacturing, and laboratory space. We lease this space under a lease that terminates on July 31, 2024. We believe our current facilities will be adequate and suitable for our operations for the foreseeable future.

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 March 31, 2021, we had approximately 63 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.

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.

Management

Executive officers and directors

The following table sets forth information regarding our executive officers and directors, as of March 31, 2021:

Name	Age	Position(s)
Executive Officers		
Nadim Yared	53	President and Chief Executive Officer
Jared Oasheim	38	Chief Financial Officer
John Brintnall	68	Chief Strategy Officer and Secretary
Dean Bruhn-Ding	63	Vice President of Regulatory Affairs and Quality Assurance
Liz Galle	54	Vice President of Global Clinical Research
Paul Verrastro	63	Chief Marketing Officer
Non-Employee Directors		
Ali Behbahani, M.D.	45	Director
Mudit K. Jain, Ph.D.	52	Director
John M. Nehra	72	Director
Kirk Nielsen	47	Director
Geoff Pardo	49	Director
Joseph Slattery	56	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

Executive Officers

Nadim Yared has been our President and Chief Executive Officer and one of our directors since October 2006. Mr. Yared previously served as Vice President and General Manager of Medtronic Navigation, a supplier of integrated image-guided surgery products, from 2002 to 2006. He also worked at GE Medical for ten years, where he was Vice President of Global Marketing for OEC Medical Systems, Inc. and Vice President and General Manager of General Electric Company's European X-ray business based in Paris. Mr. Yared is a member of the boards of directors of AdvaMed, Lightpoint Medical, the Medical Device Innovation Consortium ("MDIC") and NanoWear, Inc. In addition, Mr. Yared is currently the chairman of the MDIC Board of Directors and has recently served as Chairman of the AdvaMed Board of Directors. Mr. Yared has an engineering degree from Ecole Nationale Supérieure des Télécommunications and an M.B.A. from INSEAD, France.

Jared Oasheim has been our Chief Financial Officer since October 2020 and has over 15 years of finance experience. Mr. Oasheim joined CVRx in August 2015 as VP of Finance/Controller. Prior to CVRx, he held various leadership roles at three emerging growth technology companies after starting his career with KPMG LLP. Mr. Oasheim graduated from the Carlson School of Management at the University of Minnesota with a B.S. in Accounting and is a certified public accountant (inactive).

John Brintnall has been our Chief Strategy Officer and Secretary since October 2020 and previously served as our Chief Financial Officer and Secretary from October 2003 until October 2020. He has 45 years of business experience and has been the head of finance at six emerging companies (three in technology and three in medical devices), including Computer Network Technology Corporation, Integ and Survivalink. Mr. Brintnall earned a B.B.A. in Finance from the University of Notre Dame.

Dean Bruhn-Ding has been our Vice President of Regulatory Affairs and Quality Assurance since January 2006 and has over 36 years of experience in the medical device industry. Prior to joining CVRx, Mr. Bruhn-Ding was the

Vice President of Regulatory Affairs for SJM, Cardiology Division and held other Vice President and Director positions at the SJM Daig Division in regulatory affairs, clinical affairs, and quality assurance. He also previously held positions at Guidant Corporation and Angeion Group in research, product development, regulatory affairs, quality assurance, and clinical affairs. Mr. Bruhn-Ding earned a B.S. in Medical Technology from North Dakota State University.

Liz Galle has been our Vice President of Global Clinical Research since September 2016 and has over 25 years of cardiovascular clinical trial experience. Prior to joining CVRx, she led statistical and clinical scientist groups at Guidant Corporation (Boston Scientific Cardiac Rhythm Management) from 2003 until September 2016 and was involved in the Women's Health Initiative Study while at the Fred Hutchinson Cancer Research Center. Ms. Galle earned a master's degree in biostatistics from Yale University School of Public Health.

Paul Verrastro has been our Chief Medical Officer since December 2020 and has over 30 years of experience in the cardiac rhythm market. Prior to joining CVRx, he managed his own consulting business, working with clients such as SJM, Abbott Cardiovascular and Medtronic CRDM. He started his career as a sales representative for Medtronic, and after ten years in the field, he joined Guidant Corporation as Director of Implantable Cardiac Defibrillators Marketing. He then served as Vice President of Marketing for all of Guidant Corporation in Europe and later as Vice President of Global Marketing for their customer relationship management division. In May of 2011, he rejoined Medtronic as Vice President of Global Strategic Marketing. Over his career, he has helped bring a number of new technologies to market, including implantable cardiac defibrillators, cardiac resynchronization therapies, implantable loop recorders and leadless pacing. He holds a B.S. degree from Syracuse University.

Non-Employee Directors

Ali Behbahani, M.D. has served as one of our directors since July 2013. He joined New Enterprise Associates, Inc. ("NEA") in 2007 and is a General Partner on the healthcare team. Prior to joining NEA, Dr. Behbahani served as a consultant in business development at The Medicines Company, a specialty pharmaceutical company developing acute care cardiovascular products. He previously held positions as a Venture Associate at Morgan Stanley Venture Partners and as a Healthcare Investment Banking Analyst at Lehman Brothers. Dr. Behbahani is currently on the boards of directors of Adaptimmune Therapeutics, a biopharmaceutical company, Black Diamond Therapeutics, Inc., a precision oncology medicine company, CRISPR Therapeutics AG, a biotechnology company, Genocea Biosciences, Inc., a biopharmaceutical company, Nkarta, Inc., a biotechnology company, and Oyster Point Pharma, Inc., a biopharmaceutical company and is a former director of Nevro Corp. Dr. Behbahani received an M.D. from the University of Pennsylvania School of Medicine, an M.B.A. from The Wharton School of the University of Pennsylvania and a B.S. in Biomedical Engineering, Electrical Engineering and Chemistry from Duke University.

We believe Dr. Behbahani's experience in the medical device industry and as a member of the boards of directors of multiple companies in the healthcare industry qualify him to serve on our board of directors.

Mudit K. Jain, Ph.D. has served as one of our directors since July 2020. He has been a Founding General Partner of Treo Ventures I, L.P. (formerly known as Strategic Healthcare Investment Partners) ("Treo"), a venture capital firm, since September 2018, and previously served as a Managing Director at Synergy Venture Partners, LLC, a venture capital investment firm, from April 2007 to September 2018. Dr. Jain also has served as the CEO and co-founder of NuXcel, a medical device accelerator, since October 2018. Dr. Jain currently serves on the boards of directors of Neochord, Inc., Noctrix, Inc., NuXcel and ShiraTronics, Inc., and he was previously a member of the board of directors of Inspire Medical Systems, Inc. Dr. Jain graduated with a B.E. in Electrical Engineering from National Institute of Technology, Nagpur, India. He received his Ph.D. in Biomedical Engineering from Duke University and his M.B.A. from The Wharton School of the University of Pennsylvania.

We believe Dr. Jain's experience as a venture capital investor and expertise in biomedical engineering qualify him to serve on our board of directors.

John M. Nehra has served as one of our directors since December 2017, and he previously served as a director from August 2000 to August 2014. From 1989 until his retirement in August 2014, Mr. Nehra was affiliated with

NEA, a venture capital firm, including, from 1993 until his retirement, as General Partner of several of its affiliated venture capital limited partnerships. Mr. Nehra also served as Managing General Partner of Catalyst Ventures, a venture capital firm, from 1989 to 2013. Mr. Nehra served on numerous boards of NEA's portfolio companies in healthcare and technology until his retirement in August 2014, and he remains a retired special partner of NEA. Mr. Nehra has served on the board of directors of DaVita Inc. since 1999. He graduated with a B.A. from the University of Michigan.

We believe Mr. Nehra's significant experience in the healthcare technology industry through his involvement with NEA's healthcare-related portfolio companies qualifies him to serve on our board of directors.

Kirk Nielsen has served as one of our directors September 2011. Mr. Nielsen has been a Managing Partner at Vensana Capital, a medtech-focused investment firm, since January 2019, and a Managing Director of Versant Ventures, a healthcare-focused venture capital firm, since January 2011. He currently serves on the board of directors of public company Inari Medical, Inc. and as a board member for several private companies, including: Alleviant Medical, Metavention, Monteris Medical, and SpyGlass Ophthalmics. Mr. Nielsen received an A.B. from Harvard College and an M.B.A. from Harvard Business School.

We believe Mr. Nielsen's extensive management experience serving on the boards of directors of several medical technology companies qualifies him to serve on our board of directors.

Geoff Pardo has served as one of our directors since July 2016 and as a Partner at Gilde Healthcare Partners B.V. ("Gilde"), a specialized European healthcare investor, since 2011. Previously, he was a Partner at Spray Venture Partners from 2004 to 2011, where he led investments in Cascade Ophthalmics ("Cascade"), Interlace Medical Inc., Solace Therapeutics, Inc. ("Solace") and TearScience. Mr. Pardo also served as President & CEO of Facet Solutions Inc., a spinal implant company focused on treating lumbar spinal stenosis, until the company was sold to Globus Medical, Inc. in 2011. He also has worked at Cardinal Partners as an Associate leading their investing activities in the medical device sector. Mr. Pardo represents Gilde as a member of the boards of directors of Ablative Solutions, Inc., Eargo, Inc., Inari Medical, Inc., Vesper Medical, Inc. He previously served on the boards of directors of Axonics Modulation Technologies, Inc., BionX Medical Technologies, Inc., Cascade, Inova Labs Inc., Solace, TearScience and Vapotherm, Inc. He graduated with a B.A. in History from Brown University and an M.B.A. from The Wharton School of the University of Pennsylvania.

We believe Mr. Pardo's experience leading and managing a medical technology company, as well as his healthcare industry knowledge and his experience serving on the boards of directors of other companies, qualify him to serve on our board of directors.

Joseph Slattery has served as one of our directors since October 2008. He previously served as the Executive Vice President and Chief Financial Officer of Asensus Surgical, Inc., a medical device company, from October 2013 through December 2019. Mr. Slattery also was the Executive Vice President and Chief Financial Officer of Baxano Surgical, Inc. from April 2010 until September 2013. From February 1996 through August 2007, Mr. Slattery served in various roles of increasing responsibility at Digene Corporation, including as Chief Financial Officer and Senior Vice President of Finance and Information Systems from October 2006 through August 2007. Mr. Slattery serves on the boards of directors of Alpha Omega SPAC, Morphic Therapeutic, Inc. and Replimune Group, Inc., and he previously served as a director of Baxano Surgical, Inc., Exosome Diagnostics, Inc. and Micromet, Inc. Mr. Slattery received a B.S. in Accounting from Bentley University and is a certified public accountant.

We believe Mr. Slattery's extensive finance and business experience in the life sciences industry and his expertise in public accounting qualify him to serve on our board of directors.

Board composition

Director Independence

Our board of directors currently consists of seven members. Our board of directors has determined that all of our directors, other than Mr. Yared, qualify as "independent" directors in accordance with the listing requirements

of . Mr. Yared is not considered independent because he is an employee of CVRx. The independence requirements include a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by rules, our board of directors has made a determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

Leadership structure of the board

Our bylaws and corporate governance guidelines will provide our board of directors with flexibility to combine or separate the positions of chairman of the board of directors and chief executive officer and/or appoint a lead independent director in accordance with its determination that utilizing one or the other structure would be in the best interests of our Company.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of board in risk oversight process

Risk assessment and oversight are an integral part of our governance and management processes. Our board of directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the board of directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies, and presents the steps taken by management to mitigate or eliminate such risks.

Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors as a whole is responsible for monitoring and assessing strategic risk exposure and our audit committee is responsible for overseeing our major financial risk exposures and the steps our management has taken to monitor and control these exposures. The audit committee also monitors compliance with legal and regulatory requirements.

Board committees

Audit Committee

Our audit committee oversees our corporate accounting and financial reporting process. Among other matters, the audit committee:

- appoints our independent registered public accounting firm;
- evaluates the independent registered public accounting firm's qualifications, independence and performance;
- determines the engagement of the independent registered public accounting firm;
- reviews and approves the scope of the annual audit and the audit fee;

- discusses with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly financial statements;
- approves the retention of the independent registered public accounting firm to perform any proposed permissible non-audit services;
- monitors the rotation of partners of the independent registered public accounting firm on our engagement team as required by law;
- is responsible for reviewing our financial statements and our management's discussion and analysis of financial condition and results of operations to be included in our annual and quarterly reports to be filed with the SEC;
- reviews our critical accounting policies and estimates; and
- annually reviews the audit committee charter and the committee's performance.

We expect that after this offering our audit committee will be comprised of Messrs . and that Mr. will serve as the chair of the committee. We expect that all members of our audit committee will meet the requirements for financial literacy under the applicable rules and regulations of the SEC and . Our board of directors has determined that Mr. will be an "audit committee financial expert" as defined under the applicable rules of the SEC and will have the requisite financial sophistication as defined under the applicable rules and regulations of . Under the rules and regulations of the SEC and , members of the audit committee must also meet heightened independence standards. Our board of directors has determined that all of the members of the audit committee will be independent under the applicable rules and regulations of the SEC and . The audit committee will operate under a written charter that satisfies the applicable standards of the SEC and .

Compensation committee

Our compensation committee reviews and recommends policies relating to compensation and benefits of our officers and employees. The compensation committee reviews and recommends corporate goals and objectives relevant to compensation of our Chief Executive Officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives and recommends to our board of directors the compensation of these officers based on such evaluations. The compensation committee also recommends to our board of directors the issuance of equity and other awards under our stock plans. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter. The current members of our compensation committee are Messrs. Behbahani, Jain and Slattery. We expect that after this offering, our compensation committee will be composed of Messrs. , and that Mr. will serve as the chair of the committee. Our board of directors has determined that each of the members of the compensation committee will be independent under the applicable rules and regulations of the SEC and will be a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act. The compensation committee will operate under a written charter that satisfies the applicable standards of the SEC and .

Nominating and corporate governance committee

The nominating and corporate governance committee is responsible for making recommendations to our board of directors regarding candidates for directorships and the size and composition of our board of directors. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies and reporting and making recommendations to our board of directors concerning governance matters. We expect that after this offering our nominating and corporate governance committee will be composed of Messrs. , and and that Mr. will serve as the chair of the committee. Our board of directors has determined that all of the members of the nominating and corporate governance committee will be independent under the applicable rules and regulations of . The nominating and corporate governance committee will operate under a written charter that satisfies the applicable standards of the SEC and .

Compensation committee interlocks and insider participation

During 2020, our compensation committee consisted of V. Kadir Kadhiresan and Messrs. Behbahani, Jain and Slattery. None of the members of our compensation committee has at any time been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers on our board of directors or compensation committee.

Director qualifications

Upon the closing of this offering, our nominating and corporate governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members), the nominating and corporate governance committee, in recommending candidates for election, and the board of directors, in approving (and, in the case of vacancies, appointing) such candidates, will take into account many factors, including the following:

- personal and professional integrity;
- ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly held company;
- experience in the industries in which we compete;
- experience as a board member or executive officer of another publicly held company;
- diversity (including, but not limited to, gender, race, ethnicity, age, experience and skills);
- conflicts of interest; and
- practical and mature business judgment.

Currently, our board of directors evaluates, and following the closing of this offering will evaluate, each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

Code of business conduct and ethics

In connection with this offering, our board of directors intends to adopt a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Following the closing of this offering, the code of business conduct and ethics will be available on our website at www.cvrx.com. We expect that any amendments to the code, or any waivers of its requirements, will be disclosed on our website. The reference to our web address does not constitute incorporation by reference of the information contained at or available through our website.

Limitation on liability and indemnification matters

Our amended and restated certificate of incorporation that will be effective upon the closing of this offering contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director’s duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; and
- any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and amended and restated bylaws that will be effective upon the closing of this offering will provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws also will provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions that will be included in our amended and restated certificate of incorporation and amended and restated bylaws that will be effective upon the closing of this offering may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage.

Executive compensation

This section describes our executive compensation program generally and the compensation awarded to the executive officers named in the Summary Compensation specifically. These executives, referred to as our “named executive officers,” are:

- Nadim Yared, our President and Chief Executive Officer
- John Brintnall, our Chief Strategy Officer
- Dean Bruhn-Ding, our Vice President of Regulatory Affairs and Quality Assurance

As an “emerging growth company” as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

Summary compensation table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2020.

Name and Principal Position	Year	Salary ($)	Option awards ($)(1)	Non-equity incentive plan compensation ($)(2)	All other compensation ($)(3)	Total ($)
Nadim Yared *President and Chief Executive Officer*	2020	452,000	344,735	196,620	13,259	1,006,614
John Brintnall *Chief Strategy Officer*	2020	289,200	98,435	101,220	—	488,855
Dean Bruhn-Ding *Vice President of Regulatory Affairs and Quality Assurance*	2020	285,800	65,620	64,519	—	415,939

(1) The amounts reported in this column reflect the aggregate of the grant date fair value of stock options granted during 2020 to Messrs. Yared, Brintnall and Bruhn-Ding. Such grant date fair values were computed in accordance with ASC 718 and are not reflective of amounts actually paid to or realized by the named executive officers. Information regarding the assumptions used to calculate the aggregate grant date and incremental fair values is provided in Note 7 to our audited consolidated financial statements included elsewhere in this prospectus.

(2) The amounts represent the annual cash incentive awards earned for 2020.

(3) The amounts reported in the All Other Compensation column include $12,900 for office lease payments paid directly by the Company for Mr. Yared in Coral Springs, FL and $359 for reimbursement of Mr. Yared’s commuting expenses.

Narrative to summary compensation table

2020 Salaries

The named executive officers receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Initial base salaries for the named executed officers were set forth in their respective employment agreements and are annually reviewed by the Compensation Committee. Base salaries for the named executive officers for 2020 and 2021 are set forth below.

Name	2020 Base salary ($)	2021 Base salary ($)
Nadim Yared	452,000	452,000
John Brintnall	289,200	298,000
Dean Bruhn-Ding	285,800	295,000

2020 Annual incentive awards

Each of Messrs. Yared, Brintnall and Bruhn-Ding receive annual incentive awards that entitle the named executive officer to receive a cash payment based on our achievement of certain financial and individual performance goals. The executive's and our company's performance determine the amount, if any, of awards earned. Such awards are based on performance relative to the established targets, which are established annually by our Compensation Committee.

The Compensation Committee determined that the annual incentive opportunity for the named executive officers in 2020 would be based on our company's achievement of annual revenue goals and four operational goals including enrollment in the BeAT-HF pivotal trial, enrollment in the BATwire trial, achievement of various reimbursement goals for BAROSTIM NEO and achievement of selected cash balance metrics. Mr. Yared and Mr. Brintnall also had a goal related to raising additional equity capital and a portion of Mr. Bruhn-Ding's bonus related to individual leadership goals. The weightings of the goals varied among the named executive officers with our company goals weighted at 100% for Messrs. Yared and Brintnall and at 80% for Mr. Bruhn-Ding. Achievement against the stated goals is determined annually and can range from 0% to 150% of the portion of the target incentive amount attributed to each goal for the total revenue goal, the individual leadership goal and for three of the operational goals and can range from 0% to 200% of the target incentive amount attributed to one of the operational goals. The annual target incentive opportunities (expressed as a percentage of base salary) for 2020 for the named executive officers were as follows, and, for the sake of clarify, the named executive officer can earn more or less than target based on the achievement of the respective goals:

Name	Annual target incentive amount as a percent of base salary
Nadim Yared	60%
John Brintnall	50%
Dean Bruhn-Ding	35%

The Company did not meet its revenue goals in 2020 and the named executive officers did not earn any annual incentive payments for this objective.

Achievement of our four operational goals relative to enrollment in the BeAT-HF pivotal trial, enrollment in the BATwire trial, achievement of various reimbursement goals for BAROSTIM NEO and achievement of selected cash balance metrics ranged from 0% to 200% during 2020. The goal related to raising additional equity capital was paid at the 100% level. Based on our Chief Executive Officer's assessment and recommendation, the Committee approved Mr. Bruhn-Ding's achievement of his leadership goals at the 110% level. The 2020 annual cash incentive awards paid to our named executive officers based on these company and individual performance results are set forth below.

Name	Target percentage (% of salary)	Target award value ($)	Actual award paid ($)	Paid award (% of target)
Nadim Yared	60%	271,200	196,620	72.50%
John Brintnall	50%	144,600	101,220	70.00%
Dean Bruhn-Ding	35%	100,030	64,519	64.50%

The actual 2020 annual cash incentive award amounts that were paid in 2021 are included in the Summary Compensation Table in the column entitled “Non-Equity Incentive Plan Compensation.”

2020 stock option grants

In October 2020, the Compensation Committee granted stock options to Messrs. Yared, Brintnall and Bruhn-Ding pursuant to our 2001 Plan. These stock option grants were made to restore the intended ownership levels for each named executive officer following the dilutive impact of certain aspects of the equity issued in the company’s financial transactions, and stock option grants were made to the company’s other then-current employees and directors for the same reason. Each named executive received four separate stock option grants as set forth below:

Option	Nadim Yared (# of shares)	John Brintnall (# of shares)	Dean Bruhn-Ding (# of share)
Grant A	2,013,000	573,700	382,500
Grant B	1,984,700	565,700	377,100
Grant C	1,804,800	514,400	342,900
Grant D	1,774,100	509,600	339,700
Total	7,576,600	2,163,400	1,442,200

Grant A stock options were vested upon grant.

Grant B stock options were vested as to 75% of the total shares upon grant and 25% of the total shares vest monthly over the next 12 months, subject to the executive’s continuous employment with us through the applicable vesting dates.

Grant C stock options were vested as to 25% of the total shares upon grant and 75% of the total shares vest in 1/48th increments each month thereafter, subject to the executive’s continuous employment with us through the applicable vesting dates.

Grant D stock options will vest as to 25% of the total shares one year after the date of grant date and then in 1/48th increments each month thereafter, in each case, subject to the executive’s continuous employment with us through the applicable vesting dates.

The options were granted with an exercise price of $0.11 per share, the fair market value of our common stock on the grant date. The options are not exercisable unless and until we consummate a transaction that results in our common stock being registered with the SEC. The options will terminate immediately prior to any liquidation, dissolution or winding down of our company that occurs prior to our common stock being registered with the SEC. With respect to Grants B, C and D, the vesting of 50% of the then-unvested options will accelerate on a change in control of the company that occurs after our common stock is registered with the SEC. An executive’s unvested options generally terminate on the executive’s termination of employment for any reason, except that the unvested portion of the options will vest if the executive’s employment is terminated by the executive due to Constructive Discharge or by us for any reason other than for Cause during the first six months following a Change in Control of the Company. For these purposes, Constructive Discharge and Cause are defined in the applicable award agreement and are consistent with the same terms included in executive employment agreements as described under “Employment Agreements” below. The definition of Change in Control does not include a public offering; accordingly, no options will accelerate in connection with this offering.

Other elements of compensation

401(k) plan

We currently maintain a 401(k) retirement savings plan for our employees who satisfy certain eligibility requirements, including our named executive officers. The Internal Revenue Code allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) plan. We believe that providing a vehicle for tax-deferred retirement savings though our 401(k) plan adds to the overall desirability of our executive compensation package. We do not match employee contributions to our 401(k) plan.

Other Employee Benefits and Perquisites

All of our full-time U.S.-based employees, including our named executive officers, are eligible to participate in our health and welfare plans, including:

- medical, dental and vision benefits;
- medical and dependent care flexible spending accounts;
- short-term and long-term disability insurance; and
- life insurance.

We provide the statutorily required, country specific health and welfare benefits to our European-based employees.

Our board of directors approved our Chief Executive Officer residing in a state other than where our principal office is located, due in part to the recognition of his extensive travel schedule. The company provides him office space and reimbursement of his expenses for commuting to our principal office, which were insignificant during fiscal 2020 due to COVID-19 related travel restrictions, which we report the Summary Compensation Table in the column entitled “All Other Compensation.”

Employment agreements

We have entered into an employment agreement with each of our named executive officers. Each employment agreement sets forth an initial annual base salary for the executive and provides that the executive’s future annual base salary will be determined annually by the Compensation Committee. Each employment agreement is for an indefinite term and is terminable at will, provided that 30 days advance notice must be provided in the event of a termination of the executive’s employment without Cause or in the event of the executive’s termination of employment due to resignation or Constructive Discharge. The terms “Cause” and “Constructive Discharge” are defined below.

The employment agreements provide that Messrs. Yared, Brintnall and Bruhn-Ding are eligible to receive annual bonuses with a target amount at least equal to 50%, 25% and 25% of their respective annual base salaries based upon achievement of annual performance targets. As noted above under “2020 Annual Incentive Awards,” the annual target bonus amounts for Messrs. Yared, Brintnall and Bruhn-Ding equaled 60%, 50% and 35% of their respective annual base salaries for 2020.

In the event of the executive’s termination of employment without Cause or due to Constructive Discharge, the employment agreements provide for the executive to continue to receive base salary and reimbursement of medical insurance premiums for a period of 12 months in the case of Messrs. Yared and Brintnall, or six months in the case of Mr. Bruhn-Ding. In the event the executive obtains new employment prior to the expiration of such salary continuation period, then only the excess, if any, of the executive’s base salary over the salary under the executive’s new employment shall be payable, and no reimbursement of medical insurance premiums is required if medical benefits are available with the executive’s new employment. Each executive is required to execute a release of claims in order to receive salary continuation benefits. Each of the executives have also entered into

Proprietary Information and Noncompetition Agreements that contain non-competition and non-solicitation restrictions that apply for two years following any termination of employment.

As defined in the employment agreements, “Constructive Discharge” generally means (i) without the executive’s consent, the assignment of the executive to employment responsibilities or duties which are of materially lesser status and degree of responsibility than the executive’s position, responsibilities or duties on the date when the executive commenced employment; (ii) without the executive’s consent, the requirement that the executive be based anywhere other than within 100 miles in the case of Mr. Yared (50 miles in the case of Messrs. Brintnall and Bruhn-Ding) of our office location on the date the executive commenced employment; and (iii) a material reduction in the executive’s total compensation, including any bonus for which he is eligible, other than a reduction in compensation that is part of a general reduction in compensation for our senior management.

As defined in the employment agreements, “Cause” generally means the executive’s (i) material breach of the executive’s proprietary information and noncompetition agreement with our company; (ii) willful and reckless job-related material misconduct, including material failure to perform the executive’s duties as an officer or employee; (iii) commission of fraud, misappropriation or embezzlement in connection with our business; (iv) conviction of, or plead of nolo contendere to, criminal misconduct (excluding parking violations, occasional minor traffic violations, or similar infractions); or (v) established use of narcotics, liquor or illicit drugs having a detrimental effect on the performance of the executive’s employment responsibilities.

Equity incentive plans

We maintain the 2001 Plan, which has provided our employees (including the named executive officers), non-employee directors and consultants the opportunity to participate in the equity appreciation of our business through the receipt of stock options to purchase shares of our common stock. On and after the closing of this offering and following the effectiveness of the 2021 Plan (as described below), no further grants will be made under the 2001 Plan.

In connection with this offering, we intend to adopt 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 is essential to our long-term success.

Outstanding equity awards at fiscal year-end

The following table presents information regarding outstanding equity awards held as of December 31, 2020 by our named executive officers. Pursuant to provisions in the 2001 Plan, the exercise price and number of shares subject to outstanding stock options were adjusted in connection with the 1-for- reverse stock split of our common stock effected on , 2021. Accordingly, the share numbers and exercise prices shown in the table below reflect our named executive officers' post reverse stock split holdings.

	Option awards				
Name	Vesting commencement date	Number of securities underlying unexercised options (#) exercisable(1)	Number of securities underlying unexercised options (#) unexercisable(1)	Option exercise price ($)	Option expiration date
Nadim Yared	10/4/2006	1,227,494	—	0.006	8/6/2025
	6/28/2007	150,000	—	0.006	8/6/2025
	2/21/2008	234,000	—	0.006	8/6/2025
	7/29/2009	500,000	—	0.006	8/6/2025
	4/19/2011	450,000	—	0.006	8/6/2025
	11/12/2013	622,700	—	0.006	11/11/2023
	9/11/2014	200,000	—	0.006	9/10/2024
	7/1/2015	400,000	—	0.006	6/30/2025
	—(2)	400,000(2)	—	0.006	6/30/2025
	9/28/2016	1,467,000	—	0.006	9/27/2026
	2/16/2018	2,770,000(2)	—	0.006	2/15/2028
	1/28/2019	144,229	156,771(3)	0.006	2/15/2028
	1/28/2019	—	2,729,000(4)	0.006	2/15/2028
	7/24/2019	388,166	707,834(3)	0.100	7/23/2029
	7/24/2019	—	2,071,000(4)	0.100	7/23/2029
	7/24/2019	—	333,000(4)	0.100	7/23/2029
	10/1/2020	—	2,013,000(5)	0.110	9/30/2030
	10/1/2020	—	1,984,700(6)	0.110	9/30/2030
	10/1/2020	—	1,804,800(7)	0.110	9/30/2030
	10/1/2020	—	1,774,100(4)	0.110	9/30/2030
John Brintnall	6/28/2007	75,000	—	0.006	8/6/2025
	2/21/2008	90,000	—	0.006	8/6/2025
	7/29/2009	150,000	—	0.006	8/6/2025
	4/19/2011	130,000	—	0.006	8/6/2025
	11/12/2013	188,700	—	0.006	11/11/2023
	9/11/2014	150,000	—	0.006	9/10/2024
	7/1/2015	50,000	—	0.006	6/30/2025
	9/28/2016	385,000	—	0.006	9/27/2026
	2/16/2018	860,000(2)	—	0.006	2/15/2028
	1/28/2019	45,041	48,959(3)	0.006	2/15/2028
	1/28/2019	—	846,000(4)	0.006	2/15/2028
	7/24/2019	149,812	273,188(3)	0.100	7/23/2029

	Option awards				
Name	Vesting commencement date	Number of securities underlying unexercised options (#) exercisable(1)	Number of securities underlying unexercised options (#) unexercisable(1)	Option exercise price ($)	Option expiration date
	7/24/2019	—	927,000(4)	0.100	7/23/2029
	10/1/2020	—	573,700(5)	0.110	9/30/2030
	10/1/2020	—	565,700(6)	0.110	9/30/2030
	10/1/2020	—	514,400(7)	0.110	9/30/2030
	10/1/2020	—	509,600(4)	0.110	9/30/2030
Dean Bruhn-Ding	1/30/2006	46,250	—	0.006	8/6/2025
	2/8/2007	32,500	—	0.006	8/6/2025
	6/28/2007	14,964	—	0.006	8/6/2025
	2/21/2008	62,893	—	0.006	8/6/2025
	7/29/2009	100,000	—	0.006	8/6/2025
	4/19/2011	90,000	—	0.006	8/6/2025
	11/12/2013	113,200	—	0.006	11/11/2023
	9/11/2014	50,000	—	0.006	9/10/2024
	2/17/2015	50,000	—	0.006	2/16/2025
	7/1/2015	100,000	—	0.006	6/30/2025
	9/28/2016	285,000	—	0.006	9/27/2026
	2/16/2018	597,000(2)	—	0.006	2/15/2028
	1/28/2019	31,145	33,855(3)	0.006	2/15/2028
	1/28/2019	—	588,000(4)	0.006	2/15/2028
	7/24/2019	84,645	154,355(3)	0.100	7/23/2029
	7/24/2019	—	525,000(4)	0.100	7/23/2029
	10/1/2020	—	382,500(5)	0.110	9/30/2030
	10/1/2020	—	377,100(6)	0.110	9/30/2030
	10/1/2020	—	342,900(7)	0.110	9/30/2030
	10/1/2020	—	339,700(4)	0.110	9/30/2030

(1) As noted in the footnotes below, certain of these stock options have vested but remain subject to restrictions on exercise.

In addition to the vesting schedules described in the footnotes below, each of the stock option grants disclosed in this table provides that vesting of 50% of the unvested portion of the stock option award (or our repurchase right, in respect of the option grants discussed in footnote 2) will accelerate upon a Change in Control (as defined in the applicable award agreement), and the remainder of the unvested portion of the stock option (or our repurchase right, with respect to the option grants discussed in footnote 2) will vest if, within 6 months following the effective date of a Change in Control, the executive's employment is terminated by the executive due to Constructive Discharge or by us for any reason other than for Cause. Constructive Discharge and Cause are defined in the applicable award agreement and are consistent with the same terms included in executive employment agreements as described under "Employment Agreements" above. The definition of Change in Control does not include a public offering; accordingly, no options will accelerate in connection with this offering.

(2) Terms of these option grants for Messrs. Yared, Brintnall and Bruhn-Ding, respectively, include the right for the applicable executive to exercise all or any part of this stock option at any time and for us to have the right, but not the obligation, to repurchase at $0.006 per share, some or all of the shares that have not been released from our repurchase right. With respect to Mr. Yared's grant of stock options to purchase 400,000 shares, our right to repurchase expires as to (i) 1/4th of the shares on the first anniversary of the date on which we finalize our monthly financial information where we have recognized at least $1 million in revenue in three consecutive months and (ii) 1/48th of the shares each month thereafter. With respect to each of the other grants covered by this footnote, our right to repurchase expires as to (i) 1/4th of the shares on the first anniversary of the vesting commencement date and (ii) as to 1/48th of the shares each month thereafter.

(3) The vesting schedule provides for 25% of the shares forming part of each grant to vest on the first anniversary of the grant date, and for 1/48th of the shares to vest monthly thereafter, subject to the recipient's continuous employment through the relevant vesting dates.

(4) The vesting schedule provides for 25% of the shares forming part of each grant to vest on the first anniversary of the grant date, and for 1/48th of the shares to vest monthly thereafter, subject to the recipient's continuous employment through the relevant vesting dates. Even if vested, no stock options from this award are exercisable unless or until we consummate a transaction that results in our common stock being registered with the SEC.

(5) Stock option is fully vested but no stock options from this award are exercisable unless or until we consummate a transaction that results in our common stock being registered with the SEC.

(6) The vesting schedule provides for 75% of the award to vest on the vesting commencement date and 25% of the award to vest 1/48th per month thereafter, subject to the recipient's continuous employment through the relevant vesting dates. Even if vested, no stock options from this award are exercisable unless or until we consummate a transaction that results in our common stock being registered with the SEC.

(7) The vesting schedule provides for 25% of the award to vest on the vesting commencement date and 75% of the award to vest 1/48th per month thereafter, subject to the recipient's continuous employment through the relevant vesting dates. Even if vested, no stock options from this award are exercisable unless or until we consummate a transaction that results in our common stock being registered with the SEC.

Director compensation

We pay an annual retainer in cash for each of our non-employee directors serving on the board who the board has determined is not then-serving as an affiliate of one of the Company's leading financial investors. For 2020, the cash compensation program consisted of $24,000 for each non-affiliated director, and $3,000 for each audit committee member ($10,000 for the chair) and $3,000 for each compensation committee member ($6,000 for the chair). Any non-affiliated director who serves for less than a calendar year receives a pro-rated amount of the applicable cash compensation.

In addition to the cash retainer, we provide stock-based compensation for all non-employee directors to attract and retain qualified non-employee members of our board of directors. As a general matter, the stock option awards are approved annually by the Compensation Committee for our non-employee board members. However, our Compensation Committee did not approve and grant the stock option award to our non-employee board members for 2020 until January 2021 and, accordingly, such awards are not reflected in the table below and our non-employee directors did not receive their annual stock option awards in 2020. The annual option grants we have made to our non-employee directors while we are a private company vest monthly over a four-year period.

In 2020, the Compensation Committee approved a one-time special grant of stock options to purchase shares of our common stock to Messrs. Nehra and Slattery, our two directors who are not serving as affiliates of any of our leading financial investors, totaling 251,500 and 531,300, respectively, and with a vesting commencement date in certain cases of October 1, 2020, as part of the restorative stock option grants made to the named executive officers and directors as described above. These special option grants will only become exercisable, to the extent vested, if we consummate a transaction that results in our common stock being registered with the SEC. 31,575 of the stock options granted to Mr. Nehra and 172,475 of the stock options granted to Mr. Slattery were deemed vested as of the date of grant, and the remaining stock options will generally vest in monthly installments during the four year period following the grant date or vesting commencement date. All directors are reimbursed for their reasonable out-of-pocket expenses incurred in connection with their service, including those incurred in attending meetings of the board and its committees.

The following table sets forth information concerning the compensation provided to each of our non-employee directors for services provided as a director during the year ended December 31, 2020.

Name	Fees earned or paid in cash ($)(1)	Stock awards ($)(2)	Option awards ($)(2)(3)	All other compensation ($)	Total ($)
Ali Behbahani	—	—	—	—	—
Mudit Jain	—	—	—	—	—
V. Kadir Kadhiresan	—	—	—	—	—
John Nehra	24,000	—	10,865	—	34,865
Kirk Nielsen	—	—	—	—	—
Geoff Pardo	—	—	—	—	—
Joseph Slattery	37,000	—	22,952	—	59,952

(1) Messrs. Nehra and Slattery earned $24,000 in 2020 for their board service. In addition, Mr. Slattery earned $10,000 for his service as the Chairman of the Audit Committee and $3,000 as a member of the Compensation Committee.

(2) As of December 31, 2020, none of our non-employee directors held any unvested shares of restricted stock, restricted stock units or other stock awards. The number of outstanding options held by Messrs. Behbahani, Jain, Kadhiresan (through an affiliated entity), Nehra, Nielsen, Pardo (through an affiliated entity) and Slattery as of December 31, 2020 was 157,500, 0, 120,000, 1,050,708, 0, 120,000 and 1,517,700, respectively.

(3) The amounts reported in this column reflect the aggregate of the grant date fair value of stock options granted during 2020 to Messrs. Nehra and Slattery. Such grant date fair values were computed in accordance with ASC 718 and are not reflective of amounts actually paid to or realized by the directors. Information regarding the assumptions used to calculate the aggregate grant date and incremental fair values is provided in Note 7 to our audited consolidated financial statements included elsewhere in this prospectus. The stock options granted for the services of Mr. Kadhiresan were issued to JJDC, and the stock options granted for Mr. Pardo's services were issued to Coöperatieve Gilde Healthcare IV U.A. ("Gilde IV"), in each case because their employers required that any compensation they receive as directors be paid to their employers.

We expect to assess and revise our director compensation program in connection with this offering, and expect that any compensation program for our non-employee directors after we are a public company will include a combination of cash retainers and equity compensation.

Certain relationships and related party transactions

The following is a description of transactions since January 1, 2019 to which we have been a party, in which the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member of any of the foregoing persons, had or will have a direct or indirect material interest, other than compensation arrangements for our directors and executive officers, which are described in “Executive Compensation.”

Indemnification agreements and directors’ and officers’ liability insurance

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys’ fees, judgments, penalties, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person’s services as a director or executive officer.

Investors’ rights agreement

We entered into the eighth amended and restated investors’ rights agreement (the “Investors’ Rights Agreement”) with the holders of our outstanding convertible preferred stock, including entities with which certain of our directors are affiliated, and certain holders of common stock. As of March 31, 2021, the holders of approximately 471,791,754 shares of our common stock, including the shares of common stock issuable upon the conversion of our convertible preferred stock, are entitled to rights with respect to the registration of their shares under the Securities Act. The Investors’ Rights Agreement also includes a right of first offer in favor of certain holders of convertible preferred stock with regard to certain issuances of our capital stock and a right of co-sale relating to the shares of outstanding convertible preferred shares and common stock held by the parties thereto. The right of first offer will not apply to this offering. Upon the closing of this offering, the right of first offer and the right of co-sale shall terminate. For a more detailed description of these registration rights, see “Description of Capital Stock—Registration Rights.”

Voting agreement

We entered into the eighth amended and restated voting agreement (the “Voting Agreement”) with the holders of our outstanding convertible preferred stock, including entities with which certain of our directors are affiliated, and certain holders of common stock. Pursuant to the Voting Agreement, certain holders of our capital stock have agreed to vote their shares of our capital stock on certain matters, including with respect to the size of the Company’s board of directors and the election of certain directors, including one directors designated by New Enterprise Associates 10, Limited Partnership or its affiliates, one director designated by JJDC or its affiliates, one director designated by Gilde IV or its affiliates, one director designated by Strategic Health Investment Partners (now Treo) or its affiliates, one director designated by Vensana Capital Management, LLC or its affiliates, our then-current chief executive officer and two designees selected by the Nominating and Corporate Governance Committee of the board of directors. Upon the closing of this offering, the Voting Agreement will terminate.

Policies and procedures for related party transactions

Our board of directors intends to adopt a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a

material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction with an unrelated third party and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

Principal stockholders

The following table sets forth information relating to the beneficial ownership of our common stock as of March 31, 2021, by:

- each person, or group of affiliated persons, known by us to beneficially own 5% or more of our outstanding shares of common stock;
- each of our directors;
- each of our executive officers; and
- all directors and executive officers as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of the date set forth above through the exercise of any stock option, warrant or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person. As of March 31, 2021, our outstanding capital stock was held by approximately 155 stockholders of record.

The percentage of shares beneficially owned is computed on the basis of 486,242,139 shares of our common stock outstanding as of the date set forth above, which reflects the assumed conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 471,791,754 shares of common stock. Shares of our common stock that a person has the right to acquire within 60 days of the date set forth above are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is c/o CVRx, Inc., 9201 West Broadway Avenue, Suite 650, Minneapolis, MN 55445.

	Beneficial ownership prior to this offering				Beneficial ownership after this offering	
Name and address of beneficial owner	Number of outstanding shares beneficially owned	Number of shares exercisable within 60 days	Number of shares beneficially owned	Percentage of beneficial ownership	Number of shares beneficially owned	Percentage of beneficial ownership
5% and Greater Stockholders						
Johnson & Johnson Innovation – JJDC, Inc.(1)	138,243,000	24,201,686	162,444,686	31.8%		
New Enterprise Associates(2)	82,887,104	—	82,887,104	17.0%		
Coöperatieve Gilde Healthcare IV U.A.(3)	61,458,493	88,958	61,547,451	12.7%		
Vensana Capital I, L.P.(4)	57,812,500	—	57,812,500	11.9%		
Action Potential Venture Capital Limited(5)	28,972,227	—	28,972,227	6.0%		
Treo Ventures I, L.P.(6)	28,125,000	5,208	28,130,208	5.8%		
Named Executive Officers and Directors						
Nadim Yared(7)	300,000	10,291,024	10,591,024	2.1%		

Name and address of beneficial owner	Beneficial ownership prior to this offering				Beneficial ownership after this offering	
	Number of outstanding shares beneficially owned	Number of shares exercisable within 60 days	Number of shares beneficially owned	Percentage of beneficial ownership	Number of shares beneficially owned	Percentage of beneficial ownership
Ali Behbahani(8)	—	126,458	126,458	*		
Mudit K. Jain(6)	28,125,000	5,208	28,130,208	5.8%		
John M. Nehra(9)	19,375	382,443	401,818	*		
Kirk Nielsen(10)	57,812,500	5,208	57,817,708	11.9%		
Geoff Pardo(11)	61,458,493	88,958	61,547,451	12.7%		
Joseph Slattery(12)	—	574,735	574,735	*		
John Brintnall(13)	693,175	2,820,906	3,514,081	*		
Dean Bruhn-Ding(14)	223,393	2,032,262	2,255,655	*		
All directors and executive officers as a group (12 persons)(15)	148,631,936	17,772,060	166,403,996	33.0%		

* Indicates beneficial ownership of less than 1% of the total outstanding common stock.

(1) Includes (i) options exercisable for 167,341 shares of common stock on or before May 31, 2021; (ii) shares of Series D-2, Series E-2, Series F-2 and Series G convertible preferred stock that will automatically convert into 4,032,259 shares of common stock, 6,451,188 shares of common stock, 7,587,828 shares of common stock and 120,171,725 shares of common stock, respectively, upon the closing of this offering and (iii) JJDC Warrants held by Biosense Webster, Inc. ("BWI"), an affiliate of JJDC, which will be exercisable for 24,034,345 shares of common stock (which may increase up to 25,000,000 shares of common stock if JJDC purchases shares of our common stock in this offering) upon the closing of this offering. JJDC is a wholly-owned subsidiary of Johnson & Johnson ("J&J"), and, as a result, J&J may be deemed to indirectly beneficially own the shares that are directly beneficially owned by JJDC. The principal business address of JJDC is 410 George Street, New Brunswick, New Jersey 08901, and the principal business address of J&J is One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

(2) Includes shares of Series A-2, Series B-2, Series C-2, Series D-2, Series E-2, Series F-2 and Series G convertible preferred stock that will automatically convert into 2,313,208 shares of common stock, 2,854,329 shares of common stock, 3,549,180 shares of common stock, 3,991,220 shares of common stock, 3,298,154 shares of common stock, 11,585,070 shares of common stock and 54,687,500 shares of common stock, respectively, upon the closing of this offering. The address of NEA is 1954 Greenspring Drive, Suite 600, Timonium, Maryland 21093.

(3) Includes (i) options exercisable for 88,958 shares of common stock on or before May 31, 2021 and (ii) shares of Series G convertible preferred stock that will automatically convert into 61,458,493 shares of common stock upon the closing of this offering. The address of Gilde IV is Newtonlaan 91, 3584 BP, Utrecht, The Netherlands.

(4) Includes shares of Series G convertible preferred stock that will automatically convert into 57,812,500 shares of common stock upon the closing of this offering that are owned by Vensana Capital I, L.P. ("Vensana I"). The address of Vensana I is 3601 W. 76th Street, Suite 20, Minneapolis, Minnesota 55435.

(5) Includes shares of Series B-2, Series C-2, Series D-2, Series E-2, Series F-2 and Series G convertible preferred stock that will automatically convert into 59,527 shares of common stock, 513,312 shares of common stock, 589,939 shares of common stock, 331,399 shares of common stock, 1,081,434 shares of common stock and 25,138,520 share of common stock, respectively, upon the closing of this offering. The address of Action Potential Venture Capital Limited is 5 Crescent Drive, Philadelphia, Pennsylvania 19112.

(6) Includes (i) options exercisable for 5,208 shares of common stock on or before May 31, 2021 and (ii) shares of Series G convertible preferred stock that will automatically convert into 28,125,000 shares of common stock upon the closing of this offering, in each case that are owned by Treo. Mr. Jain is the General Partner of Treo and shares voting and dispositive power over the shares held by Treo. The address of Treo is 140 Washington Street, Suite 200, Reno, Nevada 89503.

(7) Includes options exercisable for 10,291,024 shares of common stock on or before May 31, 2021.

(8) Includes options exercisable for 126,458 shares of common stock on or before May 31, 2021.

(9) Includes options exercisable for 382,443 shares of common stock on or before May 31, 2021.

(10) Includes (i) options exercisable for 5,208 shares of common stock on or before May 31, 2021 owned directly by Mr. Nielsen and (ii) shares of Series G convertible preferred stock that will automatically convert into 57,812,500 shares of common stock upon the closing of this offering that are owned by Vensana I. Mr. Nielsen is a Managing Director of Vensana, the General Partner of Vensana I, and shares voting and dispositive power over the shares held by Vensana I. Mr. Nielsen disclaims beneficial ownership of such shares except to the extent of his pecuniary interest thereof.

(11) Includes (i) options exercisable for 88,958 shares of common stock on or before May 31, 2021 and (ii) shares of Series G convertible preferred stock that will automatically convert into 61,458,493 shares of common stock upon the closing of this offering, in each case that are owned by Gilde IV. Mr. Pardo is a partner of Gilde and shares voting and dispositive power over the shares held by Gilde IV.

(12) Includes options exercisable for 574,735 shares of common stock on or before May 31, 2021.

(13) Includes (i) options exercisable for 2,820,906 shares of common stock on or before May 31, 2021 and (ii) shares of Series F-2 and Series G convertible preferred stock that will automatically convert into 88,653 shares of common stock and 223,795 shares of common stock, respectively, upon the closing of this offering.

(14) Includes options exercisable for 2,032,262 shares of common stock on or before May 31, 2021.

(15) Includes (i) options exercisable for 17,772,060 shares of common stock on or before May 31, 2021 and (ii) shares of Series A-2, Series B-2, Series C-2, Series D-2, Series E-2, Series F-2 and Series G convertible preferred stock that will automatically convert into an aggregate of 147,708,441 shares of common stock upon the closing of this offering.

Description of capital stock

The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws that will be effective upon the closing of this offering, the Investors' Rights Agreement and the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and Investors' Rights Agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is part.

Upon the closing of the offering and the effectiveness of our amended and restated certificate of incorporation, our authorized capital stock will consist of shares of common stock, par value $0.01 per share, and shares of preferred stock, par value $0.01 per share. As of March 31, 2021, 14,450,385 shares of our common stock were outstanding, 2,454,686 shares of our Series A-2 convertible preferred stock were outstanding, 2,963,069 shares of our Series B-2 convertible preferred stock were outstanding, 4,308,394 shares of our Series C-2 convertible preferred stock were outstanding, 8,631,967 shares of our Series D-2 convertible preferred stock were outstanding, 10,135,320 shares of our Series E-2 convertible preferred stock were outstanding, 29,548,318 shares of our Series F-2 convertible preferred stock were outstanding and 165,500,000 shares of our Series G convertible preferred stock were outstanding. Following the completion of the offering, shares of our common stock will be outstanding and no shares of our preferred stock will be outstanding.

Common stock

Voting rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Fully paid and nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Preferred stock

Upon the closing of this offering, all outstanding shares of our convertible preferred stock will be converted into shares of our common stock. See Note 6 to our audited consolidated financial statements for a description of our currently outstanding convertible preferred stock. Effective upon the closing of this offering, our amended and restated certificate of incorporation will be amended and restated to delete all references to such shares of convertible preferred stock. Our board of directors will have the authority, without further action by our stockholders, to issue up to shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our Company or other corporate action. Immediately after the closing of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Warrants

As of March 31, 2021, we had outstanding warrants exercisable upon our acquisition or certain asset transfers for 1,978,891 shares of Series E-2 convertible preferred stock at an exercise price of $0.01 per share (“Series E-2 Warrants”), outstanding Series F-2 Warrants currently exercisable for an aggregate of 225,000 shares of our Series F-2 convertible preferred stock at an exercise price of $1.41 per share, outstanding Series G Warrants currently exercisable for an aggregate of 1,625,000 shares of Series G convertible preferred stock at an exercise price of $0.80 per share and outstanding JJDC Warrants exercisable upon the closing of our initial public offering for 9,613,738 shares of Series G convertible preferred stock (which may increase up to 10,000,000 shares of Series G convertible preferred stock if JJDC purchases shares of our common stock in this offering) at an exercise price of $0.01 per share. Upon the closing of this offering and the conversion of all outstanding shares of convertible preferred stock into common stock, and assuming JJDC does not purchase shares of our common stock in this offering, these Warrants will be exercisable for an aggregate of 28,321,845 shares of our common stock. Unless earlier exercised and assuming JJDC does not purchase shares of our common stock in this offering, the Series E-2 Warrants will expire unexercised upon the closing of this offering, JJDC Warrants exercisable for 24,034,345 shares of our common stock will expire 180 days after the holder’s receipt of morbidity and mortality data from the post-market stage of our BeAT-HF pivotal trial, Series F-2 Warrants exercisable for an aggregate of 200,000 shares of our common stock will expire on September 11, 2024, Series F-2 Warrants exercisable for an aggregate of 25,000 shares of our common stock will expire on July 20, 2025, Series G Warrants exercisable for an aggregate of 2,187,500 shares of our common stock will expire on May 31, 2026 and Series G Warrants exercisable for an aggregate of 1,875,000 shares of our common stock will expire on September 30, 2029.

Options

As of March 31, 2021, options to purchase 79,798,591 shares of our common stock were outstanding under our 2001 Plan, including vested options to purchase 35,132,765 shares of our common stock, and non-plan options to purchase 481,922 shares of our common stock were outstanding, including vested non-plan options to purchase 261,297 shares of our common stock.

Registration rights

Under our Investors’ Rights Agreement, following the closing of this offering, the holders of approximately 471,791,754 shares of common stock, including the shares of common stock issuable upon the conversion of our convertible preferred stock, have the right to require us to register their shares under the Securities Act so that those shares may be publicly resold, or to include their shares in any registration statement we file, in each case as described below.

Demand registration rights

Based on the number of shares outstanding as of March 31, 2021, after the closing of this offering, the holders of approximately 471,791,754 shares of our common stock, including the shares of common stock issuable upon the conversion of our convertible preferred stock, will be entitled to certain demand registration rights. Beginning six months following the effectiveness of the registration statement of which this prospectus is a part, the holders of at least a majority of the common stock issuable upon the conversion of any series of convertible preferred stock can, on not more than two occasions, request in writing that we register all or a portion of their shares of common stock, provided that the aggregate price to the public of such shares of common stock offered is at least $10.0 million (net of the underwriting discount and expenses). Additionally, we will not be required to effect a demand registration during the period beginning 45 days prior to the estimated date of filing and ending 90 days following the effectiveness of a Company-initiated registration statement, which period shall be extended to six months after the effective date of the offering for an initial public offering of our securities.

Piggyback registration rights

Based on the number of shares outstanding as of March 31, 2021, after the closing of this offering, in the event that we determine to register any of our securities under the Securities Act (subject to certain exceptions), either for our own account or for the account of other security holders, the holders of approximately 471,791,754 shares of our common stock, including the shares of common stock issuable upon the conversion of our convertible preferred stock, will be entitled to certain “piggyback” registration rights allowing the holders to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to a registration related solely to employee benefit plans, or a registration relating solely to a Rule 145 transaction, the holders of these shares are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration. In an underwritten offering, the managing underwriter, if any, has the right to limit the number of shares such holders may include.

Form S-3 registration rights

Based on the number of shares outstanding as of March 31, 2021, after the closing of this offering, the holders of approximately 471,791,754 shares of our common stock, including the shares of common stock issuable upon the conversion of our convertible preferred stock, will be entitled to certain Form S-3 registration rights. The holders of these shares can make a request that we register their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the shares to be offered is at least $5.0 million. We are obligated to effect up to five registrations on Form S-3, no more than one of which shall be within any twelve-month period.

Expenses of registration

We will pay the registration expenses of the holders of the shares registered pursuant to the demand, piggyback and Form S-3 registration rights described above, including the expenses of one counsel for the selling holders.

Expiration of registration rights

The demand, piggyback and Form S-3 registration rights described above will expire, with respect to any particular stockholder, upon the earlier of seven years after the closing of this offering or when that stockholder can immediately sell all of its shares under Rule 144 of the Securities Act during any 90-day period for any continuous 180-day period.

Anti-takeover effects of provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and delaware law

Some provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws that will be effective upon the closing of this offering contain provisions that could make the

following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interests or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware anti-takeover statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed “interested stockholders” from engaging in a “business combination” with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Undesignated preferred stock

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our Company.

Special stockholder meetings

Our amended and restated bylaws will provide that a special meeting of stockholders may be called at any time by the board of directors, but such special meetings may not be called by the stockholders or any other person or persons.

Requirements for advance notification of stockholder nominations and proposals

Our amended and restated bylaws will establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of stockholder action by written consent

Our amended and restated certificate of incorporation will eliminate the right of stockholders to act by written consent without a meeting.

Classified board; election and removal of directors; filling vacancies

Our board of directors will be divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the

remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation provides for the removal of any of our directors only for cause. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of the board of directors, may only be filled by a resolution of the board of directors unless the board of directors determines that such vacancy shall be filled by the stockholders. This system of electing and removing directors and filling vacancies may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Choice of forum

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be 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, our amended and restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Although our amended and restated certificate of incorporation contains the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

Limitations of liability and indemnification matters

For a discussion of liability and indemnification, see “Management—Limitation on Liability and Indemnification Matters.”

Listing

We intend to apply to list our common stock on under the symbol “CVRX.”

Transfer agent and registrar

The transfer agent and registrar for our common stock is . The transfer agent and registrar’s address is .

Shares eligible for future sale

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock, including shares issued upon the exercise of outstanding options or Warrants, in the public market after this offering, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after the closing of this offering due to contractual and legal restrictions on resale described below. Future sales of substantial amounts of our common stock in the public market either after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital in the future.

Sale of restricted shares

Based on the number of shares of our common stock outstanding as of March 31, 2021, after giving effect to (1) the closing of this offering at an assumed initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus), (2) the conversion of our outstanding convertible preferred stock into 471,791,754 shares of common stock, (3) no exercise of the underwriters' option to purchase additional shares of common stock and (4) no exercise of any of our outstanding options or Warrants, we will have outstanding an aggregate of approximately shares of common stock. Of these shares, all of the shares of common stock to be sold in this offering, and any shares sold upon the exercise of the underwriters' option to purchase additional shares, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our "affiliates" as such term is defined in Rule 144 of the Securities Act. All remaining shares of common stock held by existing stockholders immediately prior to the closing of this offering will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701 under the Securities Act, which are summarized below.

After the completion of this offering, the holders of approximately shares of common stock, representing approximately of our outstanding shares of common stock (or shares, representing approximately % of our outstanding common stock, if the underwriters exercise their over-allotment option in full), will be entitled to dispose of their shares following the expiration of an initial 180-day underwriter "lock-up" period pursuant to the holding period, volume and other restrictions of Rule 144. J.P. Morgan Securities LLC, Piper Sandler & Co. and William Blair & Company, L.L.C. are entitled to waive these lock-up provisions at their discretion prior to the expiration dates of such lock-up agreements.

Lock-up agreements

We expect that our officers, directors and the holders of substantially all of our outstanding capital stock will enter into agreements that, without the prior written consent of J.P. Morgan Securities LLC, Piper Sandler & Co. and William Blair & Company, L.L.C., they will not, subject to limited exceptions, directly or indirectly sell or dispose of any shares of common stock or any securities convertible into or exchangeable or exercisable for shares of our common stock for a period of 180 days after the date of this prospectus. The lock-up restrictions and specified exceptions are described in more detail under "Underwriting."

Rule 144

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our "affiliates" for purposes of Rule 144 at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our "affiliates,"

is entitled to sell those shares in the public market (subject to the lock-up agreements referred to above, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than "affiliates," then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreements referred to above, if applicable). In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our "affiliates," as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- one percent of the number of shares of common stock then outstanding; or
- the average weekly trading volume of our common stock on during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale, or if no such notice is required, the date of receipt of the order to execute the transaction by the broker or the date of execution of the transaction directly with a market maker.

Such sales under Rule 144 by our "affiliates" or persons selling shares on behalf of our "affiliates" are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 under the Securities Act before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) is entitled to rely on Rule 701 to resell such shares beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act in reliance on Rule 144, but without compliance with the holding period requirements contained in Rule 144. Accordingly, subject to any applicable lock-up agreements, beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act, under Rule 701 persons who are not our "affiliates," as defined in Rule 144, may resell those shares without complying with the minimum holding period or public information requirements of Rule 144, and persons who are our "affiliates" may resell those shares without compliance with Rule 144's minimum holding period requirements (subject to the terms of the lock-up agreements referred to above, if applicable).

Registration rights

Based on the number of shares outstanding as of March 31, 2021, after the closing of this offering, the holders of approximately 471,791,754 shares of our common stock, including the shares of common stock issuable upon the conversion of our convertible preferred stock, will, subject to any lock-up agreements they have entered into, be entitled to certain rights with respect to the registration of the offer and sale of those shares under the Securities Act. For a description of these registration rights, see "Description of Capital Stock—Registration Rights." If the offer and sale of these shares are registered, they will be freely tradable without restriction under the Securities Act.

Equity plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of our common stock subject to outstanding options and shares of our common stock issued or issuable under our

incentive plans. We expect to file the registration statement covering shares offered pursuant to our incentive plans shortly after the date of this prospectus, permitting the resale of such shares by nonaffiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

Material U.S. federal income tax consequences to Non-U.S. Holders of our common stock

The following discussion is a summary of material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the "IRS"), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the alternative minimum tax or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the U.S.;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- Non-U.S. Holders that purchase or sell our common stock as part of a wash sale for U.S. federal income tax purposes;
- brokers, dealers or traders in securities, or other Non-U.S. Holders that mark their securities to market for U.S. federal income tax purposes;
- "controlled foreign corporations," "passive foreign investment companies" and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to common stock being taken into account in an applicable financial statement; and
- tax-qualified retirement plans.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our

common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity or arrangement treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the U.S.;
- a corporation created or organized under the laws of the U.S., any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and all substantial decisions of which are controlled by one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any distributions in excess of a Non-U.S. Holder's adjusted tax basis in its common stock will be treated as capital gain and will be treated as described below under "—Sale or Other Taxable Disposition."

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the U.S. (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the U.S. to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the U.S.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate

of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or other taxable disposition

Subject to the discussion below on information reporting, backup withholding and foreign accounts, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the U.S. (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the U.S. to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the U.S. for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest ("USRPI") by reason of our status as a U.S. real property holding corporation ("USRPHC") for U.S. federal income tax purposes at any applicable time within the shorter of the five-year period preceding the Non-U.S. Holder's disposition of, or the Non-U.S. Holder's holding period for, our common stock.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by certain U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the U.S.), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Information reporting and backup withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to a Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the U.S. or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not

have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional withholding tax on payments made to foreign accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such sections commonly referred to as the Foreign Account Tax Compliance Act, or "FATCA") on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax will be imposed on dividends on our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the U.S. governing FATCA may be subject to different rules.

While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

Underwriting

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Piper Sandler & Co. and William Blair & Company, L.L.C. are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discount set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of shares
J.P. Morgan Securities LLC	
Piper Sandler & Co.	
William Blair & Company, L.L.C.	
Canaccord Genuity LLC	
Total	

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the shares of common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $ per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to $ per share from the initial public offering price. After the initial offering of the shares to the public, if all of the shares of common stock are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the U.S. may be made by affiliates of the underwriters.

The underwriters have an option to buy up to additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is $ per share. The following table shows the per share and total underwriting discount to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per Share	$	$
Total	$	$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discount, will be approximately $.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the SEC a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exercisable or exchangeable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, loan, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of each of J.P. Morgan Securities LLC, Piper Sandler & Co. and William Blair & Company, L.L.C. for a period of 180 days after the date of this prospectus, other than the shares of our common stock to be sold in this offering.

The restrictions on our actions, as described above, do not apply to certain transactions, including (i) the issuance of shares of common stock or securities convertible into or exercisable for shares of our common stock pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options (including net exercise) or the settlement of restricted stock units (“RSUs”) (including net settlement), in each case outstanding on the date of the underwriting agreement and described in this prospectus; (ii) grants of stock options, stock awards, restricted stock, RSUs, or other equity awards and the issuance of shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock (whether upon the exercise of stock options or otherwise) to our employees, officers, directors, advisors, or consultants pursuant to the terms of an equity compensation plan in effect as of the closing of this offering and described in this prospectus, provided that such recipients enter into a lock-up agreement with the underwriters; or (iii) our filing of any registration statement on Form S-8 relating to securities granted or to be granted pursuant to any plan in effect on the date of the underwriting agreement and described in this prospectus or any assumed benefit plan pursuant to an acquisition or similar strategic transaction.

Our directors and executive officers and the holders of substantially all of our outstanding capital stock (such persons, the “lock-up parties”) have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 180 days after the date of this prospectus (such period, the “restricted period”), may not (and may not cause any of their direct or indirect affiliates to), without the prior written consent of each of J.P. Morgan Securities LLC, Piper Sandler & Co. and William Blair & Company, L.L.C., (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such lock-up parties in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant (collectively with the common stock, the “lock-up securities”)), (2) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of lock-up securities, in cash or otherwise, (3) make any demand for or exercise any right with respect to the registration of any lock-up securities, or (4) publicly disclose the intention to do any of the foregoing. Such persons or entities have further acknowledged that these undertakings preclude them from engaging in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer (by any person or entity, whether or not a signatory to such

agreement) of any economic consequences of ownership, in whole or in part, directly or indirectly, of any lock-up securities, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of lock-up securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including (a) transfers of lock-up securities: (i) as bona fide gifts, or for bona fide estate planning purposes, (ii) by will, other testamentary document or intestate succession, (iii) to an immediate family member of the lock-up party or to any trust for the direct or indirect benefit of the lock-up party or any immediate family member, (iv) to a corporation, partnership, limited liability company, trust or other entity of which the lock-up party and its immediate family members are, directly or indirectly, the legal and beneficial owner of all of the outstanding equity securities or similar interests, (v) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (iv), (vi) in the case of a corporation, partnership, limited liability company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of the lock-up party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the lock-up party or its affiliates or (B) as part of a transfer, distribution or disposition to members, shareholders, current or former partners (general or limited), beneficiaries, subsidiaries or other affiliates of the lock-up party, or to the estates of any such shareholders, partners, beneficiaries or other equity holders of the lock-up party; (vii) by operation of law, (viii) to us from an employee or other service provider upon death, disability or termination of employment or service relationship of such employee or service provider, (ix) as part of a sale of lock-up securities acquired in open market transactions after the completion of this offering, (x) to us in connection with the (1) vesting, settlement or exercise of RSUs, options, warrants or other rights to purchase shares of our common stock (including “net” or “cashless” exercise), including for the payment of exercise price and tax and remittance payments, or (2) any contractual arrangement in effect on the date of the preliminary prospectus that provides for the repurchase of any securities held by the lock-party, or (xi) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction approved by our board of directors and made to all shareholders involving a change in control, provided that if such transaction is not completed, all such lock-up securities would remain subject to the restrictions in the immediately preceding paragraph; (b) exercise of options, settlement of RSUs or other equity awards granted pursuant to plans or other equity compensation arrangements or exercise of warrants, in each case as described in this prospectus, provided that any lock-up securities received upon such exercise, vesting or settlement would be subject to the restrictions in the immediately preceding paragraph; (c) the conversion of outstanding preferred stock, warrants to acquire preferred stock or convertible securities into shares of our common stock or warrants to acquire shares of our common stock, provided that any common stock or warrants received upon such conversion would be subject to the restrictions in the immediately preceding paragraph; and (d) the establishment by lock-up parties of trading plans under Rule 10b5-1 under the Exchange Act, provided that such plan does not provide for the transfer of lock-up securities during the restricted period.

J.P. Morgan Securities LLC, Piper Sandler & Co. and William Blair & Company, L.L.C., in their sole discretion, may release the securities subject to any of the lock-up agreements with the underwriters described above, in whole or in part at any time.

Record holders of our securities are typically the parties to the lock-up agreements with the underwriters and the market standoff agreements with us referred to above, while holders of beneficial interests in our shares who are not also record holders in respect of such shares are not typically subject to any such agreements or other similar restrictions. Accordingly, we believe that certain holders of beneficial interests who are not record holders and are not bound by market standoff or lock-up agreements could enter into transactions with respect to those beneficial interests that negatively impact our stock price. In addition, a shareholder who is neither subject to a market standoff agreement with us nor a lock-up agreement with the underwriters may be able to sell, short sell, transfer, hedge, pledge, lend or otherwise dispose of or attempt to sell, short sell, transfer, hedge, pledge, lend or otherwise dispose of, their equity interests at any time after the closing of this offering.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

We will apply to have our common stock approved for listing/quotation on the under the symbol “CVRX”.

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the underwriters’ option to purchase additional shares referred to above, or may be “naked” shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on , in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common stock, or that the shares will trade in the public market at or above the initial public offering price.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other

services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Other than in the U.S., no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to prospective investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to prospective investors in the European Economic area

In relation to each Member State of the European Economic Area (each a "Relevant State"), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation. and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a "qualified

investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to prospective investors in the United Kingdom

In relation to the United Kingdom, no shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares that has been approved by the Financial Conduct Authority in accordance with the transitional provisions in Regulation 74 of the Prospectus (Amendment etc.) (EU Exit) Regulations 2019, except that offers of shares may be made to public in the United Kingdom at any time under the following exemptions under Regulation (EU) 2017/1129, as amended, as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018 (the "UK Prospectus Regulation"):

(a) to any legal entity which is a qualified investor as defined under the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the UK Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or

(c) in any other circumstances falling within section 86 of the Financial Services and Markets Act 2000 (as amended, the "FSMA"),

provided that no such offer of shares shall require us or the underwriters to publish a prospectus pursuant to section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares.

In the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the UK Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the FSMA.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to prospective investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards

for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, us, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to prospective investors in Australia

This prospectus:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the "Corporations Act");
- has not been, and will not be, lodged with the Australian Securities and Investments Commission ("ASIC"), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act ("Exempt Investors").

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to prospective investors in Japan

The shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to prospective investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (the "SFO") of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous

Provisions) Ordinance (Cap. 32) of Hong Kong) (the "CO") or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made thereunder.

Notice to prospective investors in Singapore

Singapore SFA Product Classification—In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of shares, we have determined, and hereby notify all relevant persons (as defined in Section 309A(1) of the SFA), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Each underwriter has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each underwriter has represented and agreed that it has not offered or sold any shares or caused the shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares or cause the shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, whether directly or indirectly, to any person in Singapore other than:

(a) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA;

to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or

otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

where no consideration is or will be given for the transfer;

where the transfer is by operation of law;

as specified in Section 276(7) of the SFA; or

as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Notice to prospective investors in China

This prospectus will not be circulated or distributed in the PRC and the shares will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

Notice to prospective investors in Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder (the "FSCMA"), and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder (the "FETL"). The shares have not been listed on any of securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

Notice to prospective investors in Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorised to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

Notice to prospective investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority ("CMA") pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended (the "CMA Regulations"). The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorised financial adviser.

Notice to prospective investors in the Dubai International Financial Centre ("DIFC")

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority ("DFSA"). This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to

restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Notice to prospective investors in the United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the DIFC) other than in compliance with the laws of the United Arab Emirates (and the DIFC) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the DIFC) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the DFSA.

Notice to prospective investors in Bermuda

Shares may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to prospective investors in the British Virgin Islands

The shares are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on our behalf. The shares may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), "BVI Companies"), but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

Notice to prospective investors in South Africa

Due to restrictions under the securities laws of South Africa, no "offer to the public" (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted) (the "South African Companies Act")) is being made in connection with the issue of the shares in South Africa. Accordingly, this document does not, nor is it intended to, constitute a "*registered prospectus*" (as that term is defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. The shares are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions stipulated in section 96 (1) applies:

Section 96 (1)(a) the offer, transfer, sale, renunciation or delivery is to:
(i) persons whose ordinary business, or part of whose ordinary business, is to deal in securities, as principal or agent;
(ii) the South African Public Investment Corporation;
(iii) persons or entities regulated by the Reserve Bank of South Africa;
(iv) authorised financial service providers under South African law;
(v) financial institutions recognised as such under South African law;
(vi) a wholly-owned subsidiary of any person or entity contemplated in (c), (d) or (e), acting as agent in the capacity of an authorised portfolio manager for a pension fund, or as manager for a collective investment scheme (in each case duly registered as such under South African law); or
(vii) any combination of the person in (i) to (vi); or

Section 96 (1)(b) the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000 or such higher amount as may be promulgated by notice in the Government Gazette of South Africa pursuant to section 96(2)(a) of the South African Companies Act.

Information made available in this prospectus should not be considered as "*advice*" as defined in the South African Financial Advisory and Intermediary Services Act, 2002.

Notice to prospective investors in Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Israeli Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares of common stock is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Legal matters

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Faegre Drinker Biddle & Reath LLP. Shearman & Sterling LLP, New York, New York, is acting as counsel for the underwriters in connection with this offering.

Experts

The consolidated financial statements included in this prospectus and elsewhere in the registration statement have been so included in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in auditing and accounting.

Where you can find more information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to CVRx, Inc. and the common stock offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address is www.sec.gov.

Upon the closing of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available on the website of the SEC referred to above. We maintain a website at www.cvrx.com, and upon the closing of this offering, you also may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock.

CVRx, Inc.
Index

Report of independent registered public accounting firm

Board of Directors and Stockholders
CVRx, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of CVRx, Inc. (a Delaware corporation) and subsidiary (the “Company”) as of December 31, 2020 and 2019, 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 consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of their operations and their 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 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 and in accordance with auditing standards generally accepted in the United States of America. 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 include 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
April 9, 2021

CVRx, Inc.
Consolidated balance sheets

(in thousands, except share and per share amounts)	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 59,112	$ 25,741
Accounts receivable, net	1,281	719
Inventory	3,343	2,072
Prepaid expenses and other current assets	605	375
Total current assets	64,341	28,907
Property and equipment, net	410	174
Other non-current assets	26	26
Total assets	$ 64,777	$ 29,107
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 483	$ 437
Accrued expenses	3,583	4,637
Warrant liability	3,911	3,540
Total current liabilities	7,977	8,614
Long-term debt	19,278	18,992
Other long-term liabilities	777	561
Total liabilities	28,032	28,167
Commitments and contingencies		
Convertible preferred stock, no par value, 237,370,645 and 188,120,645 authorized as of December 31, 2020 and 2019, respectively; 223,541,754 and 161,041,754 shares issued and outstanding as of December 31, 2020 and 2019, respectively	329,983	279,983
Stockholders' equity (deficit):		
Common stock, $.01 par value, 625,217,795 and 438,044,756 authorized as of December 31, 2020 and 2019, respectively; 14,253,564 and 19,138,493 shares issued and outstanding as of December 31, 2020 and 2019, respectively	143	192
Additional paid-in capital, common stock	58,485	58,521
Accumulated deficit	(351,676)	(337,567)
Accumulated other comprehensive loss	(190)	(189)
Total stockholders' equity (deficit)	(293,238)	(279,043)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 64,777	$ 29,107

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 amounts)

	Year ended December 31,	
	2020	2019
Revenue	$ 6,053	$ 6,257
Cost of goods sold	1,440	1,683
Gross profit	4,613	4,574
Operating expenses:		
Research and development	6,410	8,662
Selling, general and administrative	9,717	6,106
Total operating expenses	16,127	14,768
Loss from operations	(11,514)	(10,194)
Interest expense	(2,470)	(1,720)
Other income (expense), net	(40)	(2,646)
Loss before income taxes	(14,024)	(14,560)
Provision for income taxes	(85)	(73)
Net loss	(14,109)	(14,633)
Cumulative translation adjustment	(1)	(6)
Comprehensive loss	$ (14,110)	$ (14,639)
Net loss per share, basic and diluted	$ (0.94)	$ (0.77)
Weighted-average common shares used to compute net loss per share, basic and diluted	15,308,364	19,085,104

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 amounts)

	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, 2018	130,166,754	$255,283	18,921,785	$ 190	$ 58,469	$ (323,130)	$ (183)	$ (264,654)
Adoption of ASC 606	—	—	—	—	—	196	—	196
Issuance of Series G convertible preferred stock, net of issuance costs	30,875,000	24,687	—	—	—	—	—	—
Accretion of Series G issuance costs	—	13	—	—	(13)	—	—	(13)
Exercise of stock options	—	—	216,708	2	(1)	—	—	1
Employee stock compensation	—	—	—	—	66	—	—	66
Net loss for the year ended December 31, 2019	—	—	—	—	—	(14,633)	—	(14,633)
Cumulative translation adjustment	—	—	—	—	—	—	(6)	(6)
Balances as of December 31, 2019	161,041,754	$279,983	19,138,493	$ 192	$ 58,521	$ (337,567)	$ (189)	$ (279,043)
Exercise of stock options	—	—	6,875	—	—	—	—	—
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)
Repurchase of common stock	—	—	(4,891,804)	(49)	49	—	—	—
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	14,253,564	$ 143	$ 58,485	$ (351,676)	$ (190)	$ (293,238)

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,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$(14,109)	$(14,633)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	132	66
Depreciation of property and equipment	75	56
Amortization of deferred financing costs and loan discount	286	195
Loss on debt extinguishment	—	261
Changes in allowance for doubtful accounts	—	(27)
Changes in fair value of convertible preferred stock warrants	371	2,632
Changes in operating assets and liabilities:		
Accounts receivable	(562)	(183)
Inventory	(1,271)	(216)
Prepaid expenses and other current assets	(226)	(94)
Accounts payable	46	(1,051)
Accrued expenses	(838)	209
Net cash used in operating activities	(16,096)	(12,785)
Cash flows from investing activities:		
Purchase of property and equipment	(311)	(106)
Net cash used in investing activities	(311)	(106)
Cash flows from financing activities:		
Proceeds from issuance of Series G Preferred Stock, net of fees	49,783	24,688
Proceeds from long-term borrowings	—	20,000
Debt financing fees	—	(479)
Repayment on debt financing	—	(14,661)
Proceeds from the exercise of common stock options	—	1
Net cash provided by financing activities	49,783	29,549
Effect of currency exchange on cash and cash equivalents	(5)	(5)
Net change in cash and cash equivalents	33,371	16,653
Cash and cash equivalents at beginning of year	25,741	9,088
Cash and cash equivalents at end of year	$ 59,112	$ 25,741
Supplemental Information:		
Cash paid for interest	$ 2,033	$ 1,215
Cash paid for income taxes	$ 10	$ 15

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

CVRx, Inc.
Notes to consolidated financial statements

1. Business organization

CVRx, Inc. (the “Company”) was incorporated in Delaware and is headquartered in Minneapolis, Minnesota. The Company has developed and is marketing a medical device, BAROSTIM NEO, for heart failure 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.

The Company anticipates that the existing cash balance together with cash generated from the collections of existing accounts receivable and revenue resulting from new and existing customers will be adequate to meet its working capital requirements for at least the next twelve months.

The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

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”).

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 expects to qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). As a result, the Company is eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies such as transition period for adopting new or revised accounting standards that have different effective dates for public and private companies until such time as those standards apply to private 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.

Foreign currency

The Company’s reporting currency is the U.S. dollar; however, for operations located in Switzerland and Italy, the functional currency is the local currency. Assets and liabilities of these foreign operations are translated to U.S. dollars at period-end exchange rates, while accounts in the consolidated statements of operations and comprehensive loss and cash flows are translated to U.S. dollars at the average exchange rates for the period. For these operations, translation gains and losses are recorded as a cumulative translation adjustment, a component of accumulated other comprehensive loss on the consolidated balance sheets, until the foreign entity is sold or liquidated.

Transaction gains and losses result from transactions that are denominated in a currency other than the functional currency of the operation. These foreign currency transaction gains and losses are included in other income (expense), net in the consolidated statements of operations and comprehensive loss.

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, 2020, and 2019, cash equivalents consisted of money market funds, which are stated at cost and approximate fair value.

Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash and cash equivalents. The majority of the Company's cash and cash equivalents is held by one financial institution in the United States of America in excess of federally insured limits. The Company maintained investments in money market funds that are not federally insured as of December 31, 2020, and 2019. The Company has not experienced any losses on its deposits of cash and cash equivalents.

Accounts receivable, net

The Company grants credit to customers in the normal course of business, but generally does not require collateral. An allowance for doubtful accounts is maintained when deemed necessary and balances are written off when deemed to be uncollectible. The Company had an allowance for doubtful accounts of $0 as of December 31, 2020, and 2019, respectively.

Fair value of financial instruments

The carrying amount of the Company's cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities and long-term debt approximates fair value due to the short-term nature or market interest rates of these items.

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.

Debt issuance costs and discounts

Debt issuance costs and discounts are recorded as a reduction of long-term debt. The amortization of debt issuance costs and discounts is calculated using the effective interest method over the term of the debt and is recorded in interest expense in the consolidated statements of operations and comprehensive loss.

Property and equipment and recoverability of long-lived assets

Property and equipment are stated at cost. Additions and improvements that extend the lives of assets are capitalized while expenditures for repairs and maintenance are expensed as incurred. Depreciation is computed using the straight-line method over the assets' estimated useful lives of three to five years. Leasehold improvements are amortized on a straight-line basis over the shorter of the assets' useful lives or the remaining life of the lease.

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The carrying amount of a long-lived asset group is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset group. If it is determined that an impairment loss has occurred, the loss is measured as the amount by which the carrying amount of the long-lived asset group exceeds its fair value. There were no impairment charges recorded in the years ended December 31, 2020, and 2019.

Revenue recognition

We sell our products primarily through a direct sales force and to a lesser extent through a combination of sales agents and independent distributors. Our revenue consists primarily of the sale of our BAROSTIM NEO, which consists of two implantable components: a pulse generator and a stimulation lead.

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

Research and development

Research and development costs are expensed as incurred. Research and development costs include costs of all basic research activities as well as other research, engineering and technical effort required to develop a new product, service or indication of use, or make significant improvement to an existing product or manufacturing process. Research and development costs also include pre-approval regulatory and clinical trial expenses.

Advertising expense

Expenditures for advertising are charged to operations as incurred. Advertising expenses were $0.1 million and $7,000 during the years ended December 31, 2020, and 2019, respectively.

Stock-Based compensation

The Company’s compensation programs include share-based payments. All awards under share-based payment programs are accounted for at fair value and these fair values are generally amortized on a straight-line basis over the vesting terms into general and administrative expense, research and development expense and cost of goods sold in the consolidated statements of operations and comprehensive loss.

Freestanding preferred stock warrants

Warrants to purchase the Company’s preferred stock are classified as a liability on the consolidated balance sheets. These warrants are subject to remeasurement at each balance sheet date and any change in fair value is recognized in other income (expense), net. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants or when the warrants become exercisable to purchase the Company’s common stock at which time the liability will be reclassified to stockholders’ equity (deficit).

Income taxes

The Company records income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company’s consolidated financial statements or income tax returns. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

The impact of uncertain tax positions taken or expected to be taken on an income tax return are recognized in the consolidated financial statements at the largest amount that is more likely than not to be sustained upon audit

by the relevant taxing authority. An uncertain tax position is not recognized in the consolidated financial statements unless it is more likely than not of being sustained upon audit. The Company recognizes accrued interest and penalties related to unrecognized tax positions as a component of income tax expense.

Net loss per share

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares. For purpose of this calculation, outstanding options and shares of convertible preferred stock are considered potential dilutive common shares.

The Company's shares of convertible preferred stock contractually entitle the holders of such shares to participate in dividends but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2020, and 2019.

Comprehensive loss

Comprehensive loss includes all changes in stockholders' equity (deficit) except those resulting from distributions to stockholders. The Company's comprehensive loss consists of net loss and currency translation adjustments and is presented in the consolidated statements of operations and comprehensive loss.

Recent accounting pronouncements

In February 2016, the Financial Accounting Standards Board issued ASC Update No. 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 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. While the Company is still in the process of determining the effect that the new standard will have on its financial position and results of operations, the Company expects to recognize additional assets and corresponding liabilities on its consolidated balance sheets, as a result of its operating lease portfolio as disclosed in Note 10 — Commitments and Contingencies.

3. Selected balance sheet information

Inventory consists of the following on:

	December 31,	
(in thousands)	**2020**	**2019**
Raw material	$1,361	$ 671
Work-in-process	321	373
Finished goods	1,661	1,028
	$3,343	$2,072

Property and equipment, net consists of the following on:

	December 31,	
(in thousands)	**2020**	**2019**
Office furniture and equipment	$ 189	$ 189
Lab equipment	1,272	1,207
Computer equipment and software	516	374
Leasehold improvements	44	29
Capital equipment in process	89	—
	2,110	1,799
Less: Accumulated depreciation and amortization	1,700	1,625
	$ 410	$ 174

Depreciation expense was $75,000 and $56,000 for the years ended December 31, 2020, and 2019, respectively.

Accrued expenses consist of the following on:

	December 31,	
(in thousands)	**2020**	**2019**
Clinical trial and other professional fees	$1,690	$3,073
Bonuses	794	677
Paid time off	552	413
Other	547	474
	$3,583	$4,637

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:

(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	$—	$—	$3,991	$3,911

Balance as of December 31, 2019	Level 1	Level 2	Level 3	Total
Liabilities:				
Convertible preferred stock warrant liability	$—	$—	$3,540	$3,540
Total liabilities	$—	$—	$3,540	$3,540

The Company's recurring fair value measurements using significant unobservable inputs (Level 3) relate solely to the Company's convertible preferred stock warrant liability. 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 shares of Series G convertible preferred stock. The Company issued to Biosense Webster, Inc. ("BWI"), an affiliate of Johnson & Johnson Innovation — JJDC, Inc. ("JJDC"), a warrant to purchase shares of Series E-2 convertible preferred stock that only becomes exercisable in the event of an acquisition or asset transfer involving the Company and it expires on the earlier of (i) a qualifying public company transaction, as defined, and (ii) 180 days after receipt of the data from the post-market stage of the BeAT-HF pivotal trial. 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 shall become exercisable if and only if a qualifying public company transaction is consummated and expires 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. Accordingly, under no event will the BWI warrant to purchase Series E-2 Preferred Shares and the BWI warrant to purchase Series G Preferred Shares both become exercisable. In connection with the loan and security agreement entered into in September 2019, the Company issued a warrant to purchase shares of Series G convertible preferred stock. The convertible preferred stock warrant liability is 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.

The fair value of the convertible preferred stock warrant liability was determined using the Black-Scholes option pricing model with the following inputs during the years ended:

	December 31,	
	2020	2019
Expected life in years	1.3 – 8.8	0.5 – 9.8
Expected volatility	51.4% – 75.6%	42.2% – 46.5%
Expected dividend yield	0%	0%
Risk-free interest rate	0.10% – 0.93%	1.60% – 1.92%

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:

	December 31,	
(in thousands)	**2020**	**2019**
Beginning of the period	$3,540	$ 303
Issued	—	605
Change in fair value	371	2,632
End of the period	$3,911	$3,540

There were no transfers in or out of Level 1, Level 2 or Level 3 fair value measurements during the years ended December 31, 2020 and 2019.

5. Debt

Oxford loan agreement

In May 2016, the Company entered into a loan and security agreement with Oxford Finance ("Oxford loan agreement") under which it could borrow up to a total of $20 million at a floating per annum rate equal to the greater of 8.5% or the 30-day U.S. dollar LIBOR rate on the last business day of the month plus 7.87%. The Oxford loan agreement required interest only payments through December 2017 and then 36 monthly principal and interest payments beginning in January 2018. A final payment of $1.2 million, equal to 6% of the original principal, would have been due to be paid in December 2020. The borrowings were collateralized by substantially all assets of the Company except intellectual property. The Oxford loan agreement contained a subjective acceleration clause that required the payment of certain penalties if the loan was paid off prior to maturity and included various restrictive covenants, including a restriction on the payment of dividends. The Company was in compliance with these covenants as of December 31, 2018.

In September 2019, the Company paid the outstanding balance of the Oxford loan agreement. The Company recognized a loss of $0.3 million related to the extinguishment of the Oxford loan agreement as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss.

Horizon loan agreement

In September 2019, the Company entered into a loan and security agreement with Horizon Technology Finance Corporation ("Horizon loan agreement") under which it could borrow up to a total of $20 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, is due to be paid in October 2024. The Horizon loan agreement initially required the Company to maintain cash on deposit in accounts in which Horizon maintains an account control agreement of not less than $5.0 million. This minimum cash on deposit requirement was released in July 2020 following the satisfaction of a financing milestone. The borrowings are collateralized by all or substantially all of the assets of the Company. The Horizon loan agreement requires the payment of certain penalties if the loan is paid off prior to maturity for any reason, including pursuant to a subjective acceleration clause, and includes various restrictive covenants, including a restriction on the payment of dividends. The Company was in compliance with these covenants as of December 31, 2020.

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 shares of Series G convertible preferred stock 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.

The following table provides information related to the warrants issued in connection with the Horizon loan agreement, including the assumptions used in the Black-Scholes option pricing model:

Grant date	9/30/2019
Number of shares available for purchase	750,000
Expected life in years	10.0
Expected volatility	42.6%
Expected dividend yield	0%
Risk-free interest rate	1.68%
Grant date fair value	$ 604,951

The fair value of these warrants was recorded as a debt discount and is subsequently amortized to interest expense over the life of the Horizon loan agreement utilizing the effective interest method.

The annual principal maturities of debt as of December 31, 2020 are as follows (in thousands):

2021	$ —
2022	5,333
2023	8,000
2024	6,667
	20,000
Less: Unamortized debt costs and discounts	(722)
Long-term debt	$19,278

6. Stockholders' equity

Series G preferred stock issuance

During 2016, the Company issued 72,125,000 shares of Series G convertible preferred stock ("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 have 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 consists of the following (in thousands, except share data):

	Authorized	Issued and outstanding	Carrying value	Aggregate liquidation preference
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

Conversion

All Preferred Shares shall be automatically converted into common stock on a one-for-one basis (subject to certain anti-dilutive adjustments of the conversion price, as defined) upon the closing of a public offering of the Company's common stock with gross proceeds of at least $50.0 million or upon the vote of the holders of at least 52% of the Preferred Shares, voting as a single class on an as-converted basis. In addition, Preferred Shares are also convertible into common stock on a one-for-one basis (subject to certain anti-dilutive adjustments of the conversion price, as defined) at the option of the holder. Furthermore, in the case of the conversion of the Series G Preferred Shares in connection with any transaction that results in the Company's common stock being registered with the Securities and Exchange Commission, the number of shares of common stock issuable upon conversion of the Series G Preferred Shares will be 2.5 times the number of shares otherwise issuable upon such conversion.

The Company has reserved 501,079,254 shares of unissued common stock for the purpose of effecting the conversion of the Preferred Shares.

Voting rights

The holders of Preferred Shares are entitled to a number of votes equal to the number of shares of common stock into which such shares of Preferred Shares are convertible. In addition, an affirmative vote of the holders of a majority of the outstanding Preferred Shares, on an as-converted basis, is required to, among other things, sell the Company and approve certain amendments to the Company's Certificate of Incorporation. Furthermore, each series of Preferred Shares has certain series voting rights on matters affecting that series.

Dividends

The holders of Preferred Shares shall be entitled to receive noncumulative dividends in preference to any dividend on the common stock. The dividend rate for the Preferred Shares is 8% of the applicable respective liquidation price per share. Dividends shall be payable on the Preferred Shares from funds legally available for declaration of dividends, only if and when declared by the Company's Board of Directors. No such dividends have been declared.

Liquidation preference

In the event of any liquidation, dissolution or winding up of the Company, including a merger, acquisition or reorganization, where the beneficial owners of the Company's common stock and convertible preferred stock do

not own a majority of the outstanding shares of the surviving, purchasing or newly resulting corporation, or where a sale occurs of all or substantially all of the assets of the Company, Series G stockholders are entitled to a per share distribution in preference to other preferred stockholders and the common stockholders equal to $2.80, plus declared but unpaid dividends. After payment of these amounts to the holders of Series G Preferred Shares, Series F-2 stockholders are entitled to a per share distribution in preference to other preferred stockholders and the common stockholders equal to $3.53, plus declared but unpaid dividends. After payment of these amounts to the holders of Series F-2 Preferred Shares, Series E-2 stockholders are entitled to a per share distribution in preference to other preferred stockholders and the common stockholders equal to the original issue price per share of $7.58, plus declared but unpaid dividends. After payment of these amounts to the holders of Series E-2 Preferred Shares, Series D-2 stockholders are entitled to a per share distribution in preference to other preferred stockholders and the common stockholders equal to the original issue price per share of $6.20, plus any declared but unpaid dividends. After payment of these amounts to the holders of Series D-2 Preferred Shares, Series A-2, Series B-2 and Series C-2 stockholders are entitled to a per share distribution in preference to common stockholders equal to the original issue price per share of $2.00, $2.54 and $3.05, respectively, plus any declared but unpaid dividends. In the event that the remaining assets are insufficient to make a complete liquidation distribution to holders of the Series A-2, B-2 and C-2 Preferred Shares, the holders shall share ratably in proportion to the applicable liquidation amount each holder is otherwise entitled to receive. After these distributions, the remaining assets, if any, shall be distributed pro rata among the holders of the common stock, Series F-2 Preferred Shares and Series G Preferred Shares (treating such Series F-2 Preferred Shares and Series G Preferred Shares on an as-converted basis).

The Company's Board of Directors approved a Sale Bonus Plan (the "Plan"). Pursuant to the terms of the Plan, in certain circumstances constituting a change in control and/or partial sale or license of assets of the Company, the Company's employees may be entitled to the payment of a bonus. This Plan is terminated upon the completion of an initial public offering ("IPO"). The payments under the Plan shall be made prior to the determination of any liquidation preferences payable to the holders of Preferred Shares.

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, 105,781,000 shares of common stock have been reserved for the issuance of incentive stock options, nonstatutory stock options, restricted stock awards or performance-based stock awards 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. 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. As of December 31, 2020, there were 44,755,127 shares available for future issuance under the 2001 Plan, respectively.

During the years 2008 through December 31, 2020, 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, 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	38,219,789	$0.04	
Granted	20,468,700	0.11	
Cancelled / Forfeited	(402,557)	0.11	
Exercised	(6,875)	0.01	
Balance as of December 31, 2020	58,279,057	$0.07	$ 3,745
Options exercisable as of December 31, 2020	22,855,772	$0.03	$ 2,442

For the years ended December 31, 2020 and 2019, stock options outstanding included 331,922 and 355,883 options that were not granted under the 2001 Plan. For options outstanding as of December 31, 2020, the weighted average remaining contractual life was 7.9 years. For options exercisable as of December 31, 2020, the weighted average remaining contractual life was 6.0 years.

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 estimates pre-vesting forfeitures at the time of grant by analyzing historical data and revises those estimates in subsequent periods if actual forfeitures differ from those estimates.

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,	
	2020	2019
Weighted average fair value of options granted	$ 0.05	$ 0.03
Expected term (in years) — non-officer employees	2.7	3.4
Expected term (in years) — officer employees	3.0	5.9
Expected volatility	62.6%	42.3% to 46.4%
Expected dividend yield	0%	0%
Risk-free interest rate	0.16% to 0.18%	1.61% to 2.50%

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. 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, 2020 and 2019, the Company recognized stock-based compensation expense as follows:

	Year ended December 31,	
(in thousands)	**2020**	**2019**
Selling, general & administrative	$ 88	$ 42
Research & development	43	23
Cost of goods sold	1	1
	$ 132	$ 66

As of December 31, 2020, unrecognized compensation expense related to unvested stock-based compensation arrangements was $0.4 million. As of December 31, 2020, the related weighted average period over which it is expected to be recognized is approximately 2.8 years.

Performance-based options

As of December 31, 2020, the Company had 415,000 stock options outstanding that contained vesting conditions contingent on the achievement of certain milestones. Assuming continued service by the employees, the options would start vesting over a 48-month period upon achievement of the performance criteria. As of December 31, 2020, the Company determined that the likelihood of achieving the milestones was not probable and therefore no stock-based compensation expense was recorded.

As of December 31, 2020, the Company had 24,920,700 stock options outstanding that contained restrictions on vesting and exercisability contingent on the achievement of certain financing milestones. These stock options will be cancelled at the completion of a change in control event if completed before an IPO. As of December 31, 2020, the Company determined that the likelihood of achieving the milestones was not probable and therefore no stock-based compensation expense was recorded.

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, 2020, and 2019, there have been no early exercises and therefore there is no liability recorded for the early exercise of stock options.

8. Income taxes

The Company recognized $85,000 and $73,000 of income tax expense during the years ended December 31, 2020 and 2019, respectively. The components of income tax expense are as follows for the years ended December 31 (in thousands):

	Year ended December 31,	
	2020	**2019**
Current:		
Federal	$ —	$ —
State	—	—
Foreign	85	73
Total current	85	73

	Year ended December 31,	
	2020	2019
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred	—	—
Total income tax expense	$85	$73

The following table reconciles the U.S. statutory income tax rate with the Company's effective income tax rate for the years ended December 31:

	Year ended December 31,	
	2020	2019
U.S. statutory rate	21.0%	21.0%
Permanent differences	(0.5)	(0.6)
Research and development credit	2.6	4.2
Uncertain tax position	(0.5)	(0.5)
State taxes	0.3	0.2
Deferred rate change	(0.3)	—
Change in valuation allowance	(23.2)	(24.8)
Effective tax rate	(0.6)%	(0.5)%

In assessing the realization of deferred tax assets, the Company has considered whether it is more likely than not that some or all the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based on the level of historical losses and projections of future taxable income over the periods in which the deferred tax assets are deductible, management believes that it is more likely than not that the Company will not realize the benefits of these deductible differences. Accordingly, the Company has recorded a full valuation allowance against its net deferred tax assets as of December 31, 2020 and 2019.

The tax effects of temporary differences that give rise to the deferred tax assets and liabilities are as follows as of December 31 (in thousands):

	December 31,	
	2020	2019
Deferred tax assets		
Net operating loss carryforwards	$ 68,957	$ 65,970
Research and development credit carryforwards	8,318	7,960
IRC Section 59e election	7,955	7,909
Start-up costs	1,198	1,401
Non-qualified stock options	136	139
Property and equipment	90	102
Accrued vacation	106	71
Preferred stock warrants	607	530
Other	67	103
Total deferred tax assets	87,434	84,185
Valuation allowance	(87,434)	(84,185)
Net deferred tax assets	$ —	$ —

As of December 31, 2020, the Company had federal and state net operating loss carryforwards, or NOLs, of approximately $296.1 million and $88.0 million, respectively. The federal NOLs begin to expire in 2021 and state NOLs began expiring in 2020. The Company has federal and state tax credit carryforwards of approximately $8.6 million and $1.5 million, respectively. The federal and state tax credit carryforwards begin to expire in 2021 and 2028, respectively. Utilization of the net operating loss carryforward may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986 and similar state provisions. We have not performed a detailed analysis to determine whether an ownership change has occurred. Such a change of ownership would limit our utilization of the net operating losses and could be triggered by subsequent sales of securities by us or stockholders.

The Company had unrecognized tax benefits of $1.8 million and $1.8 million as of December 31, 2020 and 2019, respectively. The following table summarizes the activity related to unrecognized tax benefits for the years ended December 31 (in thousands):

	Year ended December 31,	
	2020	2019
Gross Unrecognized tax benefits at beginning of year	$ 1,757	$ 1,628
Gross increases:		
Prior year tax positions	—	29
Current year tax positions	83	99
Gross decreases:		
Prior year tax positions	—	—
	$ 1,840	$ 1,756

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 $56,000 and $53,000 of interest or penalties for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, and 2019, total accrued interest and penalties are $0.3 million and $0.2 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. 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):

	Year Ended December 31,	
	2020	2019
Numerator:		
Net loss	$ (14,109)	$ (14,633)
Accretion of preferred stock to redemption value	(217)	(13)
Net loss attributable to common stockholders	$ (14,326)	$ (14,646)
Denominator:		
Weighted average common shares outstanding — basic and diluted	15,308,364	19,085,104
Net loss per share attributable to common stockholders — basic and diluted	$ (0.94)	$ (0.77)

The Company's potentially dilutive securities, which include stock options, shares of convertible preferred stock and warrants to purchase shares of convertible preferred 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,	
	2020	2019
Options to purchase common stock	58,279,057	38,219,789
Warrants to purchase redeemable convertible preferred stock (as converted to common stock)	4,287,500	4,287,500
Redeemable convertible preferred stock (as converted to common stock)	471,791,754	315,541,754
	534,358,311	358,049,043

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, 2020 and 2019 was $0.4 million and $0.4 million, respectively. Future minimum lease payments under all operating leases as of December 31, 2020 are as follows for the years ending (in thousands):

December 31, 2021	$231
December 31, 2022	227
December 31, 2023	234
December 31, 2024	138
	$830

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, 2020 or 2019.

11. Employee benefit plans

The Company sponsors a voluntary defined-contribution employee retirement plan, or 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):

	December 31,	
	2020	2019
Germany	$3,790	$4,186
U.S.	1,733	1,004
Other countries	530	1,067
	$6,053	$6,257

As December 31, 2020 and 2019, long-lived assets were located primarily in the U.S.

13. Subsequent events

The Company is not aware of any subsequent events as of April 9, 2021, the date the consolidated financial statements were available to be issued, that would require recognition or disclosure in the consolidated financial statements.

Through and including , 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in the common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Shares

CVRx®

Common stock

Prospectus

J.P. Morgan **Piper Sandler** **William Blair**

Canaccord Genuity

, 2021

PART II

Information not required in prospectus

Item 13. Other expenses of issuance and distribution.

The following table sets forth the costs and expenses, other than the underwriting discount, payable by the registrant in connection with the sale of common stock being registered. All amounts are estimates except for the SEC, registration fee, the FINRA filing fee and the exchange listing fee.

Item	Amount to be paid
SEC registration fee	$ *
FINRA filing fee	*
Exchange listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* To be completed by amendment.

Item 14. Indemnification of directors and officers.

As permitted by Section 102 of the Delaware General Corporation Law, provisions in our amended and restated certificate of incorporation and amended and restated bylaws that will be effective upon the closing of this offering limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our amended and restated certificate of incorporation also will authorize us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws will provide that:

- we may indemnify our directors, officers, and employees to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;
- we may advance expenses to our directors, officers and employees in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; and
- the rights provided in our amended and restated bylaws are not exclusive.

Our amended and restated certificate of incorporation and our amended and restated bylaws that will be effective upon the closing of this offering provide for the indemnification provisions described above and elsewhere herein. We have entered into separate indemnification agreements with our directors and officers which generally require us, among other things, to indemnify our officers and directors against liabilities that may arise by reason of their status or service as directors or officers. These indemnification agreements also generally require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified. In addition, we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment in some circumstances. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act.

The form of Underwriting Agreement, which is to be filed as Exhibit 1.1 hereto, will provide for indemnification by the underwriters of us and our officers who sign this Registration Statement and directors for specified liabilities, including matters arising under the Securities Act.

Item 15. Recent sales of unregistered securities.

The following list sets forth information as to all securities we sold in the three years preceding the filing of this Registration Statement that were not registered under the Securities Act.

1. On September 28, 2018, the Company issued Series E-2 Warrants exercisable for 1,978,891 shares of Series E-2 convertible preferred stock at an exercise price of $0.01 per share and JJDC Warrants exercisable for 9,613,738 shares of Series G convertible preferred stock (which may increase up to 10,000,000 shares of Series G convertible preferred stock if JJDC purchases shares of our common stock in this offering) at an exercise price of $0.01 per share to BWI as partial consideration for the execution of that certain Structured Rights Termination Letter Agreement, dated as of September 28, 2018, by and between BWI and the Company. Upon the closing of this offering, the Series E-2 Warrants will expire unexercised and the JJDC Warrants will become exercisable.

2. On October 10, 2018, the Company issued 20,363 shares of its Series G convertible preferred stock to certain investors in exchange for cash consideration totaling approximately $16,290.

3. On January 28, 2019, the Company issued 8,825,000 shares of its Series G convertible preferred stock to certain investors in exchange for cash consideration totaling approximately $7.1 million.

4. On May 23, 2019, the Company issued 13,237,500 shares of its Series G convertible preferred stock to certain investors in exchange for cash consideration totaling approximately $10.6 million.

5. On August 19, 2019, the Company issued 8,812,500 shares of its Series G convertible preferred stock to certain investors in exchange for cash consideration totaling approximately $7.1 million.

6. On September 12, 2019, the Company issued 29,175 shares of its Series G convertible preferred stock to a certain investor in exchange for cash consideration totaling $23,340.

7. On July 1, 2020, the Company issued 62,500,000 shares of its Series G convertible preferred stock to certain investors in exchange for cash consideration totaling $50.0 million.

8. On September 30, 2019, the Company issued Series G Warrants exercisable for an aggregate of 750,000 shares of its Series G convertible preferred stock at an exercise price of $0.80 per share to Horizon Technology Finance Corporation as partial consideration for the execution of that certain Venture Loan and Security Agreement, dated as of September 30, 2019, by and among Horizon Technology Finance Corporation and the Company.

9. On November 6, 2020, the Company issued 11,250,000 shares of its Series G convertible preferred stock to a certain investor in exchange for cash consideration totaling $9.0 million.

10. During the past three years, we have issued options to purchase an aggregate of 55,721,200 shares of our common stock at exercise prices ranging from $0.01 to $0.18 per share in connection with services provided to us by such parties or affiliated persons. Upon the exercise of options, we have issued an aggregate of 503,586 shares of our common stock for an aggregate purchase price of approximately $3,022.

We claimed exemption from registration under the Securities Act for the sale and issuance of securities in the transactions described in paragraphs (1) through (9) by virtue of Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder as transactions not involving any public offering. All of the purchasers of unregistered securities for which we relied on Section 4(a)(2) and/or Regulation D represented that they were accredited investors as defined under the Securities Act. We claimed such exemption on the basis that (a) the purchasers in each case represented that they intended to acquire the securities for investment only and not with a view to the distribution thereof and that they either received adequate information about the registrant or had access, through employment or other relationships, to such information and (b) appropriate legends were affixed to the stock certificates issued in such transactions.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraph (10) above under Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering or under Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701.

Item 16. Exhibits and financial statement schedules.

(a) Exhibits. See the Exhibit Index attached to this Registration Statement, which is incorporated by reference herein.

Exhibit index

Exhibit number	Exhibit description
1.1*	Form of Underwriting Agreement.
3.1*	Twelfth Amended and Restated Certificate of Incorporation, as currently in effect.
3.2*	Form of Amended and Restated Certificate of Incorporation to be in effect upon the closing of this offering.
3.3*	Bylaws, as currently in effect.
3.4*	Form of Amended and Restated Bylaws to be in effect upon the closing of this offering.
4.1	Reference is made to exhibits 3.1 through 3.4.
4.2*	Form of Common Stock Certificate.
4.3*	Warrant to Purchase Stock, dated as of September 12, 2014, issued by the Company to Life Science Loans, LLC.
4.4*	Warrant to Purchase Stock, dated as of September 12, 2014, issued by the Company to Silicon Valley Bank.
4.5*	Warrant to Purchase Stock, dated as of July 21, 2015, issued by the Company to Life Science Loans, LLC.
4.6*	Warrant to Purchase Stock, dated as of July 21, 2015, issued by the Company to Silicon Valley Bank.
4.7*	Warrant to Purchase Stock, dated as of May 31, 2016, issued by the Company to Oxford Finance LLC.
4.8*	Warrant to Purchase Stock, dated as of May 31, 2016, issued by the Company to Oxford Finance LLC.
4.9*	Warrant to Purchase Stock, dated as of May 31, 2016, issued by the Company to Oxford Finance LLC.
4.10*	Warrant to Purchase Stock, dated as of May 31, 2016, issued by the Company to Oxford Finance LLC.

Exhibit number	Exhibit description
4.11*	Warrant to Purchase Series E-2 Convertible Preferred Stock, dated as of September 28, 2018, issued by the Company to Biosense Webster, Inc.
4.12*	Warrant to Purchase Series G Convertible Preferred Stock, dated as of September 28, 2018, issued by the Company to Biosense Webster, Inc.
4.13*	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.
4.14*	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.
4.15*	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.
4.16*	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.
5.1*	Opinion of Faegre Drinker Biddle & Reath LLP.
10.1*	Lease, dated October 13, 2008, by and between the Company and Duke Realty Limited Partnership.
10.2*	First Lease Amendment, dated November 30, 2010, by and between the Company and Duke Realty Limited Partnership.
10.3*	Second Lease Amendment, dated October 22, 2012, by and between the Company and Duke Realty Limited Partnership.
10.4*	Lease Amending Agreement No. 3, dated May 20, 2016, by and between the Company and AX CROSSTOWN VI L.P.
10.5*	Lease Amending Agreement No. 4, dated May 18, 2020, by and between the Company and AX CROSSTOWN VI L.P.
10.6*	Eighth Amended and Restated Voting Agreement, dated July 1, 2020, by and among the Company and the holders listed therein.
10.7*	Eighth Amended and Restated Investors' Rights Agreement, dated July 1, 2020, by and among the Company and the holders listed therein.
10.8#*	2001 Stock Incentive Plan, as amended and restated.
10.9#*	Sales Bonus Plan (adopted and effective July 1, 2020).
10.10#*	Executive Bonus Plan.
10.11#*	Form of 2021 Equity Incentive Plan.
10.12*	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.
21.1*	List of Subsidiaries.
23.1*	Consent of Grant Thornton LLP, independent registered public accounting firm.
23.2*	Consent of Faegre Drinker Biddle & Reath LLP (included in Exhibit 5.1).
24.1*	Powers of Attorney (included on signature page).

# Indicates management contract or compensatory plan.

* To be filed by amendment. All other exhibits are submitted herewith.

(b) Financial Statement Schedules. <Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

1. For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

2. For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Signatures

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Minneapolis, State of Minnesota, on , 2021.

CVRx, INC.

By: _____

Name: Nadim Yared
Its: President and Chief Executive Officer

Power of attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Nadim Yared and Jared Oasheim, and each of them acting individually, as his true and lawful attorneys-in-fact and agents, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this Registration Statement, including post-effective amendments or any abbreviated registration statement and any amendments thereto filed pursuant to Rule 462(b) increasing the number of securities for which registration is sought, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Nadim Yared	President and Chief Executive Officer (Principal Executive Officer)	
Jared Oasheim	Chief Financial Officer (Principal Financial and Accounting Officer)	
Ali Behbahani, M.D.	Director	
Mudit K. Jain, Ph.D.	Director	
John M. Nehra	Director	
Kirk Nielsen	Director	
Geoff Pardo	Director	
Joseph Slattery	Director	