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

Form 10-K

(Mark One)

X **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number 0-21419

BIOCARDIA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**23-2753988**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

125 Shoreway Road, Suite B
San Carlos, California 94070
(Address of Principal Executive Offices, Including Zip Code)

(650) 226-0120
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	BCDA	The Nasdaq Capital Market
Warrant to Purchase Common Stock	BCDAW	The Nasdaq Capital Market

Securities Registered Pursuant to Section 12(g) of the Act: None

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes X No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	X	Smaller reporting company	X
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $20.6 million, computed by reference to the last sale price of $2.40 for the common stock on the Nasdaq Capital Marketed reported for such date. Shares of the registrant's common stock held by each executive officer, director and holder of 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares of the registrant's Common Stock outstanding as of March 23, 2021 was 16,339,061.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K is incorporated by reference to our Definitive Proxy Statement on Schedule 14A to be filed in respect to our 2021 Annual Meeting of Stockholders.

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All references in this Annual Report on Form 10-K to "we," "us," the "Company" and "BioCardia" mean BioCardia, Inc., including subsidiaries and predecessors, except where it is clear that the term refers only to BioCardia, Inc. This Annual Report on Form 10-K contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under "Special Note Regarding Forward-Looking Statements" and under "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Any and all statements contained in this Annual Report that are not statements of historical fact may be deemed forward-looking statements. Terms such as "may," "might," "would," "should," "could," "project," "estimate," "pro-forma," "predict," "potential," "strategy," "anticipate," "attempt," "develop," "plan," "help," "believe," "continue," "intend," "expect," "future" and terms of similar import (including the negative of any of the foregoing) may be intended to identify forward-looking statements. However, not all forward-looking statements may contain one or more of these identifying terms. Those statements appear in this Annual Report, and include statements regarding the intent, belief or current expectations of the company and management that are subject to known and unknown risks, uncertainties and assumptions and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to those discussed in the section entitled "Risk Factors" in Item 1A of this Annual Report.

Forward-looking statements in this prospectus may include, without limitation, statements regarding:

(i) the plans and objectives of management for future operations, including plans or objectives relating to the development of our cell therapy systems;

(ii) the timing and conduct of the clinical trials for our products, including statements regarding the timing, progress and results of current and future preclinical studies and clinical trials as well as our research and development programs;

(iii) the timing or likelihood of regulatory filing, approvals and required licenses for our cell therapy systems;

(iv) our ability to adequately protect our intellectual property rights and enforce such rights to avoid violation of the intellectual property rights of others;

(v) the timing, costs and other aspects of the commercial launch of our products;

(vi) our estimates regarding the market opportunity, clinical utility, potential advantages and market acceptance of our products;

(vii) the impact of government laws and regulations;

(viii) our ability to recruit and retain qualified clinical, regulatory and research and development personnel;

(ix) the availability of reimbursement or other forms of funding for our products from government and commercial payors;

(x) difficulties in maintaining commercial scale manufacturing capacity and capability and our ability to generate growth;

(xi) uncertainty in industry demand;

(xii) general economic conditions and market conditions in our industry;

(xiii) the effects that the COVID-19 outbreak, or similar pandemics, could have on our business, preclinical studies and clinical trials;

(xiv) the depth of the trading market in our securities;

(xv) a projection of income (including income/loss), earnings (including earnings/loss) per share, capital expenditures, dividends, capital structure or other financial items;

(xvi) our future financial performance, including any such statement contained in a discussion and analysis of financial condition by management or in the results of operations included pursuant to the rules and regulations of the Securities and Exchange Commission (SEC); and

(xvii) the assumptions underlying or relating to any statement described in points (i), (ii) or (iii) above. These statements are not guarantees of future performance and are subject to numerous risks, uncertainties, and assumptions that are difficult to predict.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, including the securities laws of the United States and the rules and regulations of the SEC, we do not assume any obligation to update any forward-looking statement. We disclaim any intention or obligation to update or revise any forward-looking statement contained herein, whether as a result of new information, future events or otherwise.

PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage regenerative medicine company developing novel autologous and allogeneic therapeutics for cardiovascular and pulmonary diseases with large unmet medical needs. We are committed to applying our expertise in the fields of autologous and allogeneic cell-based and cell-derived therapies to improve the lives of patients with cardiovascular and pulmonary conditions. Our CardiAMP cell therapy platform is intended to provide an autologous bone marrow derived cell therapy (using a patient's own cells) for the treatment of two indications: heart failure that develops after a heart attack (BCDA-01) and chronic myocardial ischemia (BCDA-02). CardiAMP cell therapy utilizes a proprietary pre-procedure cell analysis of a patient's own cells to identify patients believed likely be most responsive to the therapy and uses proprietary U.S. Food and Drug Administration (FDA) cleared or CE Marked device technologies to process and deliver therapeutic cells in a minimally invasive setting, typically by an interventional cardiologist. Our allogeneic culture expanded mesenchymal stem cell therapy product candidates are derived from donor bone marrow cells and are intended to be provided "off the shelf," for two indications, ischemic heart failure (BCDA-03) and for the pulmonary indication of acute respiratory distress syndrome (BCDA-04).

These cell therapy approaches are not aimed at repopulating heart or lung tissue, but rather at providing potent paracrine effects. Our investigators believe that these therapies facilitate the natural repair responses of bone marrow derived cells homing to injury in chronic settings where homing signals have either dissipated or were inadequate. These adult cell therapies are among the only cell therapies with significant and promising clinical experience aimed at addressing the large unmet needs in cardiovascular and pulmonary disease.

Heart Failure

Heart failure is a clinical condition in which the output of blood from the heart is insufficient to meet the metabolic demands of the body. In 2019, the American Heart Association, or AHA, report on heart disease statistics estimated that 6.5 million American adults have heart failure and that heart failure cost the nation an estimated $30.7 billion in 2012, including the cost of health care services, medicines for treatment and missed days of work. In 2019, the Centers for Disease Control and Prevention reported that heart failure was a contributing cause of 1 in 8 deaths in 2017. Heart failure is increasingly prevalent due to the aging population and the increase in major cardiovascular risk factors, including obesity and diabetes. The AHA also estimates that one in five adults will develop heart failure after the age of 40.

During heart failure progression, the heart steadily loses its ability to respond to increased metabolic demand, and mild exercise soon exceeds the heart's ability to maintain adequate output. Towards the end stage of the disease, the heart cannot pump enough blood to meet the body's needs at rest. At this stage, fluids accumulate in the extremities or in the lungs making the patient bedridden and unable to perform the activities of daily living. The long-term prognosis associated with heart failure is approximately 50% mortality at five years following the initial diagnosis.

Heart failure is classified in relation to the severity of the symptoms experienced by the patient. The most commonly used classification system, established by the New York Heart Association, or NYHA, is as follows:

- ***Class I (mild):*** patients experience no or very mild symptoms with ordinary physical activity;
- ***Class II (mild):*** patients experience fatigue and shortness of breath during moderate physical activity;
- ***Class III (moderate):*** patients experience shortness of breath during even light physical activity; and
- ***Class IV (severe):*** patients are exhausted even at rest.

Despite guideline-directed therapies employing a wide range of pharmacologic, device, and surgical options, many patients deteriorate over time and develop advanced heart failure symptoms that cannot be effectively managed by existing medical therapies. At the end stage of heart failure, current treatment options include heart transplant surgery or implantation of a left ventricular assist device, or LVAD, a battery operated mechanical circulatory device used to partially or completely replace the function of the left ventricle of the heart. LVADs are used for patients awaiting a heart transplant or as a destination therapy for patients with NYHA Class IV heart failure who may never receive a heart transplant. Both of these end-stage treatment options require invasive open-chest surgery and can cost in excess of $150,000 per procedure, as reported by the Journal of Heart and Lung Transplantation.

There are approximately 2.9 million NYHA Class II and Class III heart failure patients, of which we estimate approximately 60% are patients with ischemic systolic heart failure. Of this subset of 1.7 million patients, we estimate that approximately 70%, or over 1.2 million patients, will have a cell potency score sufficient to qualify for treatment with the CardiAMP Cell Therapy System.

Chronic Myocardial Ischemia

Refractory angina is a condition characterized by severe pain in the chest, often also spreading to the shoulders, arms, and neck, caused by an inadequate blood supply to the heart. In the U.S. alone, it is estimated that between 600,000 and 1.8 million patients suffer this condition, with approximately 75,000 new cases diagnosed each year. There is a growing population of patients with chronic angina that suffer with severely limiting symptoms and are not amenable to current therapies. These patients have significant impairments in quality of life, suffer from poor perceived health status and represent a significant burden to the health care system due to high use of health care resources. We believe the CardiAMP Cell Therapy System has the potential to provide a treatment for these patients not met by current therapeutic alternatives.

Acute Respiratory Distress Syndrome

Acute respiratory distress syndrome (ARDS) occurs when fluid builds up in the tiny, elastic air sacs (alveoli) in a patient's lungs. The fluid keeps the lungs from filling with enough air, which means less oxygen reaches the bloodstream. This deprives vital organs of the oxygen they need to function. ARDS typically occurs in people who are already critically ill or who have significant injuries. It can also develop after a COVID-19 infection. Severe shortness of breath, a key symptom of ARDS, usually develops within a few hours to a few days after the precipitating injury or infection. Many people who develop ARDS don't survive. The risk of death increases with age and the severity of illness. Of the people who do survive ARDS, some recover completely while others experience lasting damage to their lungs.

Although the majority of COVID-19 cases either are asymptomatic or result in mild disease, in a substantial percentage of patients, a respiratory illness requiring hospital care develops, and such infections can progress to critical illness with hypoxemic respiratory failure requiring prolonged ventilatory support. Efforts to modulate inflammation-mediated lung injury and thereby reduce progression to respiratory failure using mesenchymal stem cells have shown promising results in previous studies by other groups. Our own preclinical animal studies with venous infusion of these mesenchymal stem cells have shown feasibility with no significant adverse events.

Our Product Candidates

CardiAMP Cell Therapy System

The CardiAMP Cell Therapy System, or CardiAMP, is our lead therapeutic program being advanced for two clinical indications. This investigational cell therapy system is comprised of (i) a cell potency screening test, (ii) a point of care cell processing platform, and (iii) a biotherapeutic delivery system. In the screening process, the physician extracts a small sample of the patient's bone marrow in an outpatient procedure performed under local anesthesia. The clinic sends the sample to a centralized diagnostic lab, which tests for identified biomarkers from which we generate a potency assay score for the patient. During the treatment for patients who are assessed as meeting the indication specific CardiAMP cell potency assay score, a doctor harvests and then prepares the patient's own bone marrow mononuclear cells, or autologous cells, using our point of care cell processing platform, which a cardiologist then delivers into the heart using our proprietary biotherapeutic delivery system.

CardiAMP Cell Therapy for Heart Failure and Chronic Myocardial Ischemia

The Company's lead platform, CardiAMP cell therapy, is an autologous cell therapy being advanced for two indications in pivotal clinical trials: heart failure and chronic myocardial ischemia.

The CardiAMP Heart Failure Trial is a Phase III, multi-center, randomized, double-blinded, sham-controlled study of up to 260 patients at up to 40 centers nationwide, which includes a 10-patient roll-in cohort. The Phase III pivotal trial is designed to provide the primary support for the safety and efficacy of the CardiAMP Cell Therapy System for this indication (BCDA-01). The trial is active at 24 clinical sites and 91 patients have been enrolled to date. The independent Data Safety Monitoring Board (DSMB) completed its most recent prespecified data review in December 2020, which included the safety follow-up results available for 86 patients. From this review, the DSMB indicated there were no safety concerns with the study results and recommended that the trial continue as planned.

The CardiAMP Chronic Myocardial Ischemia Trial is a Phase III, multi-center, randomized, double-blinded, controlled study of up to 343 patients at up to 40 clinical sites. The Phase III pivotal trial is designed to provide the primary support for the safety and efficacy of the CardiAMP Cell Therapy System for this indication (BCDA-02). This therapeutic approach uses many of the same novel aspects as the CardiAMP Heart Failure Trial and is expected to leverage our experience and investment in the heart failure trial. The trial has been activated and we are working towards initial patient enrollment.

We are continuing to assess the impact of COVID-19 on the enrollment in the CardiAMP trials. Some of our clinical centers stopped performing elective procedures and advised us that they would not be performing elective procedures until restrictions on elective procedures are lifted. Many centers also delayed patient follow-up visits out of concern for patient exposure to COVID-19. In alignment with recent FDA guidance on clinical trials, "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic Guidance for Industry, Investigators, and Institutional Review Boards", we have taken steps to address unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures. Clinical sites remain engaged, and most are resuming elective procedures, including enrollment activities in our trial.

The Department of Health & Human Services Centers for Medicare & Medicaid Services, or CMS, has designated that both CardiAMP pivotal trials qualify for Medicare national coverage. Covered costs include patient screening, the CardiAMP Cell Therapy System and procedure, and clinical follow-up at one and two years after the procedure. Private insurance plans covering 50 million insured Americans follow this CMS reimbursement policy and are similarly anticipated to cover these costs. This coverage significantly reduces our cost of conducting these pivotal trials.

CardiAMP Cells Phase I Heart Failure Study: Transendocardial Autologous Marrow Cells in Myocardial Infarction

The CardiAMP Phase I Transendocardial Autologous Marrow Cells in Myocardial Infarction or TABMMI trial enrolled 20 patients with ischemic systolic heart failure in an open label safety trial of bone marrow cells delivered with the Helix™ biotherapeutic delivery system at a dosage of 100 million cells. Results showed improvement in cardiac function as measured by left ventricular ejection fraction, improved exercise tolerance, and superior survival as compared to historical controls. The complete results of the 20 patients at two-year follow-up have been published in the journal Eurointervention in 2011.

CardiAMP Cells Phase II Heart Failure Trial: Transendocardial Autologous Cells in Heart Failure Trial (TAC-HFT)

The CardiAMP Phase II Transendocardial Autologous Cells in Heart Failure Trial (TAC-HFT), patients with ischemic systolic heart failure were randomized on a one-to-one basis into two double-blind, placebo-controlled trials: TACHFT-BMC and TACHFT-MSC. TACHFT-BMC met its primary safety endpoint at both dosages (100 million and 200 million cells) and treated patients had increased functional capacity, improved quality of life, symptoms and key markers of cardiac function predictive of survival, such as end systolic volume, or ESV. The TACHFT-BMC trial included a single dose of CardiAMP cells with a follow up observation period of 12 months. The Phase II, randomized, placebo-controlled study met its primary safety endpoint and demonstrated statistically significant and clinically meaningful improvements in secondary efficacy endpoints of functional capacity, as measured by the six-minute walk distance (6MW), and in quality of life, as measured by the Minnesota Living with Heart Failure Questionnaire score. Phase II results were published in the Journal of the American Medical Association in 2014 and were presented at the World Congress of Regenerative Medicine in 2015.

CardiAMP Cell Phase III Heart Failure Trial

The CardiAMP Heart Failure Trial is a Phase III, multi-center, randomized, double-blinded, sham-controlled study of up to 260 patients at up to 40 centers nationwide, which includes a 10-patient roll-in cohort. The Phase III pivotal trial is designed to provide the primary support for the safety and efficacy of the CardiAMP Cell Therapy System. The primary endpoint of the ongoing CardiAMP Heart Failure study is an outcomes composite score based on a three-tiered Finkelstein-Schoenfeld hierarchical analysis. The tiers, starting with the most serious events, would be (1) all-cause death, including cardiac death equivalents such as heart transplant or left ventricular assist device placement, ordered by time to event; (2) non-fatal Major Adverse Coronary and Cerebrovascular Events (MACCE), excluding those deemed procedure-related occurring within the first seven days post-procedure (heart failure hospitalization, stroke or myocardial infarction), ordered by time to event, and (3) change from baseline in Six Minute Walk Distance at 12 months. Additional prespecified secondary hierarchical and nonhierarchical endpoints are also being assessed. If the true effect size is only 50% of that observed in the Phase II trial, the CardiAMP Heart Failure Phase III trial is still 90% powered to meet the primary endpoint with statistical significance. Statistical significance denotes the mathematical likelihood that the results observed are real and not due to chance.

Particularly novel aspects of this trial include a cell potency assay to screen subjects who are most likely to respond favorably to treatment, a point of care treatment method, use of a high target dose of 200 million cells and an efficient transcatheter delivery method that is associated with high cell retention. Success in the primary endpoint of the trial may lead to a new treatment for those suffering from heart failure in the aftermath of a heart attack.

The Department of Health & Human Services Centers for Medicare & Medicaid Services, or CMS, has designated the CardiAMP Heart Failure Trial as a qualifying trial for Medicare national coverage determination that routine costs of care will be covered for Medicare beneficiaries. Private insurance plans covering 50 million insured Americans follow this CMS reimbursement policy and are also anticipated to pay for these costs in the CardiAMP Heart Failure Trial. Covered costs today for both the treatment and control arms of the trial include patient screening, the CardiAMP Cell Therapy System and procedure, and clinical follow-up at one and two years after the procedure.

The Phase III CardiAMP Heart Failure Trial was initiated in the fourth quarter of 2016, and the first patient treated in Q1 2017. The trial design was published in the peer reviewed American Heart Journal in 2018. Efficacy data from the primary endpoint in the open label roll-in cohort showing improvements in exercise capacity, quality of life and functional improvements as measured by the echocardiography core lab were presented at the American Heart Association Scientific Sessions in 2018 and were published in the International Journal of Cardiology in 2020. The trial is currently enrolling at 24 clinical sites and has enrolled 91 patients as of the date of this filing.

The independent DSMB completed prespecified data reviews of the randomized trial in September 2019, March 2020 and December 2020. In all reviews, the DSMB indicated there were no safety concerns with the study results and recommended that the trial continue as planned. The interim DSMB readout in December 2020 included a non-futility analysis with 60 patients having reached one-year follow-up and an assessment of the first randomized efficacy data set including the primary endpoint of the trial.

In alignment with recent FDA guidance on clinical trials, "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic Guidance for Industry, Investigators, and Institutional Review Boards," the Company has taken steps to address unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures.

Enrollment remains our primary focus and challenge. To complete the heart failure trial enrollment requires our active centers to randomize an additional seven patients each on average. Our clinical centers appear to be coming out of COVID-19 with renewed energy and interest in the trial. Enrollment is expected to be enhanced in the months ahead by reductions in COVID-19 cases over time, the recent successful CardiAMP Heart Failure DSMB review, the recent CardiAMP Heart Failure positive results published in the peer reviewed International Journal of Cardiology, the addition of new high-enrolling clinical sites to the trial, obtaining FDA authorization to provide therapy for patients in the control arm of the trial as soon as they reach the two year follow-up endpoint in the trial, enhanced outreach to sites and increased clinical marketing activities. Starting the parallel CardiAMP Chronic Myocardial Ischemia trial is also anticipated to enhance enrollment in the CardiAMP Heart Failure trial.

We believe the remaining clinical efficacy risk is modest based on the Phase I, II, and III data available, the most recent positive DSMB review and the broader literature which supports CardiAMP Cell Therapy System as a therapeutic candidate for heart failure secondary to having had a heart attack. Because the CardiAMP cells do not become heart cells, we believe they have a low likelihood of becoming ectopic foci that could cause life threatening arrhythmias. Because CardiAMP cells are autologous, patients will not require chronic immunosuppression to prevent their immune system from attacking the donor cells. Unlike other investigational autologous cell therapies, the CardiAMP autologous cell therapies are expected to have low manufacturing costs and utilize established distribution channels, significantly enhancing prospects for commercial success. The CardiAMP Cell Therapy System has the potential to significantly benefit patients who have limited options and provide a cost-effective therapy to help reduce the substantial heart failure hospitalization and care costs.

CardiAMP Chronic Myocardial Ischemia Phase III Pivotal Trial

In January 2018, the FDA approved the investigational device exemption for the CardiAMP Cell Therapy system to be studied in a second related clinical indication, chronic myocardial ischemia, based on the strength of our Phase I and II ischemic heart failure trial data and clinical data showing support for the efficacy of one component of our cell therapy (the CD34+ cells) in this indication. The trial is approved to enroll up to 343 patients at up to 40 clinical sites in the United States. An update to the statistical analysis plan to enable an adaptive trial design is anticipated. Success in the primary endpoint of the trial, which is exercise tolerance, may lead to a new treatment for those suffering from chronic myocardial ischemia and having sustained debilitating heart pain, referred to as refractory angina.

In 2018, CMS approved BioCardia's request for the designation of the CardiAMP Chronic Myocardial Ischemia Trial as a qualifying trial for Medicare national coverage determination similar to the designation received for the CardiAMP Heart Failure Trial. It is anticipated that this second pivotal trial will build on and benefit from the experience and infrastructure from the CardiAMP Heart Failure Trial. We are working to initiate this trial with a 5-patient roll-in cohort. Timing is entirely dependent on the course of COVID-19 and the response in the United States.

ALLOGENEIC Cell Therapy for Cardiac and Pulmonary Disease

Our second therapeutic platform is our investigational culture expanded bone marrow derived allogeneic, Neurokinin-1 Receptor Positive mesenchymal stem cells. Mesenchymal stem cells are multipotent stromal cells that can differentiate into a variety of cell types, including osteoblasts (bone cells), chondrocytes (cartilage cells), myocytes (muscle cells) and adipocytes (fat cells which give rise to marrow adipose tissue).

Our "off the shelf" mesenchymal cell therapy is being advanced for cardiac and pulmonary disease. These cells are anticipated to be the cells that respond to the release of Substance P. Substance P (SP), a neuropeptide released from sensory nerves that is associated with the inflammatory processes and pain. These Neurokinin-1 Receptor Positive cells are believed to be an important subset of the cells that we have delivered in our previous preclinical and clinical mesenchymal stem cell studies. We believe this therapy presents the advantages of an "off the shelf" therapy that does not require tissue harvesting from patients or cell processing.

ALLOGENEIC MSC for Ischemic Heart Failure (CardiALLO Cell Therapy)

We are working to obtain FDA acceptance of an Investigational New Drug (IND) application for a Phase I/II trial for CardiALLO Cell Therapy System for the treatment of ischemic systolic heart failure in 2021. The subset of patients we are targeting initially for this cardiac indication are those that have been excluded from the CardiAMP Heart Failure Trial due to their lower cell potency assay scores. Activation of the phase I/II trial is expected to enhance enrollment in the CardiAMP Heart Failure Trial. There is potential for this allogeneic therapy to be designated as an orphan indication. While being initially advanced to treat heart failure and acute respiratory distress, variations of this allogeneic therapy may have the potential for numerous other therapeutic applications.

CardiALLO related Phase I /II Studies: POSEIDON, TAC-HFT-MSC, and TRIDENT

We have co-sponsored three clinical trials for MSCs for the treatment of ischemic systolic heart failure. In substantially similar trial designs, the POSEIDON Phase I/II trial compared autologous MSCs to allogeneic MSCs, the TACHFT-MSC Phase II trial compared autologous MSCs to placebo, and the TRIDENT Phase II compared allogeneic MSCs at different doses. The first two trials shared common arms of autologous MSCs, enabling a bridge to placebo, leading us to conclude that allogeneic MSC therapy has potential to be superior to placebo. The IND for the TACHFT trial was filed with the FDA Center for Biologics Evaluation and Research in 2008 by the University of Miami, our co-sponsor for the trial. The POSEIDON trial and the TRIDENT trials were submitted by amendment under the same IND filed for the TACHFT study, and was co-sponsored by the University of Miami, the National Institutes of Health and us. The results from all three of these studies can be submitted to the FDA in support of an IND for the CardiALLO Cell Therapy System.

ALLOGENEIC MSC for Acute Respiratory Distress Syndrome Secondary to COVID-19

Allogeneic MSCs may have the potential to increase survival in management of COVID-19 induced ARDS. Preclinical and clinical evidence from published studies indicate that intravenously delivered MSCs migrate to the lung and respond to the pro-inflammatory lung environment by releasing anti-inflammatory factors reducing the proliferation of pro-inflammatory cytokines while modulating regulatory T cells and macrophages to promote resolution of inflammation. Therefore, MSCs may have the potential to increase survival in management of COVID-19 induced ARDS.

The anti-inflammatory effects of MSC have been well-documented and MSC have been shown to reduce inflammation and injury in models of lung disease. The specific MSCs used in BioCardia's allogeneic cell therapy are Neurokinin-1 receptor positive, which is the receptor for the ligand substance P, an important neuropeptide associated with inflammation throughout the body and a primary mediator of inflammation in the airways. In patients with ARDS, culture expanded bone marrow cells have been shown to also have benefits across multiple endpoints and are a compelling therapeutic pathway to advance BioCardia's off the shelf MSC therapy.

We are working to obtain FDA acceptance of an Investigational New Drug (IND) application for a Phase I/II trial for these allogeneic MSC to treat COVID-19 induced ARDS in 2021.

Helix™ Biotherapeutic Delivery System

BioCardia's Helix Biotherapeutic Delivery System or "Helix" delivers therapeutics into the heart muscle with a penetrating helical needle from within the heart. It enables local delivery of cell and gene-based therapies, including CardiAMP and CardiALLO cell therapies, to treat cardiovascular indications. The Helix catheter is CE marked in Europe and is under investigational use in the United States as part of our CardiAMP Cell Therapy System and CardiALLO Cell Therapy System development programs.

BioCardia selectively partners with firms developing other cell, gene, and protein therapeutic programs utilizing the Helix biotherapeutic delivery system. These partnered programs provide additional data, intellectual property rights, and opportunities to participate in the development of combination products for the treatment of cardiac diseases.

Morph Deflectable Guide and Sheaths Products

BioCardia's Morph catheter is designed to enable physicians to navigate through tortuous anatomy, customize the shape of the catheter to the patient's anatomy and their clinical needs during the procedure, and to have stellar back-up support once positioned. Morph catheters enable all Helix procedures and have been commercially used to treat more than 10,000 patients. A number of Morph guides and sheaths are cleared for commercial sale in the United States.

Business Strategy

We are committed to applying our expertise in the fields of autologous and allogeneic cell-based therapies to improve the lives of patients with cardiovascular conditions. We are pursuing the following business strategies:

- *Complete the ongoing 260 patient, 40 center Phase III pivotal IDE trial of our autologous CardiAMP Cell Therapy for patients with ischemic systolic heart failure.*
- *Complete the FDA approved, 343 patient, 40 center Phase III pivotal IDE trial of our autologous CardiAMP Cell Therapy for patients with chronic myocardial ischemia.*
- *Obtain FDA approval and commercialize CardiAMP Cell Therapy System using a highly targeted cardiology sales force in the United States.*
- *Advance our allogeneic mesenchymal stem cell therapy for the treatment of ischemic systolic heart failure, initially targeting patients for whom the CardiAMP Cell Therapy System is not optimal due to the lower potency of their bone marrow cells.*
- *Advance our allogeneic mesenchymal stem cell therapy for the treatment acute respiratory distress.*
- *Continue to develop and selectively partner our Helix™ biotherapeutic delivery system for use with other biotherapeutics.*
- *Continue to develop and commercialize Morph catheter products.*

Intellectual Property

We strive to protect and enhance the proprietary technologies that we believe are important to our business and seek to obtain and maintain patents for any patentable aspects of our therapeutic candidates or products, including our anticipated companion diagnostic, their methods of use and any other inventions that are important to the development of our business. Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the fields targeted by our therapeutic candidates.

We have a large patent portfolio of issued and pending claims covering the CardiAMP Cell Therapy System, the CardiALLO Cell Therapy System, the Helix™ biotherapeutic delivery system product and the Morph vascular access catheter products. As of December 31, 2019, we had developed or secured rights to over 65 issued or pending U.S. and international patents or patent pending applications. We have sole ownership of the patents that we consider to be material, other than the patents that we license exclusively from Biomet Biologics, LLC. Our issued U.S. patents expire between 2020 and 2034, without taking into consideration patent term extension. We maintain trade secrets covering a significant body of know-how and proprietary information related to our core therapeutic candidates, biotherapeutic delivery systems and technologies. As a result, we believe our intellectual property position provides us with substantial competitive advantages for the commercial development of novel therapeutics for cardiovascular diseases.

Ten of our most recently issued United States Patents are listed below,

US Patent No.	Patent Title	Expiration on or after
10,874,831	Devices and methods for accessing the vasculature of a patient	2024
10,780,248	Radial and trans-endocardial delivery catheter	2034
10,520,505	Methods of measuring therapeutic potency and defining dosages for autologous cell therapy	2034
10,071,226	Radial and trans-endocardial delivery catheter	2034
10,035,982	Method of preparing autologous cells and methods of use for therapy	2029
9,945,854	Methods of measuring therapeutic potency potential and defining dosages for autologous cell therapy	2034
9,752,123	Method of Preparing Autologous Cells and Methods of Use for Therapy	2029
9,517,199	Treatment for chronic myocardial infarct	2027
9,504,642	Treatment for chronic myocardial infarct	2027
9,301,975	Method of preparing autologous cells and method of use for therapy	2029

U.S. Regulatory Protection for CardiAMP and CardiALLO

In addition to patent and trade secret protection, we may receive a 12-year period of regulatory exclusivity from the FDA upon approval of our cell therapies pursuant to the Biologics Price Competition and Innovation Act. The exclusivity period, if granted, will run from the time of FDA approval. This exclusivity period, if granted, will supplement the intellectual property protection discussed above, providing an additional barrier to entry for any competitor seeking approval for bio-similar versions.

In addition, it is possible to extend the patent term of at least one patent covering our therapies following FDA approval. This patent term extension, or PTE, is intended to compensate a patent owner for the loss of patent term during the FDA approval process. If eligible, we may use a PTE to extend the term of one or more of our patents beyond the expected expiration date. Because CardiAMP and CardiALLO cell therapy systems may involve multiple simultaneous approvals under the IDE and IND applications, each pre-market approval, or PMA or biologics license application, or BLA, associated with an approval is anticipated to have the ability to have an extended patent term.

Trademarks

We have registered or applied for registration of our name, logo and the trademarks "BioCardia," "CardiAMP," "CardiALLO," and "Morph" in the United States. We have registered or applied for registration of the trademarks "CardiAMP" and "CardiALLO" for use in connection with a biological product, namely, a cell-based therapy product composed of bone marrow derived cells for medical use. We also have rights to use the "Helix" trademark in the United States. We have registered Morph for use in connection with steerable vascular access technology. We intend to pursue additional registrations in markets outside the United States where we plan to sell our therapies and products.

Patent Term

The term of individual patents and patent applications will depend upon the legal term of the patents in the countries in which they are obtained. In most countries, the patent term is 20 years from the date of filing of the patent application (or parent application, if applicable). For example, if an international Patent Cooperation Treaty, or PCT, application is filed, any patent issuing from the PCT application in a specific country expires 20 years from the filing date of the PCT application. In the United States, however, if a patent was in force on June 8, 1995, or issued on an application that was filed before June 8, 1995, that patent will have a term that is the greater of 20 years from the filing date, or 17 years from the date of issue.

Under the Hatch-Waxman Act, the term of a patent that covers an FDA-approved drug, biological product may also be eligible for PTE. PTE permits restoration of a portion of the patent term of a U.S. patent as compensation for the patent term lost during product development and the FDA regulatory review process if approval of the application for the product is the first permitted commercial marketing of a drug or biological product containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. The Hatch-Waxman Act permits a PTE for only one patent applicable to an approved drug, and the maximum period of restoration is five years beyond the expiration of the patent. A PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and a patent can only be extended once, and thus, even if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions may be available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors involved in the filing of a BLA, we expect to apply for PTEs for patents covering our therapeutic candidates and products and their methods of use. For additional information on PTE, see "Government Regulation."

Proprietary Rights and Processes

We may rely, in some circumstances, on proprietary technology and processes (including trade secrets) to protect our technology. However, these can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our proprietary technology and processes may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors, contractors, or any future collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more comprehensive risks related to our proprietary technology and processes, please see "Risk Factors-Risks Related to our Intellectual Property."

Manufacturing

The CardiAMP cell processing platform is manufactured for us by our partner Biomet Biologics, LLC. We currently produce allogeneic cells for preclinical development in our preclinical development tissue culture facility and anticipate manufacturing for clinical development in our clinical cell manufacturing facility. We currently manufacture our Helix™ biotherapeutic delivery system and Morph vascular access products in our San Carlos, California device manufacturing facility using components we source from third-party suppliers.

Sales and Marketing

Our sales and marketing strategy is to market the CardiAMP and CardiALLO cell therapy systems, if approved by the FDA, for heart failure and chronic myocardial ischemia indications using a dedicated direct sales model focused on selected cardiologists. These physicians are typically affiliated with leading hospitals and medical centers and we believe that they tend to have well-established referral networks of interventional cardiologists and cardiac catheterization laboratories. We believe they represent a concentrated customer base suitable to a specialist care sales model. We believe that the CardiAMP and CardiALLO cell therapy systems will be adopted first by leading cardiologists at high-volume U.S. hospitals and medical centers, and progressively by a broader segment of the market. Cardiologists and interventional cardiologists have a history of early adoption of innovative products and technologies, in part because the rate of innovation in this sector has been sustained, and in part because of the large unmet medical needs of heart failure patients.

We anticipate marketing and selling the BCDA-04 allogeneic mesenchymal cell therapy for acute respiratory distress syndrome also with a dedicated sales force focused initially on pulmonary and critical care groups at leading hospitals in the United States.

Competition

The biotechnology and pharmaceutical industries in which we operate are subject to rapid change and are characterized by intense competition to develop new technologies and proprietary products. We face potential competition from many different sources, including larger and better-funded companies. While we believe that our programs unique benefits provide us with competitive advantages, we have identified several companies which are active in the advancement of cell-based and gene-based therapeutic products in the heart failure, chronic myocardial ischemia and acute respiratory distress syndrome indications. Not only must we compete with other companies that are focused on cell-based therapy treatments, but any products also that we may commercialize will have to compete with existing therapies and new therapies that may become available in the future.

However, potential competitors in the cardiovascular indications may require delivery platforms for their own therapeutic programs. Because the clinical need is so large and our biotherapeutic delivery products have potential to enable multiple biotherapeutics for multiple cardiac indications, we view these companies also as potential collaborators and partners. None of these relationships are believed to be material to our business at this time.

License Agreement with Biomet Biologics, LLC

In October 2012, we entered into a license and distribution agreement with Biomet Biologics, LLC under which we obtained an exclusive, nontransferable, worldwide distribution right, patent license and trademark license to a point of care cell processing platform. Under the terms of the agreement, we are obligated to pay a royalty based on the price of the disposables in the CardiAMP cell processing platform for the duration of the agreement. We expect the royalty payments to Biomet Biologics, LLC for the licensed product to amount to a low or mid-single digit percentage of the expected price that we will charge for the CardiAMP Cell Therapy System. The agreement has a term of 10 years or the time the last patent pursuant to the agreement expires, whichever is later. The agreement may be terminated by Biomet Biologics, LLC for a failure by us to meet any milestone requirements, including minimum purchase requirements, as well as by either party upon 30 days prior written notice in the event of a breach of any material term by the other party. We have the right to terminate the agreement upon 90 days prior written notice in the event the safety, efficacy or comparative effectiveness of the product is insufficient to meet our commercial needs.

Technology Access Program for Biotherapeutic Delivery Systems

Our preclinical work with partners and collaborators generally takes place under arrangements where we secure access to data, reports, and a non-exclusive license to delivery technology improvement inventions.

Clinical Research Agreements for Biotherapeutic Delivery Systems

Our clinical work with partners generally takes place under arrangements where we secure access to data, reports, and a non-exclusive license to technology improvement inventions. Financial terms of each agreement are anticipated to cover our costs and provide milestone payments. We hope to generate sales if any of our partners are successful with commercializing their products with our delivery platform.

Government Regulation

Biological products, including cell-based therapy products, and medical devices are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and the Public Health Service Act, or PHS Act, and other federal, state, local and foreign statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, identity, potency and purity, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products. FDA acceptance must be obtained before clinical testing of an investigational biological and medical device begins, and each clinical trial protocol for a cell-based therapy product is submitted to and reviewed by the FDA. FDA approval must be obtained before marketing of a biological product. Unless an exception applies, FDA approval or clearance is required for medical devices. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and we may not be able to obtain the required regulatory approvals on a timely basis, or at all. To date, the FDA has never approved for commercial sale a cell-based therapy product intended to treat the heart.

Within the FDA, the Center for Biologics Evaluation and Research, or CBER, regulates cell-based therapy products. For products that use medical devices, including diagnostics, to deliver cell therapies, CBER works closely with the FDA's Center for Devices and Radiological Health, or CDRH.

U.S. Biological Product Development and Regulatory Approval Process

Our allogeneic therapeutic candidates will be regulated in the United States as biological products. The process required by the FDA before a biological product may be tested and marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLP, regulations and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial begins;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations, commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety, purity and potency of the proposed biological product for its intended use;
- preparation of and submission to the FDA of a BLA for marketing approval, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with GMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA for particular indications for use in the United States, which must be updated annually when significant changes are made.

The testing and approval process require substantial time, effort and financial resources, and we cannot be certain that any approvals for our therapeutic candidates or product candidates will be granted on a timely basis, if at all. Before testing any biological product candidate, including a cell-based therapy product, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Clinical trials also must be reviewed by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- ***Phase I.*** The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses and, if possible, to gain early evidence on effectiveness.

- ***Phase II.*** The biological product is evaluated in a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule. Multiple Phase II clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase III clinical trials.

- ***Phase III.*** Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites, to provide statistically significant evidence of clinical efficacy and to further test for safety. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product approval and labeling.

Post-approval clinical trials, sometimes referred to as Phase IV clinical trials, may be required by the FDA or voluntarily conducted after initial marketing approval to gain more information about the product, including long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the NIH and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Human cell-based therapy products administered directly into heart tissue are a relatively new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of human cell-based therapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval.

Concurrently with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

After the successful completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for biological products and an annual establishment fee on facilities used to manufacture prescription biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, for its intended use, and whether the product is being manufactured in accordance with GMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure GMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post-marketing clinical trials, sometimes referred to as Phase IV clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved therapies and products that have been commercialized.

The FDA has agreed to certain review goals under PDUFA and aims to complete its review of 90% of standard BLAs within ten months from filing and 90% of priority BLAs within six months from filing. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests, or the BLA sponsor otherwise provides, additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Fast Track Designation, Accelerated Approval, Priority Review and Breakthrough Therapy Programs

The FDA has a Fast-Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biological product may request the FDA to designate the drug or biological product as a Fast-Track product at any time during the clinical development of the product. Unique to a Fast-Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Other types of FDA programs intended to expedite development and review, such as priority review, accelerated approval and Breakthrough Therapy designation, also exist. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

A product may also be eligible for receipt of a Breakthrough Therapy designation. The Breakthrough Therapy designation is intended to expedite the FDA's review of a potential new drug for serious or life-threatening diseases where "preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." The designation of a drug as a Breakthrough Therapy provides the same benefits as are available under the Fast-Track program, as well as intensive FDA guidance on the product's development program. Where appropriate, we intend to utilize regulatory programs that can help expedite our product development and commercialization efforts. However, Fast Track designation, priority review, accelerated approval and Breakthrough Therapy designation do not change the standards for approval, but may expedite the development or approval process.

Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to GMP. We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the GMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products include reporting of GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity and potency of biological products.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in-patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMPs and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain GMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Abbreviated Licensure Pathway of Biological Products as Biosimilar or Interchangeable

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products shown to be highly similar to an FDA-licensed reference biological product. The BPCIA attempts to minimize duplicative testing, and thereby lower development costs and increase patient access to affordable treatments. If our allogeneic products are approved by the FDA, we could face competition from products regulated by the FDA as biosimilar products.

Biosimilarity means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. In addition, the law provides for a designation of "interchangeability" between the reference and biosimilar products, whereby the biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. The higher standard of interchangeability must be demonstrated by information sufficient to show that:

- the proposed product is biosimilar to the reference product;
- the proposed product is expected to produce the same clinical result as the reference product in any given patient; and
- for a product that is administered more than once to an individual, the risk to the patient in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the reference product is no greater than the risk of using the reference product without such alternation or switch.

FDA approval is required before a biosimilar may be marketed in the United States. However, complexities associated with the large and intricate structures of biological products and the process by which such products are manufactured pose significant hurdles to the FDA's implementation of the law that are still being worked out by the FDA. For example, the FDA has discretion over the kind and amount of scientific evidence—laboratory, preclinical and/or clinical—required to demonstrate biosimilarity to a licensed biological product.

The FDA intends to consider the totality of the evidence, provided by a sponsor to support a demonstration of biosimilarity, and recommends that sponsors use a stepwise approach in the development of their biosimilar products. Biosimilar product applications thus may not be required to duplicate the entirety of preclinical and clinical testing used to establish the underlying safety and effectiveness of the reference product. However, the FDA may refuse to approve a biosimilar application if there is insufficient information to show that the active ingredients are the same or to demonstrate that any impurities or differences in active ingredients do not affect the safety, purity or potency of the biosimilar product. In addition, as with BLAs, biosimilar product applications will not be approved unless the product is manufactured in facilities designed to assure and preserve the biological product's safety, purity and potency.

The submission of a biosimilar application does not guarantee that the FDA will accept the application for filing and review, as the FDA may refuse to accept applications that it finds are insufficiently complete. The FDA will treat a biosimilar application or supplement as incomplete if, among other reasons, any applicable user fees assessed under the Biosimilar User Fee Act of 2012 have not been paid. In addition, the FDA may accept an application for filing but deny approval on the basis that the sponsor has not demonstrated biosimilarity, in which case the sponsor may choose to conduct further analytical, preclinical or clinical studies and submit a BLA for licensure as a new biological product.

The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the branded product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving any products that are biosimilar to the branded product. The FDA cannot approve a biosimilar application for twelve years from the date of first licensure of the reference product. Additionally, a biosimilar product sponsor may not submit an application for four years from the date of first licensure of the reference product. A reference product may also be entitled to exclusivity under other statutory provisions. For example, a reference product designated for a rare disease or condition (an "orphan drug") may be entitled to seven years of exclusivity, in which case no product that is biosimilar to the reference product may be approved until either the end of the twelve-year period provided under the biosimilarity statute or the end of the seven-year orphan drug exclusivity period, whichever occurs later. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block biosimilarity applications from being approved on or after the patent expiration date. In addition, the FDA may under certain circumstances extend the exclusivity period for the reference product by an additional six months if the FDA requests, and the manufacturer undertakes, studies on the effect of its product in children, a so-called pediatric extension.

The first biological product determined to be interchangeable with a branded product for any condition of use is also entitled to a period of exclusivity, during which time the FDA may not determine that another product is interchangeable with the reference product for any condition of use. This exclusivity period extends until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued.

U.S. Premarket Clearance and Approval Requirements for Medical Devices

Unless an exemption applies, each medical device we wish to distribute commercially in the United States will require either prior premarket notification, or 510(k) clearance, or prior approval of a PMA application from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose low to moderate risk are placed in either class I or II, which, absent an exemption, requires the manufacturer to file with the FDA a 510(k) submission requesting permission for commercial distribution. This process is known as 510(k) clearance. Some low-risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or certain implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in class III, requiring approval of a PMA application.

Regulation of CardiAMP through the PMA Pathway

Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products. Because combination products involve components that would normally be regulated under different types of regulatory authorities, and frequently by different centers of the FDA, they raise regulatory, policy, and review management challenges. Differences in regulatory pathways for each component of the product can impact the regulatory processes for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications.

A combination product is assigned to an FDA Agency Center or alternative organizational component that will have primary jurisdiction for its premarket review and regulation. For cell-based therapy and related products, the FDA established the Office of Cellular, Tissue and Gene Therapies within CBER to consolidate the review of such products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In our case, the CardiAMP Cell Therapy System involves minimal manipulation of cells within the procedure room, enabling it to be the first cardiac cell-based therapy we are aware of that CBER has indicated it will regulate through the PMA pathway.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction reasonable safety and effectiveness of the cell-based therapy. After a PMA application is deemed complete, the FDA will accept the application for filing and begin an in-depth review of the submitted information. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory 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. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA application is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained, or problems are identified following initial marketing.

The FDA may approve a PMA application 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, collection of long-term follow-up data from patients in the clinical trial that supported approval, or new post-approval studies. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. PMA supplements are required for modifications that could affect device safety or effectiveness, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as an original PMA application, except that the supplement is limited to information needed to support any changes to the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

A clinical trial is almost always required to support a PMA application. We expect that the CardiAMP Cell Therapy System will require a single pivotal trial for PMA approval in the CardiAMP Heart Failure and CardiAMP Chronic Myocardial Ischemia trials. However, there is no guarantee that the FDA will grant us regulatory approval to market the CardiAMP Cell Therapy System on the basis of a single pivotal trial. Two well-controlled pivotal studies could be necessary to provide the FDA assurance of safety or effectiveness. In the United States, absent certain limited exceptions, human clinical trials intended to support product clearance or approval require an IDE application, which the FDA reviews. Some types of trials deemed to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed, and IRB approval is obtained. If the device presents a "significant risk" to human health, as defined by FDA regulations, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory trial results, showing that it is safe to evaluate the device in humans and that the trial protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the responsible institutional review boards at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials. Additionally, after a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to unacceptable health risks that outweigh the benefits of participation in the trial. During a trial, we are required to comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, record keeping and prohibitions on the promotion or commercialization of investigational devices or making safety or efficacy claims for them, among other things. We are also responsible for the appropriate labeling and distribution of investigational devices. Our clinical trials must be conducted in accordance with FDA regulations and federal and state regulations concerning human subject protection, including informed consent and healthcare privacy, and the clinical trials must be conducted pursuant to GCPs. The investigators must also obtain patient-informed consent, rigorously follow the investigational plan and trial protocol, control the disposition of investigational devices and comply with all reporting and record keeping requirements, among other things. The FDA's grant of permission to proceed with clinical trials does not constitute a binding commitment that the FDA will consider the trial design adequate to support marketing clearance or approval. In addition, there can be no assurance that the data generated during a clinical trial will meet the chosen study endpoints or otherwise produce results that will lead the FDA to grant marketing clearance or approval. Similarly, in Europe, the clinical trial must be approved by the local ethics committee and in some cases, including trials of high-risk devices, by the Ministry of Health in the applicable country.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

Failure by us or our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions and related consequences including, but not limited to:

- adverse publicity, untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusal of or delay in granting our requests for 510(k) clearance or premarket approval of new products or modified products;
- withdrawing 510(k) clearance or premarket approvals that are already granted;
- refusal to grant export approval for our products;
- criminal prosecution; and
- unanticipated expenditures to address or defend such actions.

Because elements of the CardiAMP Cell Therapy System are already approved or cleared and manufactured for commercial use, we believe regulatory approval risks are primarily those of clinical safety and efficacy in each of the two indications being assessed under separate IDEs.

Regulation of Companion Diagnostics

Companion diagnostics are subject to regulation by the FDA, the EMA and other foreign regulatory authorities as medical devices and require separate regulatory clearance or approval prior to commercial use. While we anticipate that the CardiAMP diagnostic potency assay for each indication will require approval under a PMA submitted to the CDRH prior to commercialization, we are also exploring potential options to develop the CardiAMP potency diagnostic assay as a laboratory-developed test (LDT). We and our third-party collaborators who may develop our companion diagnostics will work cooperatively to generate the data required to commercialize our CardiAMP potency diagnostic assay and will remain in close contact with the CDRH to ensure that any changes in the regulatory requirements are incorporated into the development plans. We further anticipate that regulatory approval of the CardiAMP potency assay for each indication will be a prerequisite to our ability to market the CardiAMP Cell Therapy System. Representatives of CDRH have participated in our meetings with CBER regarding CardiAMP Cell Therapy System to discuss the potential use of the CardiAMP potency assay, and we anticipate that future meetings will include representatives from both CBER and CDRH to ensure that the PMA submissions (for CardiAMP Cell Therapy System and the CardiAMP potency diagnostic assay) are coordinated and subject to parallel review by these respective FDA centers. Accordingly, our objective is to align the development programs such that the CardiAMP potency assay will be developed and approved contemporaneously with CardiAMP.

On July 31, 2014, the FDA issued "Guidance for Industry: In Vitro Companion Diagnostic Devices," to help companies identify the need for companion diagnostics at an earlier stage in the drug development process and to plan for co-development of the drug and companion diagnostic test. The ultimate goal of the guidance is to stimulate early collaborations that will result in faster access to promising new treatments for patients living with serious and life-threatening diseases. According to the draft guidance, for novel products such as CardiAMP, the PMA for a companion diagnostic device should be developed and approved contemporaneously with the biological product. We believe our programs for the development of the CardiAMP potency assay are consistent with the draft guidance as proposed.

To the extent we elect to develop our diagnostic assay as an LDT, FDA may nonetheless regulate the LDT as a medical device. The FDA has historically exercised enforcement discretion in not enforcing the medical device regulations against LDTs and LDT manufacturers. However, on October 3, 2014, the FDA issued two draft guidance documents that set forth the FDA's proposed risk-based framework for regulating LDTs, which are designed, manufactured, and used within a single laboratory. In January 2017, the FDA announced that it would not issue final guidance on the oversight of LDTs and LDT manufacturers but would seek further public discussion on an appropriate oversight approach and give Congress an opportunity to develop a legislative solution. In 2019, the FDA issued warning letters to genomics labs for illegally marketing genetic tests that claim to predict patients' responses to specific medications, noting that the FDA has not created a legal "carve- out" for LDTs and retains discretion to take action when appropriate, such as when certain genomic tests raise significant public health concerns. As laboratories and manufacturers develop more complex genetic tests and diagnostic software, the FDA may increase its regulation of LDTs. Any future legislative or administrative rule making or oversight of LDTs and LDT manufacturers if and when finalized, may impact the sales of our products and how customers use our products, and may require us to change our business model in order to maintain compliance with these laws.

In August 2020, as part of the U.S. government's efforts to combat COVID-19 and consistent with the direction in Executive Orders 13771 and 13924, the Department of Health and Human Services (HHS) announced rescission of guidance and other informal issuances of the FDA regarding premarket review of LDTs absent notice-and-comment rulemaking, stating that, absent notice-and-comment rulemaking, those seeking approval or clearance of, or an emergency use authorization, for an LDT may nonetheless voluntarily submit a premarket approval application, premarket notification or an EUA request, respectively, but are not required to do so. While this HHS policy is expected to reduce the regulatory burden on clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 that develop LDTs, it is unclear how this action as well as other legislative and executive actions of the Biden administration and state governments and FDA regulation will impact the industry, including our business and that of our customers and collaborators. FDA's position with respect to LDTs in the short term and in general in the long-term may change, especially given the change in FDA leadership under the Biden administration. Congress could also enact legislation restricting LDTs. Any restrictions on LDTs and IVDs by the FDA, HHS, Congress, or state regulatory authorities may increase our compliance costs, delay approval of our products, and decrease the demand for our products.

To the extent FDA determines that any LDT product we may develop in the future is subject to additional regulation as a medical device or disagrees with our LDT determination and asserts that such product is considered an in vitro diagnostic device, our ability to market and sell such LDT would be impeded and our business, prospects, results of operations and financial condition may be adversely affected. In addition, FDA could consider our product to be misbranded or adulterated under the Federal Food, Drug, and Cosmetic Act and subject to recall and/or other enforcement action. Such enforcement action may also delay or negatively impact FDA approval of our regulatory submissions. If FDA disagrees without our LDT determination, we would not be able to commercialize our assay until we obtain PMA approval and comply with the applicable quality system requirements.

Coverage and Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government healthcare programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our therapeutic candidates or a decision by a third-party payor to not cover our therapeutic candidates could reduce physician usage of our products once approved and have a material adverse effect on our sales, results of operations and financial condition.

Affordable Care Act

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, was enacted, which includes measures that have or will significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Effective in 2010, the Affordable Care Act made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and biologic agents from 15.1% of average manufacturer price (AMP) to 23.1% of AMP and adding a new rebate calculation for "line extensions" (*i.e.*, new formulations, such as extended-release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The Affordable Care Act also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid-managed care utilization as of 2010. Per a ruling by the U.S. Supreme Court in 2012, states have the option to expand their Medicaid programs which in turn expands the population eligible for Medicaid drug benefits. The Centers for Medicare & Medicaid Services, or CMS, has proposed to expand Medicaid rebate liability to the territories of the United States as well. In addition, the Affordable Care Act provides for the public availability of retail survey prices and certain weighted average AMPs under the Medicaid program. The implementation of this requirement by the CMS may also provide for the public availability of pharmacy acquisition of cost data, which could negatively impact our sales.

- In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. Effective in 2010, the Affordable Care Act expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In July 2013, the Health Resources and Services Administration (HRSA) issued a final rule allowing the newly eligible entities to access discounted orphan drugs if used for non-orphan indications. While the final rule was vacated by a federal court ruling, HRSA has stated it will continue to allow discounts for orphan drugs when used for any indication other than for orphan indications. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

- Effective in 2011, the Affordable Care Act imposed a requirement on manufacturers of branded drugs and biologic agents to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (*i.e.*, "donut hole").

- Effective in 2011, the Affordable Care Act imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.

- The Affordable Care Act required pharmaceutical manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any "transfer of value" made or distributed to such entities, as well as any ownership or investment interests held by physicians and their immediate family members. Manufacturers were required to begin tracking this information in 2013 and to report this information to CMS by March 2014.

As of 2010, a new Patient-Centered Outcomes Research Institute was established pursuant to the Affordable Care Act to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.

There have been judicial and Congressional challenges and amendments to certain aspects of the Affordable Care Act, and with recent legislative activity we expect there could be additional challenges, amendments and attempts to repeal the Affordable Care Act. New state and federal healthcare reform measures could limit the amounts that federal and state governments will pay for our product candidates if we obtain regulatory approval for them and could have other impacts on consequences which cannot be reasonably predicted at this time.

Other Healthcare Laws and Compliance Requirements

If we obtain regulatory approval for any of our product candidates, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sale, marketing and education programs. In addition, we may be subject to patient privacy regulations by both the federal government and the states in which we conduct our business. The laws may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- the federal transparency laws, including the federal Physician Payment Sunshine Act, that requires drug manufacturers to disclose payments and other transfers of value provided to physicians and teaching hospitals and ownership and investment interest held by such physicians and their immediate family members;

- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

- State law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical 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 drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. In addition, the Affordable Care Act broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that 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 false claims laws or the civil monetary penalties statute.

We are also subject to the Foreign Corrupt Practices Act, or FCPA, which prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business.

Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, and others may be ineffective, and violations of the FCPA and similar state laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and results of operations.

If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, such as Medicare and Medicaid and imprisonment, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Government Regulation outside the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Because biologically-sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval or clearance for a product, we must obtain the requisite approvals or clearances from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the PMA or IND prior to the commencement of human clinical trials. In Europe, for example, a Clinical Trial Authorization, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational biological product under European regulatory systems, we must submit a marketing authorization application. The application used to file the PMAs for CardiAMP Cell Therapy System and BLA for allogeneic cells in the United States are similar to that required in Europe, with the exception of, among other things, country-specific document requirements. Europe also provides opportunities for market exclusivity. For example, in Europe, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in Europe from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by Europe's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

For other countries outside of Europe, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

In Europe, we expect both CardiAMP and CardiALLO Cell Therapy Systems to be regulated as advanced therapy medicinal products, or ATMPs. To provide for a common framework for the marketing of ATMPs, Regulation (EC) No 1394/2007 of the European Parliament and of the Council on advanced therapy medicinal products, or ATMP Regulation, was adopted in 2007. The ATMP Regulation was designed to ensure a high level of human health protection as well as the free movement of ATMPs in Europe. The cornerstone of the ATMP Regulation is that a marketing authorization must be obtained prior to the marketing of ATMPs. In turn, the marketing authorization can only be granted if, after a scientific assessment of the quality, efficacy and safety profile, it is demonstrated that the benefits outweigh the risks. The application for a marketing authorization must be submitted to the EMA and the final decision is taken by the European Commission. This procedure ensures that these products are assessed by a specialized body (the Committee for Advanced Therapies, or CAT) and that the marketing authorization is valid in all the European Union Member States.

The ATMP Regulation empowered the EMA to make scientific recommendations as to whether a given product should be considered an ATMP (hereinafter "classifications"). Additionally, it provided for a new instrument, the so-called certification procedure, designed as an incentive for small and medium-sized enterprises, or SMEs, that were involved in the first stages of the development of ATMPs but lacked the resources to conduct clinical trials. Specifically, the certification that the quality and preclinical aspects of the development are in conformity with the relevant regulatory requirements was expected to help SMEs attract capital and to facilitate the transfer of research activities to entities with the capacity to market medicinal products.

The ATMP Regulation builds on the procedures, concepts, and requirements designed for chemical-based medicinal products. However, ATMPs present very different characteristics. Additionally, in contrast to chemical-based medicinal products, research in advanced therapies is, for the most part, conducted by academia, non-for-profit organizations, and SMEs, which only have limited financial resources and often lack exposure to the regulatory system that governs medicines.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

The advertising and promotion of our products in the EEA is subject to the provisions of the 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 national legislation in the EEA countries governing the advertising and promotion of medical devices. The European Commission has submitted a Proposal for a Regulation of the European Parliament and the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, to replace, inter alia, Directive 93/42/EEC and to amend regulations regarding medical devices in the European Union, which could result in changes in the regulatory requirements for medical devices in Europe. In Germany, the advertising and promotion of our products can also be subject to restrictions provided by the German Act Against Unfair Competition (Gesetzgegen den unlauteren Wettbewerb) and the law on the advertising of medicines (Heilmittelwerbegesetz), criminal law, and some codices of conduct with regard to medical products and medical devices, among others. 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.

Sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our products outside the United States, we must obtain regulatory approvals or CE Certificates of Conformity and comply with extensive safety and quality regulations. The time required to obtain approval by a foreign country or to obtain a CE Certificate of Conformity may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. In the EEA, we are required to obtain Certificates of Conformity before drawing up an EC Declaration of Conformity and affixing the CE Mark of conformity to our medical devices. Many other countries accept CE Certificates of Conformity or FDA clearance or approval although others, such as Brazil, Canada and Japan require separate regulatory filings.

Employees and Human Capital

As of December 31, 2020, we had 24 full-time and 5 part-time employees, consisting of clinical development, product development, regulatory, manufacturing, quality, finance, administration, sales, and marketing. We also regularly use independent contractors across the organization to augment our regular staff. None of our employees are covered by collective bargaining agreements and we consider relations with our employees to be good.

We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate Information

We were originally incorporated as NAM Corporation in Delaware on January 12, 1994. We changed our name to BioCardia, Inc. on October 26, 2016 in connection with a reverse merger transaction (the Merger) in which our wholly owned subsidiary, Icicle Acquisition Corp., merged with and into BioCardia Lifesciences, Inc. (which was named BioCardia, Inc. prior to the Merger), with BioCardia Lifesciences continuing as the surviving company. Following the completion of the reverse merger transaction, we assumed the business and operations of BioCardia Lifesciences and changed our name to BioCardia, Inc.

We operate in only one business segment, which is a clinical-stage regenerative medicine company developing novel therapeutics for diseases with large unmet medical needs. See Note 1 to our consolidated financial statements for the year ended December 31, 2020 included in this Annual Report. Our principal executive offices are located at 125 Shoreway Road, Suite B, San Carlos, CA 94070. Our telephone number is (650) 226-0120.

Our website address is *www.biocardia.com*. Information contained in our website is not incorporated by reference into this Annual Report and should not be considered to be a part of this Annual Report. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our investor relations website as soon as reasonably practicable after we electronically file such material with, or furnish it to the Securities and Exchange Commission, or SEC. The SEC also maintains a website that contains these reports and our other electronic SEC filings.

ITEM 1A. RISK FACTORS

SUMMARY OF RISK FACTORS

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report and our other filings with the SEC before making an investment decision regarding our common stock.

Risks Related to Our Business, Financial Condition and Capital Requirements

- We have a history of operating losses, and we may not be able to achieve or sustain profitability.
- We will require substantial additional financing to achieve our goals, and our failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- We may not be able to access sufficient funds under the LPC Purchase Agreement when needed.

Risks Related to Development and Commercialization

- Our success depends in large part on our ability to obtain approval for, and successfully commercialize, the CardiAMP Cell Therapy System. Because the CardiAMP Cell Therapy System is, to our knowledge, the first cardiac cell-based therapy with an accepted pivotal trial that is to be regulated by the FDA via the premarket approval pathway, the approval process for the CardiAMP Cell Therapy System is uncertain.
- Our CardiAMP and CardiALLO cell therapy systems and other therapeutic candidates are based on novel technology, which makes it difficult to accurately and reliably predict the time and cost of product development and subsequently obtaining regulatory approval. At the moment, no cell-based therapies have been approved in the United States for a cardiac indication.
- We have encountered, and may in the future encounter, substantial delays in our clinical studies.
- We may find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our therapeutic candidates.
- We rely on third parties to conduct some or all aspects of our product manufacturing, diagnostic protocol development, research, and preclinical and clinical testing, and these third parties may not perform satisfactorily.
- We rely on third parties to conduct, supervise and monitor our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- We depend on third-party vendors to manufacture some of our components and sub-assemblies, which could make us vulnerable to supply shortages and price fluctuations that could harm our business.
- Our future commercial success depends upon attaining significant market acceptance of our therapeutic candidates, if approved, among physicians, patients and healthcare payors.
- Our ability to compete is highly dependent on demonstrating the benefits of CardiAMP to physicians, hospitals and patients.
- We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our therapeutic candidates, if approved, we may be unable to generate any revenues.
- We have limited experience manufacturing our therapeutic candidates or products in commercial quantities, which could harm our business.
- If we fail to obtain and sustain an adequate level of reimbursement for our products by third-party payors, sales and profitability would be adversely affected.

Risks Relating to Government Regulation, Compliance and Litigation

- Even if we obtain regulatory approval for a product candidate, including our CardiAMP and CardiALLO Cell Therapy Systems and other therapeutic candidates, these products or therapies, along with our other regulated products, will be subject to ongoing regulatory scrutiny.
- We may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory agencies.
- If we fail to obtain and maintain necessary regulatory clearances or approvals for our therapeutic candidates or products, or if clearances or approvals for our therapeutic candidates or products in additional indications are delayed or not issued, our commercial operations would be harmed.
- Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of our therapeutic candidates or products or limit the scope of any approved indication or market acceptance.
- Our therapeutic candidates are intended to treat patients who are extremely ill, and patient deaths that occur in our clinical trials could negatively impact our business even if they are not shown to be related to our therapeutic candidates.
- If we or our suppliers fail to comply with the FDA's QSRs, our manufacturing operations could be delayed or shut down and product sales could suffer.

- The requirements to obtain regulatory approval of the FDA and regulators in other jurisdictions can be costly, time-consuming, and unpredictable. If we are unable to obtain timely regulatory approval for our therapeutic candidates, our business may be substantially harmed.
- Even if we obtain and maintain approval for our therapeutic candidates or products from the FDA, we may never obtain approval for our therapeutic candidates or products outside of the United States, which would limit our market opportunities and adversely affect our business.
- We may face competition from biosimilars due to changes in the regulatory environment.
- A recall of any of our commercialized products, or the discovery of serious safety issues, could have a significant negative impact on us.
- Modifications to our products may require reclassifications, new regulatory approvals or clearances, or may require us to cease marketing or recall the modified products until new CE marking is obtained.
- Our employees, principal investigators, consultants and collaboration partners may engage in misconduct or other improper activities, including noncompliance with laws and regulatory standards and requirements and insider trading.
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our therapeutic candidates or products.

Risks Related to the Operation of Our Business

- If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our therapeutic candidates, conduct our clinical trials and commercialize our therapeutic candidates.
- We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.
- Our business and operations would suffer in the event of system failures.
- The outbreak of the novel strain of coronavirus, SARS-CoV-2, and its variants, which causes COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.

Risks Relating to Our Intellectual Property

- We may not be able to protect our proprietary technology in the marketplace.
- The patent protection of biotherapeutics is complex and uncertain.
- We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.
- We may be forced to litigate to enforce or defend our intellectual property rights, and/or the intellectual property rights of our licensors.
- Intellectual property disputes could cause us to spend substantial resources and distract our personnel from their normal responsibilities.
- Patent reform legislation and recent court decisions could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.
- If third parties claim that our therapeutic candidates or other products infringe upon their intellectual property, commercialization of our therapeutic candidates or products and our operating profits could be adversely affected.
- If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity of our therapeutic candidates or products, our business may be materially harmed.

Risks Related to Our Securities

- An active trading market may not develop for our securities or what the market price of our securities will be and as a result it may be difficult for you to sell your shares of our securities.
- The market price and trading volume of our securities may be volatile and may be affected by economic conditions beyond our control.
- We may be exposed to additional risks as a result of our reverse merger transaction.
- Our annual and quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.
- Raising additional funds through debt or equity financing could be dilutive and may cause the market price of our common stock to decline.
- The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.
- Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

General Risks

- We are at risk of securities class action litigation.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes, before investing in our securities. If any of the following risks occur, our business, financial condition, results of operations and prospects could be materially harmed. In that event, market prices of our securities could decline, and you could lose part or all of your investment.

Risks Relating to Our Business, Financial Condition and Capital Requirements

We have a history of operating losses, and we may not be able to achieve or sustain profitability.

We are a clinical-stage regenerative medicine company and we have not yet generated a profit. We have incurred net losses during each of our fiscal years since our inception. Our net loss for the year ended December 31, 2020 was $15.0 million and our accumulated deficit totaled $116.1 million as of December 31, 2020. We do not know whether or when we will become profitable, if ever. We currently expect operating losses and negative cash flows to continue for at least the next several years.

To date, our only approved or cleared products are our Morph universal deflectable guide catheters and Morph AccessPro sheaths, in the United States and Europe; our AVANCE™ steerable introducer and our Morph DNA deflectable guides in the United States only; and our Helix biotherapeutic delivery system, or Helix, in Europe. Our limited commercialization experience and number of approved products makes it difficult to evaluate our current business and predict our future prospects. Our short commercialization experience and limited number of approved products also makes it difficult for us to forecast our future financial performance and growth and such forecasts are limited and subject to a number of uncertainties, including our ability to successfully complete our Phase III pivotal trials in heart failure and chronic myocardial ischemia and obtain FDA approval for, and then successfully commercialize, the CardiAMP Cell Therapy System.

Our ability to generate sufficient revenue to achieve profitability depends on our ability, either alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize our therapeutic candidates. We do not anticipate generating revenues from sales of the CardiAMP Cell Therapy System, the CardiALLO Cell Therapy System or any other biotherapeutic candidates within the next few years, and we may never generate sales of these products.

We anticipate that our expenses will increase in the future as we continue to incur significant research and development and other expenses related to our ongoing operations, seek regulatory approvals for our therapeutic candidates, scale-up manufacturing capabilities and hire additional personnel to support the development of our therapeutic candidates and commercialization efforts. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To achieve and maintain profitability, we must successfully develop our therapeutic candidates, obtain regulatory approvals and manufacture, market and sell those products for which we obtain regulatory approvals. If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our therapeutic candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors and adequate market share for our therapeutic candidates in those markets. We may not succeed in these activities, and we may never generate revenue from product sales that is significant enough to achieve profitability. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, discover or develop other product candidates or continue our operations. A decline in the value of our company could cause you to lose part or all of your investment.

Based upon our current operating plan, we believe that the cash and cash equivalents on hand will enable us to fund our operations for at least the next 12-month period following the date of issuance of our 2020 financial statements.

We will require substantial additional financing to achieve our goals, and our failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to incur significant expenses and operating losses for the foreseeable future in connection with our planned research, development and product commercialization efforts, including our planned clinical trials for our CardiAMP and CardiALLO Cell Therapy System therapeutic candidates. In addition, we will require additional financing to achieve our goals and our failure to do so could adversely affect our commercialization efforts. Other than the purchase agreement we entered into with Lincoln Park Capital Fund, LLC in March 2021 (the LPC Purchase Agreement), we do not currently have any agreements or understandings with respect to any potential financing. We anticipate that our expenses will increase substantially if and as we:

- continue the research and clinical development of our CardiAMP and CardiALLO Cell Therapy System therapeutic candidates;
- initiate and advance our CardiAMP and CardiALLO Cell Therapy System therapeutic candidates in expensive clinical studies, including the ongoing Phase III pivotal trial for our CardiAMP Cell Therapy System therapeutic candidate in heart failure and our approved Phase III pivotal trial for our CardiAMP Cell Therapy System therapeutic candidate in chronic myocardial ischemia;

- seek to identify, assess, acquire, and/or develop other product candidates and technologies;
- seek regulatory and marketing approvals in multiple jurisdictions for our therapeutic candidates that successfully complete clinical studies;
- build and maintain a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval, or otherwise establish collaborations with third parties for the development and commercialization of our therapeutic candidates;
- further develop and implement our manufacturing processes and expand our manufacturing capabilities and resources for commercial production;
- seek coverage and reimbursement from third-party payors, including government and private payors for future products;
- seek to maintain, protect and expand our intellectual property portfolio; and
- seek to attract and retain skilled personnel.

We have experienced delays, and if we were to experience any future delays or encounter issues with any of the above, including clinical holds, failed studies, inconclusive or complex results, safety or efficacy issues, or other regulatory challenges that require longer follow-up of existing studies, additional major studies, or additional supportive studies in order to pursue marketing approval, it could further increase the costs associated with the above. Further, the net operating losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

We may not be able to access sufficient funds under the LPC Purchase Agreement when needed.

Our ability to sell shares to Lincoln Park and obtain funds under the LPC Purchase Agreement is limited by the terms and conditions in the Purchase Agreement, including restrictions on the amounts we may sell to Lincoln Park at any one time, and a limitation on our ability to sell shares to Lincoln Park to the extent that it would cause Lincoln Park to beneficially own more than 9.99% of our outstanding shares of common stock. Additionally, under the Purchase Agreement, we will only be able to sell or issue to Lincoln Park a maximum aggregate number of shares equal to 19.99% of the shares of common stock outstanding on the date of the LPC Purchase Agreement (the Exchange Cap), unless we obtain shareholder approval to issue shares in excess of the Exchange Cap, or the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement is equal to or greater than the base price of $4.2736, such that the Exchange Cap would not apply to issuances and sales of common stock to Lincoln Park under the LPC Purchase Agreement. Therefore, we currently do not, and may not in the future, have access to the full amount otherwise available to us under the LPC Purchase Agreement. In addition, any amounts we sell under the LPC Purchase Agreement may not satisfy all of our funding needs, even if we are able and choose to sell and issue all of our common stock otherwise issuable pursuant to the LPC Purchase Agreement.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future and we may never achieve profitability. None of our pre-Merger tax attributes remain available after the Merger as a result of limitations Section 382 due to lack of business continuity. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Losses generated after 2017 do not have an expiration date. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. Our prior equity offerings and other changes in our stock ownership may have resulted in ownership changes. We have not performed an analysis to assess whether an ownership change has occurred. If we have experienced an ownership change at any time since our formation, utilization of our net operating loss carryforwards would be subject to an annual limitation under Section 382 and 383 of the Code. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside of our control. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income and tax credits may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Recent U.S. tax legislation and future changes to applicable U.S. or foreign tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.

We are subject to income and other taxes in the U.S. Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. For example, the U.S. government recently enacted significant tax reform, and certain provisions of the new law may adversely affect us. Changes include, but are not limited to, a federal corporate tax rate decrease from 34% to 21% for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a more generally territorial system, and a one-time transition tax on the mandatory deemed repatriation of foreign earnings. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. or foreign tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations. Changes with respect to the transition to a territorial tax system are generally expected to have little impact given our lack of foreign operations.

Risks Relating to Development and Commercialization

Our success depends in large part on our ability to obtain approval for, and successfully commercialize, the CardiAMP Cell Therapy System.

The long-term viability of our company is largely dependent on the successful development and commercialization of the CardiAMP Cell Therapy System. We are currently enrolling patients in a Phase III pivotal trial that will be used to support regulatory approval, and we do not have significant long-term data on the CardiAMP Cell Therapy System's safety and efficacy in either heart failure or chronic myocardial ischemia. While we expect to successfully complete our ongoing Phase III pivotal trial of the CardiAMP Cell Therapy System in heart failure, there can be no guarantee that the study will be completed, that the primary endpoints will be achieved, or that we will receive regulatory approval for the sale and marketing in the United States. A number of companies in similar fields have suffered significant setbacks during clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising preliminary results. Because we are depending heavily on sales of the CardiAMP Cell Therapy System to achieve our revenue goals, failure to successfully complete the study and receive FDA approval, in a timely manner or at all, will harm our financial results and ability to become profitable. Even if we obtain regulatory approval, our ability to successfully market this product will be limited due to a number of factors, including regulatory restrictions in our labeling or requirements to obtain additional post-approval data, if any. In addition, there can be no guarantee that the CardiAMP Cell Therapy System will be accepted by the medical community as a valid alternative to currently available products. If we cannot sell the CardiAMP Cell Therapy System as planned, our financial results will be harmed.

FDA acceptance of a Phase III pivotal trial is not a guarantee of an approval of a product candidate or any permissible claims about the product candidate. Failure to successfully complete our ongoing Phase III trial of CardiAMP in heart failure would significantly impair our financial results. Such a failure could (i) delay or prevent the CardiAMP Cell Therapy System from obtaining regulatory approval, (ii) require us to perform another clinical trial, which will be expensive, may not be successful and will significantly delay our ability to commercialize the CardiAMP Cell Therapy System and (iii) impair our ability to convince hospitals and physicians of the benefits of our CardiAMP Cell Therapy System product. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for CardiAMP, which may limit the market for this product.

Because the CardiAMP Cell Therapy System is, to our knowledge, the first cardiac cell-based therapy with an accepted pivotal trial that is to be regulated by the FDA via the premarket approval pathway, the approval process for the CardiAMP Cell Therapy System is uncertain.

Although we have obtained FDA acceptance of Phase III pivotal trials of the CardiAMP Cell Therapy System for the treatment of ischemic systolic heart failure and chronic myocardial ischemia, this does not guarantee any particular outcome from regulatory review. To the best of our knowledge, the CardiAMP Cell Therapy System for the treatment of ischemic systolic heart failure is the first cardiac cell-based therapy with an accepted pivotal trial that is to be regulated by the FDA Center for Biologics Evaluation and Research, or CBER, via the premarket approval, or PMA, pathway requiring a single trial. The CardiAMP Cell Therapy System for the treatment of chronic myocardial ischemia is also to be regulated under the same IDE/PMA pathway. All other cardiac cell-based therapies in clinical trials are believed to be regulated by the same agency, but as biologics which generally require two separate pivotal trials. There is no guarantee that the FDA will grant us regulatory clearance or approval to market the CardiAMP Cell Therapy System on the basis of a single pivotal trial, or that the FDA will continue to allow us to develop the CardiAMP Cell Therapy System via the PMA pathway. Two well-controlled pivotal studies could be necessary to provide FDA assurance of safety or effectiveness. If the FDA approval process does not occur as we anticipate or we are required to conduct more than one pivotal study to obtain approval, we may incur substantial additional costs and delays to obtain approval, if at all, which would have a material adverse impact on our business, financial condition and prospects.

Our CardiAMP and CardiALLO cell therapy systems and other therapeutic candidates are based on novel technology, which makes it difficult to accurately and reliably predict the time and cost of product development and subsequently obtaining regulatory approval. At the moment, no cell-based therapies have been approved in the United States for a cardiac indication.

The success of our business depends on our ability to develop and commercialize our therapeutic candidates, including CardiAMP. We have concentrated our product research and development efforts on our CardiAMP therapeutic candidate, a novel type of cell-based therapy. Our future success depends on the successful development of this therapeutic approach. There can be no assurance that any development problems we experience related to our therapeutic candidates and products, that we have experienced or that we may experience in the future, will not cause significant delays or unanticipated costs, or that such development problems can be solved. For example, in 2020, our efforts to lift a clinical hold on our CardiALLO allogenic cell therapy product candidate was not successful when reviewed by the FDA due to issues they identified with respect to our chemistry, manufacturing and controls for the approach we had taken. Each element of an IND submission has technical, regulatory, commercial, and other risks and there is no guarantee we will be successful in advancing our therapeutic programs. Also, we may be unable to maintain and further develop sustainable, reproducible and scalable manufacturing processes, or transfer these processes to collaborators, which may prevent us from completing our clinical studies or commercializing our products on a timely or profitable basis, if at all.

In addition, the clinical study requirements of the FDA, the European Medicines Agency, or EMA, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, intended use and market of the potential product candidates. The regulatory approval process for novel product candidates such as our CardiAMP and CardiALLO Cell Therapy Systems may be more expensive and take longer than other, better known or extensively studied pharmaceutical or other product candidates to develop. In addition, adverse developments in clinical trials of cell-based products or therapies conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our therapeutic candidates. At the moment, no other cell-based therapies have been approved in the United States for a cardiac indication, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our therapeutic candidates in either the United States or elsewhere.

Regulatory requirements governing cell-based therapy products have changed frequently and may continue to change in the future. For example, the FDA established the Office of Cellular, Tissue and Gene Therapies within CBER to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. These regulatory authorities and advisory groups and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with the FDA and other regulatory authorities, and our products could be reviewed by the FDA's advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates.

We have encountered, and may in the future encounter, substantial delays in our clinical studies.

We have encountered, and may in the future encounter, substantial delays in our clinical studies. We cannot guarantee that any preclinical testing or clinical trials will be conducted as planned or completed on schedule, if at all. As a result, we may not achieve our expected clinical milestones. A failure can occur at any stage of testing. Events that may prevent successful or timely commencement, enrollment or completion of clinical development include:

- delays in raising, or inability to raise, sufficient capital to fund the planned trials;
- delays in reaching a consensus with regulatory agencies on trial design;
- changes in trial design;
- inability to identify, recruit and train suitable clinical investigators;
- inability to add new clinical trial sites;
- delays in reaching agreement on acceptable terms for the performance of the trials with prospective clinical research organizations, or CROs, and clinical trial sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical trial site;
- delays in recruiting suitable clinical sites and patients (i.e., subjects) to participate in clinical trials;
- imposition of a clinical hold by regulatory agencies for any reason, including negative clinical results, safety concerns or as a result of an inspection of manufacturing or clinical operations or trial sites;
- failure by us, CROs or other third parties to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's current Good Clinical Practices, or GCP, or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery to the clinical sites;
- delays caused by patients not completing participation in a trial or not returning for post-treatment follow-up;
- delays caused by clinical trial sites not completing a trial;
- failure to demonstrate adequate efficacy;
- occurrence of serious adverse events in clinical trials that are associated with the therapeutic candidates or products that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or
- disagreements between us and the FDA or other regulatory agencies interpreting the data from our clinical trials.

Delays, including those caused by the above factors, can be costly and could negatively affect our ability to complete clinical trials for our therapeutic candidates. If we are not able to successfully complete clinical trials or are not able to do so in a timely and cost-effective manner, we will not be able to obtain regulatory approval and/or will not be able to commercialize our therapeutic candidates or products, which would have an adverse effect on our business. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our therapeutic candidates or products or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our therapeutic candidates or products and may harm our business and results of operations.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our therapeutic candidates.

Identifying and qualifying patients to participate in clinical trials of our therapeutic candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our therapeutic candidates as well as completion of required follow-up periods. In general, if patients are unwilling to participate in our cell-based therapy trials because of negative publicity from adverse events in the biotechnology or cell-based industries or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting trials and obtaining regulatory approval for our therapeutic candidates may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our therapeutic candidates or termination of the clinical trials altogether.

Patient enrollment and completion of clinical trials are affected by factors including:

- size of the patient population;
- severity of the disease under investigation;
- design of the trial protocol;
- eligibility criteria for the particular trial;
- perceived risks and benefits of the product candidate being tested;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment; and
- the degree of treatment effect in event-driven trials.

Once enrolled, patients may choose to discontinue their participation at any time during the trial, for any reason. Participants also may be terminated from the study at the initiative of the investigator, for example if they experience serious adverse clinical events or do not follow the study directions. If we are unable to maintain an adequate number of patients in our clinical trials, we may be required to delay or terminate an ongoing clinical trial, which would have an adverse effect on our business.

We depend on our license and distribution agreement with Biomet Biologics, LLC, and if we fail to comply with our obligations under this agreement, or if our rights under this agreement are otherwise reduced or terminated, we could lose intellectual property rights that are important to our business.

In October 2012, we entered into a license and distribution agreement with Biomet Biologics, LLC under which we obtained an exclusive, nontransferable, worldwide distribution right, patent license and trademark license to Biomet Biologic, LLC's point of care cell processing platform. Under the terms of the agreement, we are obligated to pay Biomet Biologics, LLC a royalty based on the price of the disposables in the CardiAMP cell processing platform. A breach or termination of this agreement would materially adversely affect the clinical development or commercialization strategy of our CardiAMP therapeutic candidate as currently planned. A reduction or elimination of our rights under this agreement may result in our having to negotiate new or reinstated arrangements on less favorable terms, or our not having sufficient intellectual property rights to operate our business as currently planned. The occurrence of such events could materially harm our business and financial condition.

We rely on third parties to conduct some or all aspects of our product manufacturing, diagnostic protocol development, research, and preclinical and clinical testing, and these third parties may not perform satisfactorily.

We do not currently, and do not expect to in the future, independently conduct all aspects of our product manufacturing, anticipated companion diagnostic testing, protocol development, research and monitoring and management of our ongoing preclinical and clinical programs. We currently rely, and expect to continue to rely, on third parties with respect to these items, and control only certain aspects of their activities.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, our commercialization activities or our therapeutic candidate or companion diagnostic development activities may be delayed or suspended. Our reliance on these third parties for research and development activities, including the conduct of any IDE and IND-enabling studies, reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards and any applicable trial protocols. For example, for therapeutic candidates that we develop and commercialize on our own, we will remain responsible for ensuring that each of our IDE and IND-enabling studies and clinical trials are conducted in accordance with the trial plan and protocols.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we may be delayed in completing, or unable to complete, the preclinical studies and clinical trials required to support future IDE and IND submissions and approval of our therapeutic candidates.

Reliance on third-party manufacturers entails exposure to risks to which we would not be subject if we manufactured the therapeutic candidates or companion diagnostic ourselves, including:

- we may be unable to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control over the manufacturing process for our therapeutic candidates and companion diagnostic as a result of using third-party manufacturers for many aspects of manufacturing activities;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our therapeutic candidates or companion diagnostic; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

Any of these events could lead to delays in the development of our therapeutic candidates, including delays in our clinical trials, or failure to obtain regulatory approval for our therapeutic candidates, or it could impact our ability to successfully commercialize our current therapeutic candidates, companion diagnostic or any future products. Some of these events could be the basis for FDA or other regulatory action, including injunction, recall, seizure or total or partial suspension of production.

We rely on third parties to conduct, supervise and monitor our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely on CROs and clinical trial sites to ensure our clinical trials are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA, the Competent Authorities of the Member States of the EEA, and comparable foreign regulatory authorities, enforce these GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our future clinical trials may be deemed unreliable and the FDA, the EMA, or other foreign regulatory authorities may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our future clinical trials will require a sufficient number of test subjects to evaluate the safety and effectiveness of our therapeutic candidates. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our therapeutic candidates. If any such event were to occur, our financial results and the commercial prospects for our therapeutic candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Further, switching or adding additional CROs involves additional costs and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which could materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We may also rely on other third parties to store and distribute our products for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our therapeutic candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

We depend on third-party vendors to manufacture some of our components and sub-assemblies, which could make us vulnerable to supply shortages and price fluctuations that could harm our business.

We currently manufacture some of our components and sub-assemblies internally and rely on third-party vendors for other components and sub-assemblies used in our products and therapeutic candidates. Our reliance on third-party vendors subjects us to a number of risks that could impact our ability to manufacture our products and therapeutic candidates and harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's failure to consistently produce quality components;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- inability of the manufacturer or supplier to comply with Quality System Regulations, or QSRs, enforced by the FDA and state regulatory authorities;
- inability to control the quality of products manufactured by third parties;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- delays in delivery by our suppliers due to changes in demand from us or their other customers.

Any significant delay or interruption in the supply of components or sub-assemblies, or our inability to obtain substitute components, sub-assemblies or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and harm our business.

Our future commercial success depends upon attaining significant market acceptance of our therapeutic candidates, if approved, among physicians, patients and healthcare payors.

Even when product development is successful and regulatory approval has been obtained, our ability to generate significant revenue depends on the acceptance of our products by physicians, payors and patients. Many potential market participants have limited knowledge of, or experience with, cell-based products and therapies, so gaining market acceptance and overcoming any safety or efficacy concerns may be more challenging than for more traditional therapies. Our efforts to educate the medical community and third-party payors on the benefits of our therapeutic candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by conventional therapies marketed by our competitors. We cannot assure you that our products will achieve the expected market acceptance and revenue if and when they obtain the requisite regulatory approvals. Alternatively, even if we obtain regulatory approval, that approval may be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. The market acceptance of each of our therapeutic candidates will depend on a number of factors, including:

- the efficacy and safety of the therapeutic candidate, as demonstrated in clinical trials;
- the clinical indications for which the product is approved, and the label approved by regulatory authorities for use with the product, including any warnings that may be required on the label;
- acceptance by physicians and patients of the product as a safe and effective treatment;
- the cost, safety and efficacy of treatment in relation to alternative treatments;
- the continued projected growth of markets for our various indications;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

Market acceptance is critical to our ability to generate significant revenue. Any therapeutic candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate significant revenue and our business would suffer.

Our ability to compete is highly dependent on demonstrating the benefits of CardiAMP to physicians, hospitals and patients.

In order to generate sales, we must be able to clearly demonstrate that CardiAMP is both a more effective treatment system and less costly than alternative products and treatments offered by our competitors. If we are unable to convince physicians that CardiAMP leads to significant improvement in functional capacity, improved quality of life and reduced hospitalization, our business will suffer.

We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.

Our industry is highly competitive and subject to rapid change. The industry continues to expand and evolve as an increasing number of competitors and potential competitors enter the market. Astra Zeneca, Bayer, Blue Rock Therapeutics, Bristol-Myers Squibb, Caladrius Biosciences, Capricor Therapeutics, Celixr, Cesca Therapeutics, Celyad, Daichii Sankyo, Fuji Film, Mesoblast, Moderna, Sana Biotechnology, Takeda Pharmaceuticals, Tenaya Therapeutics, Terumo, Vericel Corp, and Uniqure, among others. Many of our competitors, potentially including the aforementioned, have significantly greater development, financial, manufacturing, marketing, technical and human resources than we do. Large pharmaceutical and medical device companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical and medical device products. Recent and potential future merger and acquisition activity in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Established companies may also invest heavily to accelerate discovery and development of novel products that could make our therapeutic candidates obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing our therapeutic candidates or competitors to our therapeutic candidates before we do. Specialized, smaller or early-stage companies may also prove to be significant competitors, particularly those with a focus and expertise in the stem cell industry and/or those with collaboration arrangements and other third-party payors. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow, and our financial condition and results of operations will suffer.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our therapeutic candidates, if approved, we may be unable to generate any revenues.

We currently have a limited organization for the sales, marketing and distribution of products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, including CardiAMP and CardiALLO Cell Therapy Systems and our Neurokinin-1 Receptor Positive allogeneic therapies, we must build our sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We have limited prior experience in the marketing, sale or distribution of approved products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our therapeutic candidates.

Our strategy is to obtain FDA approval and market the CardiAMP Cell Therapy System for potential heart failure and chronic myocardial ischemia indications using a dedicated direct sales model focused on selected cardiologists and interventional cardiologists. We may in the future, choose to align ourselves with collaborators as part of our commercialization strategy, particularly outside of the United States, and our future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of our therapeutic candidates or companion diagnostic or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the sale of our therapeutic candidates and companion diagnostic to healthcare professionals and in geographical regions, including the United States, that will not be covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize our therapeutic candidates or companion diagnostic, our ability to generate revenues from product sales, including sales of CardiAMP and CardiALLO Cell Therapy Systems and other therapies, will be adversely affected.

Building an internal sales force involves many challenges, including:

- recruiting and retaining talented people;
- training employees that we recruit;
- setting the appropriate system of incentives;
- managing additional headcount; and
- integrating a new business unit into an existing corporate architecture.

If we are unable to build our own sales force or negotiate a strategic partnership for the commercialization of our autologous or allogeneic cell therapies in the United States, we may be forced to delay the potential commercialization of these therapies or reduce the scope of our sales and marketing. To fund commercialization activities, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our therapies to market or generate product revenue.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

In addition, there are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any launch. If the commercial launch of a therapeutic candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We have limited experience manufacturing our therapeutic candidates or products in commercial quantities, which could harm our business.

Because we have only limited experience in manufacturing therapeutic candidates or products in commercial quantities, we may encounter production delays or shortfalls. Such production delays or shortfalls may be caused by many factors, including the following:

- we intend to significantly expand our manufacturing capacity, and our production processes may have to change to accommodate this growth;
- key components and sub-assemblies of our products and therapeutic candidates are currently provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components and sub-assemblies; if we experience a shortage in any of these components or sub-assemblies, we will need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays;

- we may experience a delay in completing validation and verification testing for new controlled-environment rooms at our manufacturing facilities;
- we have limited experience in complying with FDA's QSRs, which applies to the manufacture of our products and therapeutic candidates; and
- to increase our manufacturing output significantly, we will have to attract and retain qualified employees, who are in short supply, for our manufacturing operations.

If we fail to obtain and sustain an adequate level of reimbursement for our products by third-party payors, sales and profitability would be adversely affected.

Our ability to commercialize any therapeutic candidates or products successfully will depend, in part, on the extent to which coverage and reimbursement for our therapeutic candidates or products and related treatments will be available from government healthcare programs, private health insurers, managed care plans, and other organizations. Additionally, even if there is a commercially viable market, if the level of third-party reimbursement is below our expectations, our revenue and profitability could be materially and adversely affected.

Third-party payors, such as government programs, including Medicare in the United States, or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved therapies or products. Reimbursement rates and coverage from private health insurance companies vary depending on the company, the insurance plan and other factors. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our therapeutic candidates to each private health insurance company separately, with no assurance that adequate coverage and reimbursement will be obtained.

A current trend in the U.S. healthcare industry as well as in other countries around the world is toward cost containment, including a number of legislative and regulatory changes to the health care system that could impact our ability to sell our approved therapies or products profitably. In particular, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 revised the payment methodology for many products under Medicare in the United States, which has resulted in lower rates of reimbursement. In 2010, the Affordable Care Act was enacted. This expansion in the government's role in the U.S. healthcare industry may further lower rates of reimbursement.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our products, if approved, and accordingly, on our financial operations.

In 2017, the European Union released new regulations to ensure patient safety with the use of pharmaceuticals, medical devices and in-vitro diagnostics that will go into effect over a three-year period from 2020 to 2022. The new regulations replace predecessor directives and emphasize a global convergence of regulations. Marketing authorization timelines will become more protracted and the costs of operating in Europe will increase. A significantly more costly path to regulatory compliance is anticipated. Adjusting to the new Medical Device Regulation may prove to be costly and disruptive to our business.

Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish, which could result in revenue and profitability being lower than anticipated.

There may be significant delays in obtaining coverage and reimbursement for newly approved therapies or products, and coverage may be more limited than the purposes for which the therapy or product is approved by the FDA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a therapy or product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels, if applicable, may also be insufficient to cover our and any partner's costs and may not be made permanent. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved therapies or products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize therapies or products and our overall financial condition.

Furthermore, reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In many countries, therapies or products cannot be commercially launched until reimbursement is approved and the negotiation process in some countries can exceed 12 months. In addition, pricing and reimbursement decisions in certain countries can be affected by decisions taken in other countries, which can lead to mandatory price reductions and/or additional reimbursement restrictions across a number of other countries, which may thereby adversely affect our sales and profitability. In the event that countries impose prices which are not sufficient to allow us to generate a profit, this would adversely affect sales and profitability.

We work with outside scientists and their institutions in developing therapeutic candidates and products. These scientists may have other commitments or conflicts of interest, which could limit our access to their expertise.

We work with scientific advisors and collaborators at academic research institutions in connection with our development programs. These scientific advisors serve as our link to the specific pools of trial participants we are targeting in that these advisors may:

- identify individuals as potential candidates for study;
- obtain their consent to participate in our research;
- perform medical examinations and gather medical histories;
- conduct the initial analysis of suitability of the individuals to participate in our research based on the foregoing; and
- collect data and biological samples from trial participants periodically in accordance with our study protocols.

These scientists and collaborators are not our employees, rather they serve as either independent contractors or the primary investigators under research collaboration agreements that we have with their sponsoring academic or research institution. Such scientists and collaborators may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for another entity arises, we may lose their services. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which would cause competitive harm to our business.

If the market opportunities for our therapeutic candidates or products are smaller than we believe they are, our revenues may be adversely affected, and our business may suffer.

It is very difficult to estimate the future commercial potential of the CardiAMP Cell Therapy System, the CardiALLO Cell Therapy System, Neurokinin-1 Receptor Positive allogeneic therapies and our commercialized products due to factors such as safety and efficacy compared to other available treatments, changing standards of care, third-party payor reimbursement standards, patient and physician preferences, and the availability of competitive alternatives that may emerge. We believe that approximately 70% of the NYHA Class II and Class III ischemic systolic heart failure patients in the United States will be eligible for CardiAMP due to a sufficient CardiAMP potency assay score. However, if considerably less than approximately 70% of NYHA Class II and Class III ischemic heart failure patients are eligible for CardiAMP due to an insufficient CardiAMP potency assay score, it would significantly and negatively impact our business, financial condition and results of operations.

Risks Relating to Government Regulation, Compliance and Litigation

Even if we obtain regulatory approval for a product candidate, including our CardiAMP and CardiALLO Cell Therapy Systems and other therapeutic candidates, these products or therapies, along with our other regulated products, will be subject to ongoing regulatory scrutiny.

Even if we obtain regulatory approval or clearance in a jurisdiction, regulatory authorities may still impose significant restrictions on the indicated uses or marketing of our therapeutic candidates or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, once a product receives regulatory approval or clearance for sale, we are obligated to monitor and report adverse events and any failure of a product to meet the specifications in the applicable regulatory approval or clearance. We must also submit new or supplemental applications and obtain FDA approval or clearance for certain changes to the approved or cleared product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with good manufacturing practices or QSRs and adherence to commitments made in the applicable regulatory approval. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any of our therapeutic candidates, a regulatory agency may impose the following:

- restrictions on the marketing or manufacturing of our products, withdrawal of our products from the market, or voluntary or mandatory product recalls;
- costly regulatory inspections;
- fines, warning letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our collaborators, or suspension or revocation of applicable regulatory approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties by FDA or other regulatory bodies.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our therapeutic candidates and generate revenues.

We may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory agencies.

We have not obtained regulatory approval for either our CardiAMP or CardiALLO Cell Therapy Systems or other therapeutic candidates. We must conduct extensive testing of our therapeutic candidates to demonstrate their safety and efficacy, including human clinical trials and, if applicable, preclinical animal testing, before we can obtain regulatory approval to market and sell them. Conducting such testing is a lengthy, time-consuming, and expensive process and there is a high rate of failure. Our current and completed preclinical and clinical results for our therapeutic candidates are not necessarily predictive of the results of our ongoing or future clinical trials. Promising results in preclinical studies of a therapeutic candidate may not be predictive of similar results in humans during clinical trials, and successful results from early human clinical trials of a therapeutic candidate may not be replicated in later and larger human clinical trials or in clinical trials for different indications. If the results of our ongoing or future clinical trials are negative or inconclusive with respect to the efficacy of our therapeutic candidates or if we or they do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our therapeutic candidates, we may be prevented or delayed in obtaining marketing approval for our therapeutic candidates.

If we fail to obtain and maintain necessary regulatory clearances or approvals for our therapeutic candidates or products, or if clearances or approvals for our therapeutic candidates or products in additional indications are delayed or not issued, our commercial operations would be harmed.

We are required to timely file various reports with the FDA, require that we report to the regulatory authorities if our therapeutic candidates or products may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose sanctions and sales may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

If we initiate a correction or removal to reduce a risk to health posed, we would be required to submit a publicly available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a product recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our therapeutic candidates or products. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of our therapeutic candidates or products to ensure that the claims we make are consistent with our regulatory approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for premarket approval of new products, new intended uses or modifications to existing products;
- withdrawing premarket approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition would be harmed.

Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of our therapeutic candidates or products or limit the scope of any approved indication or market acceptance.

Participants in clinical trials of our investigational cell-based therapies and products may experience adverse reactions or other undesirable side effects. While some of these can be anticipated, others may be unexpected. We cannot predict the frequency, duration, or severity of adverse reactions or undesirable side effects that may occur during clinical investigation. If any of our therapeutic candidates or products, prior to or after any approval for commercial sale, cause adverse events or are associated with other safety risks, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend (e.g., through a clinical hold) or terminate clinical trials;
- regulatory authorities may deny regulatory approval of our therapeutic candidates or products;
- regulatory authorities may restrict the indications or patient populations for which a therapeutic candidate or products is approved;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, and/or impose restrictions on distribution in the form of a Risk Evaluation and Mitigation Strategy, or REMS, in connection with approval, if any;
- regulatory authorities may withdraw their approval, require more onerous labeling statements or impose a more restrictive REMS than any therapeutic candidate or product that is approved;
- we may be required to change the way the therapy or therapeutic candidate or product is administered or conduct additional clinical trials;
- patient recruitment into our clinical trials may suffer;
- we could be required to provide compensation to subjects for their injuries, e.g., if we are sued and found to be liable or if required by the laws of the relevant jurisdiction or by the policies of the clinical site; or
- our reputation may suffer.

There can be no assurance that adverse events associated with our therapeutic candidates or products will not be observed, even where no prior adverse events have occurred. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that our therapeutic candidates or products are unlikely to receive regulatory approval or are unlikely to be successfully commercialized. Regulatory agencies, IRBs or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate a clinical trial for any reason this would have an adverse effect on our business.

Our therapeutic candidates are intended to treat patients who are extremely ill, and patient deaths that occur in our clinical trials could negatively impact our business even if they are not shown to be related to our therapeutic candidates.

Generally, patients remain at high risk following their treatment with our CardiAMP and CardiALLO therapeutic candidates. As a result, it is likely that we will observe severe adverse outcomes during our clinical trials for these therapeutic candidates, including patient death. If a significant number of study subject deaths were to occur, regardless of whether such deaths are attributable to our therapeutic candidates, our ability to obtain regulatory approval for the applicable therapeutic candidate may be adversely impacted and our business could be materially harmed.

If we or our suppliers fail to comply with the FDA's QSRs, our manufacturing operations could be delayed or shut down and product sales could suffer.

Our manufacturing processes and those of our third-party suppliers are required to comply with the FDA's QSRs, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping. We are also subject to similar state requirements and licenses. In addition, we must engage in extensive record keeping and reporting and must make available our manufacturing facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we fail a Quality System inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse Quality System inspection could result in, among other things, a shut-down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays and cause our revenues to decline.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Health Services, or CDHS. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDHS to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. If the FDA or CDHS inspect our facility and discover compliance problems, we may have to shut down our facility and cease manufacturing until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a shutdown or delay at our manufacturing facility, we may be unable to produce our products, which may have an adverse impact on our business.

The requirements to obtain regulatory approval of the FDA and regulators in other jurisdictions can be costly, time-consuming, and unpredictable. If we are unable to obtain timely regulatory approval for our therapeutic candidates, our business may be substantially harmed.

The regulatory approval process is expensive, and the time and resources required to obtain approval from the FDA or other regulatory authorities in other jurisdictions to sell any therapeutic candidate or product is uncertain and approval may take years. Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the discretion of the regulatory authorities. For example, governing legislation, approval policies, regulations, regulatory policies, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a therapeutic candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing or future therapeutic candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval.

Further, regulatory requirements governing cell-based therapy products in particular have changed frequently and may continue to change in the future. For example, in November 2014, Japan's parliament enacted new legislation to promote the safe and accelerated development of treatments using stem cells. The new Pharmaceuticals, Medical Devices and Other Therapeutic Products Act, or PMD Act, establishes a framework for expedited approval in Japan for regenerative medical products. As this is a new regulation, it is not clear yet what impact it will have on the operation of our business. Any regulatory review committees and advisory groups and any contemplated new guidelines may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our therapeutic candidates or products or lead to significant post-approval limitations or restrictions. As we advance our therapeutic candidates or products, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our therapeutic candidates or products. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a therapeutic candidate or product to market could decrease our ability to generate sufficient revenue to maintain our business.

Our therapeutic candidates could fail to receive regulatory approval for many reasons, including the following:

- we may be unable to successfully complete our ongoing and future clinical trials of therapeutic candidates;

- we may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a therapeutic candidate is safe, pure, and potent for any or all of a therapeutic candidate's proposed indications;
- we may be unable to demonstrate that a therapeutic candidate's benefits outweigh the risk associated with the therapeutic candidate;
- the FDA or other regulatory authorities may disagree with the design or implementation of our clinical trials;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or other regulatory authorities for approval;
- the FDA or other regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- a decision by the FDA, other regulatory authorities or us to suspend or terminate a clinical trial at any time;
- the data collected from clinical trials of our therapeutic candidates may be inconclusive or may not be sufficient to obtain regulatory approval in the United States or elsewhere;
- the inability to obtain sufficient quantities of the therapeutic candidates for use in clinical trials;
- our third-party manufacturers of supplies needed for manufacturing therapeutic candidates may fail to satisfy FDA or other regulatory requirements and may not pass inspections that may be required by FDA or other regulatory authorities;
- the failure to comply with applicable regulatory requirements following approval of any of our therapeutic candidates may result in the refusal by the FDA or similar foreign regulatory agency to approve a pending PMA or BLA, or supplement to a PMA or BLA submitted by us for other indications or new therapeutic candidates or products; and
- the approval policies or regulations of the FDA or other regulatory authorities outside of the United States may significantly change in a manner rendering our clinical data insufficient for approval.

We may gain regulatory approval for any of our therapeutic candidates in some but not all of the territories available and any future approvals may be for some but not all of the target indications, limiting their commercial potential. Regulatory requirements and timing of product approvals vary from country to country and some jurisdictions may require additional testing beyond what is required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. In addition, regulatory approval does not specify pricing or reimbursement which may not match our expectations based on the results of our clinical data.

Even if we obtain and maintain approval for our therapeutic candidates or products from the FDA, we may never obtain approval for our therapeutic candidates or products outside of the United States, which would limit our market opportunities and adversely affect our business.

Approval in the United States by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of our therapeutic candidates or products, if approved, outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval.

Even if the FDA grants marketing approval, comparable regulatory authorities of foreign countries must also approve the manufacturing and marketing in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a therapeutic candidate or product must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge, if approved, is also subject to approval. While we may decide to submit a request to the EMA for approval of our therapeutic candidates, including CardiAMP, as Advanced Therapeutic Medicinal Products, or ATMPs, in Europe, obtaining such approval is a lengthy and expensive process and the EMA has its own procedures for approval. Even if a therapeutic candidate or product is approved, the FDA or the EMA, as the case may be, may limit the indications for which it may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of therapeutic candidates or products with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval may be withdrawn. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our therapeutic candidates or products will be harmed and our business will be adversely affected.

We may face competition from biosimilars due to changes in the regulatory environment.

We may face competition for the CardiALLO Cell Therapy System and Neurokinin-1 Receptor Positive therapies from biosimilars due to the changing regulatory environment. In the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or biosimilar to, or "interchangeable" with an FDA-approved innovator (original) biological product. This new pathway could allow competitors to reference data from innovator biological products already approved after 12 years from the time of approval. In Europe, a competitor may reference data from biological products already approved but will not be able to get on the market until 10 years after the time of approval. This 10-year period will be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with CardiALLO or our allogeneic Neurokinin-1 Receptor Positive therapies, if approved. Additionally, the FDA may approve our competitors' products through a PMA pathway, similar to CardiAMP. If competitors are able to obtain marketing approval for biosimilars referencing CardiALLO, if approved, it may become subject to competition from such biosimilars with the attendant competitive pressure and consequences.

We are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse will be applicable to our business. Healthcare fraud and abuse regulations are complex and can be subject to varying interpretations as to whether or not a statute has been violated. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute which prohibits, among other things, the knowing and willful payment of remuneration to induce or reward patient referrals or the generation of business involving any item or service which may be payable by the federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients);
- the federal False Claims Act which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment for government funds (e.g., payment from Medicare or Medicaid) or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim for government funds;
- HIPAA, as amended by HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HIPAA imposes civil and criminal liability for the wrongful access or disclosure of protected health information;
- the federal Physician Payments Sunshine Act, created under Section 6002 of the Patient Protection and Affordable Care Act, as amended, the ACA, requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, those physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members;
- the federal Food, Drug and Cosmetic Act which prohibits, among other things, the adulteration or misbranding of drugs and devices;
- the U.S. Foreign Corrupt Practices Act which prohibits corrupt payments, gifts or transfers of value to non-U.S. officials; and
- non-U.S. and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The federal fraud and abuse laws have been interpreted to apply to arrangements between medical device and pharmaceutical manufacturers and a variety of health care professional. Although the federal Anti-Kickback Statute has several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, all elements of the potentially applicable exemption or safe harbor must be met in order for the arrangement to be protected, and prosecutors have interpreted the federal healthcare fraud statutes to attack a wide range of conduct by medical device and pharmaceutical companies. In addition, most states have statutes or regulations similar to the federal anti-kickback and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Further, the ACA, among other things, amended the intent standard under the Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA makes clear that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the federal False Claims Act. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could harm our ability to operate our business and our results of operations. In addition, the clearance or approval and commercialization of any of our products outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

A failure to adequately protect private health information could result in severe harm to our reputation and subject us to significant liabilities, each of which could have a material adverse effect on our business.

Throughout the clinical trial process, we may obtain the private health information of our trial subjects. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. As part of the American Recovery and Reinvestment Act of 2009, or ARRA, Congress amended the privacy and security provisions of HIPAA. HIPAA imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers conducting certain electronic transactions, healthcare clearinghouses, and health insurance plans, collectively referred to as covered entities. The HIPAA amendments also impose compliance obligations and corresponding penalties for non-compliance on certain individuals and entities that provide services to or perform certain functions on behalf of healthcare providers and other covered entities involving the use or disclosure of individually identifiable health information, collectively referred to as business associates. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. The amendments also create notification requirements to federal regulators, and in some cases local and national media, for individuals whose health information has been inappropriately accessed or disclosed. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with certain encryption or other standards developed by the U.S. Department of Health and Human Services, or HHS. Most states have laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the United States implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for noncompliance. The European Union's Data Protection Directive, Canada's Personal Information Protection and Electronic Documents Act and other data protection, privacy and similar national, state/provincial and local laws may also restrict the access, use and disclosure of patient health information abroad. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

A recall of any of our commercialized products, or the discovery of serious safety issues, could have a significant negative impact on us.

The FDA and other relevant regulatory agencies have the authority to require or request the recall in the event of material deficiencies or defects in design or manufacture or in the event an unacceptable risk to health. Manufacturers may, under their own initiative, also initiate a recall. A government-mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls would divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results.

Further, under the FDA's reporting regulations, we are required to report to the FDA any event that reasonably suggests that our products may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction of the same or similar product marketed by us were to recur, would likely cause or contribute to death or serious injury. The FDA also requires reporting of serious, life-threatening, unexpected and other adverse experiences and the submission of periodic safety reports and other information. Malfunctions or other adverse event reports may result in a voluntary or involuntary recall and other adverse actions, which could divert managerial and financial resources, impair our ability to manufacture in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results. Similar reporting requirements exist in Europe and other jurisdictions.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. For example, in 2014 we notified the FDA that we were going to initiate a voluntary recall of our Morph AccessPro product based on a manufacturing observation, which was completed to the FDA's satisfaction in the same year, and in 2017 we updated our instructions for use for the Helix™ and Morph catheter products to provide guidance on known potential risks. There can be no guarantee that we will not experience similar product recalls or changes in the future with these products or our other products or therapeutic candidates, if approved.

Modifications to our products may require reclassifications, new regulatory approvals or clearances, or may require us to cease marketing or recall the modified products until new CE marking is obtained.

Currently there are eight Morph product family model numbers that have been approved for commercial use in the United States via a 510(k) clearance. A modification to these products could lead to a reclassification and could result in further requirements (including additional clinical trials) to maintain each respective clearance or approval. If we fail to comply with such further requirements, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

The use, misuse or off-label use of our products or therapies, if approved, may result in injuries that lead to product liability suits, which could be costly to our business.

We are not permitted to make claims about the use of our marketed products and will not be permitted to make claims about the use of our therapeutic candidates, if approved, outside of their approved indications. Further, we are not and will not be able to proactively discuss or provide information on off-label uses of such products, with very specific and limited exceptions. However, we cannot prevent a physician from using our products or therapeutic candidates, if approved, for off-label applications. Off-label use of our products or therapies, if approved, is more likely to result in complications that have serious consequences. Product liability claims are especially prevalent in our industry and could harm our reputation, divert management's attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, the amount or breadth of our coverage may not be adequate for the claims that may be made against us. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in, among other things, the FDA's refusal to approve a product or therapeutic candidate, the suspension or withdrawal of an approved product or therapy from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecutions.

Our employees, principal investigators, consultants and collaboration partners may engage in misconduct or other improper activities, including noncompliance with laws and regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of activity relating to pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation, or a breach of insider trading laws. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, particularly European Union member states, Japan, Australia and Canada, the pricing of therapies and products is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a therapy or product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our partners may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our therapeutic candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our therapies or products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, revenues or profitability could be adversely affected.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our therapeutic candidates or products.

We face an inherent risk of product liability as a result of the human clinical use of our therapeutic candidates and products and will face an even greater risk if we continue to commercialize our therapeutic candidates and products. For example, we may be sued if any therapy or product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of inherent dangers, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand, even if such products or therapies are approved;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigations;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- recalls, withdrawals, or labeling, marketing or promotional restrictions;
- increased cost of liability insurance;
- loss of revenue;
- the inability to receive regulatory approvals or commercialize our approved products or therapies; and
- a decline in our share price.

Although we maintain product liability insurance with coverage that we believe is consistent with industry norms for companies at our stage of development, the amount or breadth of our coverage may not be adequate for the claims that may be made against us. Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products or therapies we develop. Additionally, our insurance policies have various exclusions, and we may be subject to a product liability claim for which we have no coverage or reduced coverage. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Risks Related to the Operation of Our Business

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our therapeutic candidates, conduct our clinical trials and commercialize our therapeutic candidates.

We are highly dependent on the members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As we mature and expand our research and development and other pre-commercialization activities, we expect to expand our existing full-time employee base and to hire more consultants and contractors. In addition, we currently plan to commercialize the CardiAMP Cell Therapy System, if approved, using an internal sales force to selected cardiologists, interventional cardiologists and third-party payors in the United States. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants and potential collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. For example, our systems have been impacted by computer viruses in the past, and while we have not experienced any material system failure, accident or security breach that has resulted in lasting impacts to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for manufacturing our therapeutic candidates and conducting clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our therapeutic candidates could be delayed.

Any cybersecurity breaches or our actual or perceived failure to comply with such legal obligations by us, or by our third-party service providers or partners, could harm our business.

We collect, store, process and use our customers' personally identifiable information and other data, and we rely on third parties that are not directly under our control to do so as well. While we take measures intended to protect the security, integrity and confidentiality of the personal information and other sensitive information we collect, store or transmit, we cannot guarantee that inadvertent or unauthorized use or disclosure will not occur, or that third parties will not, gain unauthorized access to this information. There have been a number of recent reported incidents where third parties have used software to access the personal data of their partners' customers for marketing and other purposes.

If we or our third-party service providers were to experience a breach, disruption or failure of systems compromising our customers' data, or if one of our third-party service providers or partners were to access our customers' personal data without our authorization, our brand and reputation could be adversely affected, use of our products could decrease and we could be exposed to a risk of loss, litigation and regulatory proceedings. In addition, a breach could require expending significant additional resources related to the security of information systems and disrupt our operations.

The use of data by our business and our business associates is highly regulated in all our operating countries. Privacy and information-security laws and regulations change, and compliance with them may result in cost increases due to, among other things, systems changes and the development of new processes. If we or those with whom we share information fail to comply with laws and regulations, such as the General Data Protection Regulation (GDPR) and California Consumer Privacy Act (CCPA), our reputation could be damaged, possibly resulting in lost business, and we could be subjected to additional legal risk or financial losses as a result of non-compliance. Complying with such laws may also require us to modify our data processing practices and policies and incur substantial expenditures.

Interruptions in supply or inventory loss may adversely affect our operating results and financial condition.

Our therapeutic candidates and products are manufactured and distributed using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for manufacture and storage, subjects us to production risks. While batches released for use in clinical trials or for commercialization undergo sample testing, some defects may only be identified following release. In addition, process deviations or unanticipated effects of approved process changes may result in these intermediate products not complying with stability requirements or specifications. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product or therapy launches. Any supply interruption or the loss thereof could hinder our ability to timely distribute our approved products and satisfy demand. Any unforeseen storage failure or loss in supply could delay our clinical trials and, if our therapeutic candidates are approved, result in a loss of our market share and negatively affect our revenues and operations.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. A majority of our management operates in our principal executive offices located in San Carlos, California and we currently manufacture our Helix™ and Morph products at this facility and use it for storage of our clinical trial materials and biobanking. If our San Carlos offices were affected by a natural or man-made disaster, particularly those that are characteristic of the region, such as wildfires and earthquakes, or other business interruption, our ability to manage our domestic and foreign operations could be impaired, which could materially and adversely affect our results of operations and financial condition. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. The ultimate impact of any such events on us, our significant suppliers and our general infrastructure is unknown.

The outbreak of the novel strain of coronavirus, SARS-CoV-2, and its variants, which causes COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 (COVID-19), surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States. In response to the spread of COVID-19, we have taken steps to comply with government guidelines to protect workers, resulting in many employees continuing their work outside of our offices.

As a result of the COVID-19 outbreak, or similar pandemics, we have and may in the future experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or disruptions in non-clinical experiments due to unforeseen circumstances at contract research organizations and vendors along their supply chain;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine, or not accepting home health visits;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;

- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;

- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact approval timelines;

- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; and

- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 epidemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We previously identified a material weakness in our internal control over financial reporting at December 31, 2019 and we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control in the future. If we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We previously identified a material weakness in internal control over financial reporting as of September 30, 2019. The material weakness resulted from a lack of sufficient technical resources to appropriately perform effective and timely review of the accounting for and disclosure of complex non-routine transactions, including the adoption of new accounting standards. This material weakness was remediated as of December 31, 2020.

We have implemented measures designed to improve our internal control over financial reporting and remediate the material weakness, including the following:

- we enhanced our control processes for identifying and reviewing non-routine transactions, including formalized reviews of these transactions by senior accounting management and more robust documentation of the related conclusions and required accounting; and

- we have engaged external consultants to provide expertise and assistance sufficient to evaluate, resolve and document the accounting for complex non-routine transactions.

We cannot provide assurance that the measures we have taken to date, and are continuing to implement, will be sufficient to prevent future material weakness from occurring. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting.

If we identify other material weaknesses in our internal control over financial reporting in the future, if we are unable to comply with the requirements of Section 404 in a timely manner, or if we are unable to assert that our internal control over financial reporting is effective, we may be unable to report our financial results accurately on a timely basis, 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, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

Risks Relating to Our Intellectual Property

We may not be able to protect our proprietary technology in the marketplace.

Our success will depend, in part, on our ability to obtain patents, protect our trade secrets and operate without infringing on the proprietary rights of others. We rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property of our therapeutic candidates and products. Patents might not be issued or granted with respect to our patent applications that are currently pending, and issued or granted patents might later be found to be invalid or unenforceable, be interpreted in a manner that does not adequately protect our current therapeutic candidates or products or any future therapeutic candidates or products, or fail to otherwise provide us with any competitive advantage. As such, we do not know the degree of future protection that we will have on our therapeutic candidates or products and technology, if any, and a failure to obtain adequate intellectual property protection with respect to our therapeutic candidates or products could have a material adverse impact on our business.

Filing, prosecuting and defending patents throughout the world would be prohibitively expensive, so our policy is to patent technology in jurisdictions with significant or otherwise relevant commercial opportunities or activities. However, patent protection may not be available for some of the therapeutic candidates or products we are developing. If we must spend significant time and money protecting or enforcing our patents, designing around patents held by others or licensing, potentially for large fees, patents or other proprietary rights held by others, our business, results of operations and financial condition may be harmed.

The patent protection of biotherapeutics is complex and uncertain.

The scope and extent of patent protection for our therapeutic candidates and products are particularly uncertain. To date, our principal therapeutic candidates have been based on specific subpopulations of known and naturally occurring adult stem cells. We anticipate that the therapeutic candidates or products we develop in the future will continue to include or be based on the same or other naturally occurring stem cells or derivatives or products thereof. Although we have sought and expect to continue to seek patent protection for our therapeutic candidates and products, their methods of use, methods of manufacture, and methods of delivery, any or all of them may not be subject to effective patent protection. Publication of information related to our therapeutic candidates and products by us or others may prevent us from obtaining or enforcing patents relating to these products and therapeutic candidates. Furthermore, others may independently develop similar therapeutic candidates or products, may duplicate our therapeutic candidates or products, or may design around our patent rights. In addition, any of our issued patents may be declared invalid. If we fail to adequately protect our intellectual property, we may face competition from companies who attempt to create a generic therapeutic candidate or product to compete with our therapeutic candidates or products.

Filing, prosecuting and defending patents on therapeutic candidates or products in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own therapeutic candidates or products and further, may export otherwise infringing therapeutic candidates or products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These therapeutic candidates or products may compete with our current or future therapeutic candidates or products, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing therapeutic candidates or products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions 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 and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We maintain certain of our proprietary know-how and technological advances as trade secrets, especially where we do not believe patent protection is appropriate or obtainable, including, but not exclusively, with respect to certain aspects of the manufacturing of our therapeutic candidates or products. However, trade secrets are difficult to protect. We take a number of measures to protect our trade secrets including, limiting disclosure, physical security and confidentiality and non-disclosure agreements. We enter into confidentiality agreements with our employees, consultants, outside scientific collaborators, contract manufacturing partners, sponsored researchers and other advisors and third parties to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection, or failure to adequately protect our intellectual property could enable competitors to develop generic products or use our proprietary information to develop other therapeutic candidates or products that compete with our therapeutic candidates or products or cause additional, material adverse effects upon our business, results of operations and financial condition.

We may be forced to litigate to enforce or defend our intellectual property rights, and/or the intellectual property rights of our licensors.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement by competitors, and to protect our trade secrets against unauthorized use. In so doing, we may place our intellectual property at risk of being invalidated, unenforceable, or limited or narrowed in scope and may no longer be used to prevent the manufacture and sale of competitive product. Further, an adverse result in any litigation or other proceedings before government agencies such as the United States Patent and Trademark Office, or the USPTO, may place pending applications at risk of non-issuance. Further, interference proceedings, derivation proceedings, entitlement proceedings, ex parte reexamination, inter partes reexamination, inter partes review, post-grant review, and opposition proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be used to challenge inventorship, ownership, claim scope, or validity of our patent applications. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation.

Intellectual property disputes could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

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/or 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 substantial adverse effect on the market price of our shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of litigation proceedings more effectively than we can because of their greater financial resources and personnel. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research programs, in-license needed technology or enter into strategic collaborations that would help us bring our therapeutic candidates to market. As a result, uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Patent reform legislation and recent court decisions 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, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has and continues to develop and implement 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. The full effect of these changes is currently unclear as the USPTO has not yet adopted all pertinent final rules and regulations, the courts have yet to address these provisions and the applicability of the Leahy-Smith Act and new regulations on specific patents, including our patents discussed herein, have not been determined and would need to be reviewed.

Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. As a result, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, all of which could have a material adverse effect on our business and financial condition.

On June 13, 2013, the U.S. Supreme Court decision in Association for Molecular Pathology v. Myriad Genetics, Inc., held that isolated DNA sequences are not patentable because they constitute a product of nature. The Supreme Court did not address stem cells in particular, and as a result, it is not yet clear what, if any, impact this Supreme Court decision or future decisions will have on the operation of our business.

If third parties claim that our therapeutic candidates or other products infringe upon their intellectual property, commercialization of our therapeutic candidates or products and our operating profits could be adversely affected.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry. We may, from time to time, be notified of claims that we are infringing upon patents, trademarks, copyrights, or other intellectual property rights owned by third parties, and we cannot provide assurances that other companies will not, in the future, pursue such infringement claims against us or any third-party proprietary technologies we have licensed. Any such claims could also be expensive and time consuming to defend and divert management's attention and resources and could delay or prevent us from commercializing our therapeutic candidates or products. Our competitive position could suffer as a result. Although we have reviewed certain third-party patents and patent filings that we believe may be relevant to our therapeutic candidates or products, we have not conducted a freedom-to-operate search or analysis for our therapeutic candidates or products, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our therapeutic candidates or products. Thus, we cannot guarantee that our therapeutic candidates or products, or our commercialization thereof, do not and will not infringe any third-party's intellectual property.

From time to time, we have reviewed the claims of specific patents owned by third parties. While we have concluded that no claims of any of these patents would be infringed by our products, that all relevant claims would expire before our products would be commercialized, or both, we cannot guarantee that the patent owners would not disagree and conclude that our products would infringe these claims.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity of our therapeutic candidates or products, our business may be materially harmed.

Depending on the timing, duration and specifics of FDA marketing approval of our therapeutic candidates or products, if any, one of the U.S. patents covering each of such approved therapeutic candidate or product or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our therapeutic candidates, including by the EMA in the European Union or the Pharmaceutical and Medical Devices Agency in Japan. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. In addition, if a patent we wish to extend is owned by another party and licensed to us, we may need to obtain approval and cooperation from our licensor to request the extension.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our therapeutic candidates or products will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties for manufacturing, and because we collaborate with various organizations and academic institutions on the advancement of our clinical trials, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future will usually expect to be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. In the future we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks Related to Our Securities

An active trading market may not develop for our securities or what the market price of our securities will be and as a result it may be difficult for you to sell your shares of our securities.

Although our common stock and warrants to purchase common stock are listed on the Nasdaq Capital Market under the symbols "BCDA" and "BCDAW," respectively, an active trading market for our common stock or warrants may never develop or be sustained. You may not be able to sell your shares quickly or at the market price if trading in shares of our securities is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our securities and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our securities as consideration, which could have a material adverse effect on our business, financial condition, and results of operations.

The market price and trading volume of our securities may be volatile and may be affected by economic conditions beyond our control.

The market price of our securities is likely to be volatile. Some specific factors that could negatively affect the price of our securities or result in fluctuations in its price and trading volume include:

- results of clinical trials of our therapeutic candidates;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our therapeutic candidates or products or our competitors' products;
- actual or anticipated fluctuations in our quarterly operating results or those of our competitors;
- publication of research reports by securities analysts about us or our competitors in the industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- issuances by us of debt or equity securities;
- litigation involving our company, including stockholder litigation, investigations or audits by regulators into the operations of our company, or proceedings initiated by our competitors or clients;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry, fluctuations in the valuation of companies perceived by investors to be comparable to us;
- trading volume of our common stock and warrants;

- sales or perceived potential sales of our common stock and/or warrants by us, our directors, senior management or our stockholders in the future;
- short selling or other market manipulation activities;
- announcement or expectation of additional financing efforts;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biopharmaceutical stocks; and
- conditions in the U.S. financial markets or changes in general economic conditions.

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, the price and trading volume of our securities could decline.

The trading market for our securities 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 securities would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue 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, the price of our securities 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 the price or trading volume of our securities to decline.

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 December 31, 2020, our executive officers, directors, 5% stockholders and their affiliates beneficially owned approximately 34.9% of our voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, 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. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

As a smaller reporting company, we are subject to scaled disclosure requirements that may make it more challenging for investors to analyze our results of operations and financial prospects.

Currently, we are a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act. As a "smaller reporting company," we are able to provide simplified executive compensation disclosures in our filings and have certain other decreased disclosure obligations in our filings with the SEC, including being required to provide only two years of audited financial statements in annual reports. Consequently, it may be more challenging for investors to analyze our results of operations and financial prospects.

Furthermore, we are a non-accelerated filer as defined by Rule 12b-2 of the Exchange Act, and, as such, are not required to provide an auditor attestation of management's assessment of internal control over financial reporting, which is generally required for SEC reporting companies under Section 404(b) of the Sarbanes-Oxley Act. Because we are not required to, and have not, had our auditors provide an attestation of our management's assessment of internal control over financial reporting, a material weakness in internal controls may remain undetected for a longer period.

We may be exposed to additional risks as a result of our reverse merger transaction.

We may be exposed to additional risks as a result of our "reverse merger" transaction and rules and regulations relating to shell companies or former shell companies. There has been increased focus in recent years by government agencies on transactions such as the reverse merger transaction, and we may be subject to increased scrutiny and/or restrictions by the SEC and other government agencies and holders of our securities as a result of the completion of that transaction. This may make it more difficult for us to obtain coverage from securities analysts of major brokerage firms. The occurrence of any such event could cause our business or stock price to suffer.

Our annual and quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to annual and quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our therapeutic candidates, products or future development programs;
- if any of our therapeutic candidates receives regulatory approval, the level of underlying demand for these therapeutic candidates and wholesalers' buying patterns;
- addition or termination of clinical trials or funding support;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our therapeutic candidates or products or those of our competitors;
- the timing and cost of, and level of investment in, research and development activities relating to our therapeutic candidates, which may change from time to time;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to acquire or develop additional therapeutic candidates and technologies;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of clinical studies for our therapeutic candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the risk/benefit profile, cost and reimbursement policies with respect to our therapeutic candidates, if approved, and existing and potential future therapies or biologics that compete with our products or therapeutic candidates; and
- the changing and volatile U.S., European and global economic environments.

If our annual or quarterly operating results fall below the expectations of investors or securities analysts, the price of our securities could decline substantially. Furthermore, any annual or quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that annual and quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Raising additional funds through debt or equity financing could be dilutive and may cause the market price of our common stock to decline.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, including through the LPC Purchase Agreement with Lincoln Park, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic collaborations or partnerships, or marketing, distribution or licensing arrangements with third parties, we may be required to limit valuable rights to our intellectual property, technologies, therapeutic candidates or future revenue streams, or grant licenses or other rights on terms that are not favorable to us. Furthermore, any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our therapeutic candidates.

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 or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On March 29, 2021, we entered into the LPC Purchase Agreement, pursuant to which Lincoln Park committed to purchase up to $20 million of shares our common stock (the Purchase Shares). Shares of our common stock may be sold pursuant to the LPC Purchase Agreement by us to Lincoln Park at our discretion from time to time over a 36-month period, subject to certain limitations and conditions. The purchase price for shares that we may sell to Lincoln Park under the LPC Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

In consideration for entering into the LPC Purchase Agreement, we agreed to issue 75,000 shares of our common stock (the Initial Commitment Shares) to Lincoln Park as an initial commitment fee. In addition, we agreed to issue to Lincoln Park up to an additional 50,000 shares of our common stock (the "Additional Commitment Shares" and together with the Initial Commitment Shares, the "Commitment Shares") as an additional commitment fee based on a pro-rata percentage of the Purchase Shares issued to Lincoln Park under the Purchase Agreement. The Company will not receive any cash proceeds from the issuance of the Commitment Shares.

In connection with entering into the LPC Purchase Agreement, on March 29, 2021, we sold to Lincoln Park, as an initial purchase under the LPC Purchase Agreement, 373,832 shares of common stock, at a per share price of $5.35 per share, for aggregate consideration of $2,000,000, and issued to Lincoln Park an aggregate of 80,000 Commitment Shares (which includes 5,000 Commitment Shares issued on a pro rata basis in respect of the initial purchase of $2,000,000 of Purchase Shares by Lincoln Park).

We have the right to control the timing and amount of any sales of additional shares to Lincoln Park in our sole discretion, subject to certain limits on the amount of shares that can be sold on a given date and other conditions and limitations set forth in the LPC Purchase Agreement. Additional sales of shares of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. Therefore, Lincoln Park may ultimately purchase all, some or none of the additional shares of our common stock that may be sold pursuant to the LPC Purchase Agreement and Lincoln Park may resell all, some or none of the shares is has or may purchase from us. Additional sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales, which could have a materially adverse effect on our business and operations.

Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell our common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell our common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

General Risks

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations may also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. We do not currently carry biological or hazardous waste insurance coverage.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal executive office is located at 125 Shoreway Road, Suite B, San Carlos, CA 94070 in a facility we lease encompassing 13,718 square feet of office, lab, and manufacturing space. The lease for this facility expires in December 2021. We believe that our existing facilities are adequate for our current needs. If we determine that additional or new facilities are needed in the future, we believe that sufficient options would be available to us on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

We have three legal proceedings (the (Litigation) currently pending in Federal Court in San Francisco. All three proceedings relate to matters we raised in a letter to Ms. Surbhi Sarna, nVision Medical Corporation (nVision), a company Ms. Sarna founded, and Boston Scientific Corporation (Boston Scientific), which acquired nVision, based on BioCardia's discovery in January 2019 that Ms. Sarna had assigned to nVision a patent and patent applications she had filed while a BioCardia employee. BioCardia made various claims, including that the patent and patent application rightfully belonged to BioCardia pursuant to Ms. Sarna's invention assignment agreement, and that the proceeds from the sale of nVision to Boston Scientific rightfully belonged to BioCardia because they were the direct result of Ms. Sarna's breach of her obligation to assign to BioCardia the patent and patent applications and the use of misappropriated BioCardia trade secrets.

On September 6, 2019, Boston Scientific, Boston Scientific Scimed Inc, (Boston Scimed) and Fortis Advisors LLC (Fortis Advisors, and together with Boston Scientific and Boston Scimed) (Boston Scientific Parties) filed the first legal proceeding, a complaint captioned Boston Scientific Corporation, et al. v. BioCardia, Inc., Case no. 3:19-05645-VC (the "BSC Action"), seeking declarations that the claims made in BioCardia's correspondence were without basis. On October 31, 2019, BioCardia filed a counterclaim against the Boston Scientific Parties and Ms. Sarna for breach of contract, misappropriation of trade secrets and correction of inventorship on the patent assigned to nVision by Ms. Sarna. BioCardia sought imposition of constructive trusts both on the patent naming Ms. Sarna as an inventor and the proceeds received from the sale of nVision to Boston Scientific, as well as damages, including unjust enrichment damages measured by the proceeds received from the sale of nVision to Boston Scientific.

On April 9, 2020, we entered into a Litigation Funding Agreement with BSLF, L.L.C., an entity owned and controlled by Andrew Blank, a member of our board of directors, to fund the Litigation.

On April 23, 2020, BioCardia filed a complaint (the second proceeding) captioned BioCardia, Inc. v. nVision Medical Corporation, Case no. 3:20-02829-VC (the "nVision Action") arising out of the same transaction as BioCardia's counterclaims in the BSC Action. On April 29, 2020 Judge Vincent Chhabria, the Judge who is presiding over the BSC Action, determined at BioCardia's request that the nVision Action is "related to" the BSC Action and accordingly reassigned the nVision Action to himself. On May 22, 2020, BioCardia filed an amended complaint in the nVision Action in which it added as defendants the institutional investors who funded nVision.

On July 16, 2020 and again on July 23, 2020, combined hearings were held on various motions to dismiss filed by the counter defendants in the BSC Action and the defendants in the nVision Action. As a result of those hearings, BioCardia was given leave to file Second Amended Counterclaims in the BSC Action and a Second Amended Complaint in the nVision Action. BioCardia did so on August 20, 2020.

The counter defendants in the BSC Action and the defendants in the nVision Action filed a total of eight motions on September 24, 2020 against BioCardia seeking dismissal of both Actions. BioCardia filed oppositions on October 26, 2020. One of the motions to dismiss raised the possibility that BioCardia's wholly owned subsidiary, BioCardia Lifesciences, Inc. (itself formerly named BioCardia, Inc.), actually owns the counterclaims asserted in the BSC Action and the claims asserted in the nVision Action. As a result, on October 23, 2020, BioCardia moved that BioCardia Lifesciences, Inc. be added as an additional counterclaimant in the BSC Action and as an additional plaintiff in the nVision Action. Although BioCardia believed both motions should have been granted, in case they were denied, BioCardia filed a third proceeding captioned BioCardia Lifesciences, Inc. v. Surbhi Sarna, et al., No. 4:20-cv-07510-KAW (BioCardia Lifesciences Action) asserting the same claims against the same parties who are adverse to BioCardia in the BSC Action and the nVision Action.

On December 17, 2020, a hearing was held on the various motions. During that hearing BioCardia dismissed the BSC Action and the nVision Action without prejudice in favor of proceeding with the BioCardia Lifesciences Action when it appeared that the Court was not likely to grant BioCardia's motion to add BioCardia Lifesciences as an additional counterclaimant in the Boston Scientific Action and as an additional plaintiff in the nVision Action. The Court subsequently determined that the dismissals without prejudice were not effective against those parties who had answered superseded versions of BioCardia's counterclaims and complaint, namely Boston Scientific, Boston Scimed, nVision and Fortis Advisors. The Court determined the dismissal was effective as to the other adverse parties. The Court has pending motions on what basis to dismiss Boston Scientific, Boston Scimed, nVision and Fortis Advisors, and whether such dismissal should be with or without prejudice. The Court indicated that if it decided to dismiss with prejudice, the effect of that dismissal on the claims asserted in the BioCardia Lifesciences Action would be decided by motion practice in that case.

Ms. Sarna and EXXclaim, one of the institutional shareholders of nVision and a defendant named in the nVision Action, moved for sanctions against both BioCardia and its lawyers principally on the ground that the counterclaims in the Boston Scientific Action and the claims in the nVision Action had been pursued by the wrong entity: BioCardia, Inc. rather than BioCardia Lifesciences, Inc.

On March 12, 2021, the Company agreed to settle the Litigation, which is pending final documentation and dismissal. The Company expects the settlement will not result in any material benefit or liability to the Company.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market for our Common Stock

Our common stock trades on the Nasdaq Capital Market under the symbol "BCDA."

Holders

As of December 31, 2020, there were 199 holders of record of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of our common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies.

Dividend Policy

We have never declared or paid any cash dividend on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Any determination to declare or pay dividends in the future will be at the discretion of our board of directors and will depend on a number of factors, including our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Sales of Unregistered Securities

Except as previously reported by the Company on its current reports on Form 8-K, we did not sell any securities during the period covered by this Annual Report that were not registered under the Securities Act.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this item is incorporated by reference to Item 12, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" of Part III of this Annual Report on Form 10-K.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains certain forward-looking statements that involve risk and uncertainties. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the Section entitled "Risk Factors" in Item 1A, and other documents we file with the Securities and Exchange Commission. Historical results are not necessarily indicative of future results.

Special Note Regarding Smaller Reporting Company Status

As a result of having been a "smaller reporting company" (as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended), we are allowed and have elected to omit certain information, including three years of year-to-year comparisons and tabular disclosure of contractual obligations, from this Management's Discussion and Analysis of Financial Condition and Results of Operations; however, we have provided all information for the periods presented that we believe to be appropriate and necessary.

Overview

We are a clinical-stage regenerative medicine company developing novel therapeutics for cardiovascular and pulmonary diseases with large unmet medical needs. We are committed to applying our expertise in the fields of autologous and allogeneic cell-based therapies to improve the lives of patients with cardiovascular and pulmonary conditions.

Our CardiAMP cell therapy platform provides an autologous bone marrow derived cell therapy (using a patient's own cells) for the treatment of two clinical indications: heart failure that develops after a heart attack (BCDA-01) and chronic myocardial ischemia (BCDA-02). Our allogeneic mesenchymal stem cell therapy platform, derived from donor cells and intended to be provided "off the shelf," is also being advanced for two indications, heart failure (BCDA-03) and for the pulmonary indication of acute respiratory distress that has developed from COVID-19 (BCDA-04).

Our Helix™ Biotherapeutic Delivery System platform or "Helix" delivers therapeutics into the heart muscle with a helical needle from within the heart. It enables local delivery of cell and gene-based therapies, including our own cell therapies to treat cardiac indications. The Helix system is CE marked in Europe and under investigational use in the United States. We selectively partner with firms developing other cell, gene and protein therapies utilizing the Helix and other biotherapeutic delivery systems that we have developed.

Our AVANCE™ product offering for transseptal cardiac procedures has begun early commercialization activities in the United States through commission-only 1099 sales representatives.

To date, we have devoted substantially all of our resources to research and development efforts relating to our therapeutic candidates and biotherapeutic delivery systems, including conducting clinical trials, developing manufacturing and sales capabilities, in-licensing related intellectual property, providing general and administrative support for these operations and protecting our intellectual property. We have also generated modest revenues from sales of our approved products. We have funded our operations primarily through the sales of equity and convertible debt securities, and certain government and private grants.

CardiAMP Cell Therapy System for Heart Failure and Chronic Myocardial Ischemia

The Company's lead platform, CardiAMP cell therapy, is an autologous cell therapy being advanced for two indications in pivotal clinical trials: heart failure and chronic myocardial ischemia.

The CardiAMP Heart Failure Trial is a Phase III, multi-center, randomized, double-blinded, sham-controlled study of up to 260 patients at 40 centers nationwide, which includes a 10-patient roll-in cohort. The Phase III pivotal trial is designed to provide the primary support for the safety and efficacy of the CardiAMP Cell Therapy System for heart failure which develops after a patient has a heart attack (BCDA-01). The trial is active at 24 clinical sites and 91 patients have been enrolled to date. The independent DSMB completed a prespecified data review on December 17, 2020, including all data for the 86 patients enrolled and 60 randomized patients that had reached their one-year follow-up at that date. The DSMB performed a risk-benefit review, indicated no safety concerns, and recommended in writing that the study continue as planned.

Enrollment remains our primary focus and challenge. To complete the heart failure trial enrollment requires our active centers to randomize an additional seven patients each on average. Our clinical centers appear to be coming out of COVID-19 with renewed energy and interest in the trial. Enrollment is expected to be enhanced in the months ahead by reductions in COVID-19 cases over time, the recent successful CardiAMP Heart Failure DSMB review, the recent CardiAMP Heart Failure positive results published in the peer reviewed International Journal of Cardiology, the addition of new high-enrolling clinical sites to the trial, obtaining FDA authorization to subsequently provide therapy for patients in the control arm of the trial that otherwise would not receive it, enhanced outreach to sites and increased clinical marketing activities. Starting the parallel CardiAMP Chronic Myocardial Ischemia trial is also anticipated to enhance enrollment in the CardiAMP Heart Failure trail.

The CardiAMP Chronic Myocardial Ischemia Trial is a Phase III, multi-center, randomized, double-blinded, controlled study of up to 343 patients at up to 40 clinical sites. The Phase III pivotal trial is designed to provide the primary support for the safety and efficacy of the CardiAMP Cell Therapy System for the indication of chronic myocardial ischemia (BCDA-02). This therapeutic approach uses many of the same novel aspects as the CardiAMP Heart Failure Trial and is expected to leverage our experience and investment in the heart failure trial. The trial has been activated and we are working towards initial patient enrollment in the first quarter of 2021.

We are continuing to assess the evolving impact of COVID-19 on the CardiAMP trials, including recent spikes and new emerging variants. Some of our clinical centers stopped performing elective procedures during the initial outbreak and advised that they would not be performing elective procedures until restrictions on elective procedures were lifted. Many centers also delayed patient follow-up visits out of concern for patient exposure to COVID-19. In alignment with recent FDA guidance on clinical trials, "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic Guidance for Industry, Investigators, and Institutional Review Boards," the Company has taken steps to address unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures.

The Department of Health & Human Services Centers for Medicare & Medicaid Services, or CMS, has designated that both CardiAMP pivotal trials qualify for Medicare national coverage. Covered costs include patient screening, the CardiAMP Cell Therapy System and procedure, and clinical follow-up at one and two years after the procedure. Private insurance plans covering 50 million insured Americans follow this CMS reimbursement policy and are similarly anticipated to cover these costs. This coverage significantly reduces our cost of conducting these pivotal trials.

Allogeneic Cell Therapy for Cardiac and Pulmonary Disease

Our second therapeutic platform is our investigational culture expanded bone marrow derived allogeneic, Neurokinin-1 Receptor Positive mesenchymal stem cells (NK1R+ MSC). This "off the shelf" mesenchymal cell therapy is being advanced for cardiac and pulmonary disease.

We are actively working to secure FDA acceptance of an Investigational New Drug (IND) application for a Phase I/II trial using the CardiALLO Cell Therapy System to deliver these allogeneic cells for the treatment of ischemic systolic heart failure (BCDA-03). We are working to receive FDA acceptance of the IND in 2021.

The Company also intends to submit an IND for the use of its allogeneic cell therapy for Acute Respiratory Distress Syndrome (ARDS) caused by COVID-19 (BCDA-04). Based on clinical reports on COVID-19, respiratory failure complicated by ARDS is a leading cause of death for COVID-19 patients. ARDS is a type of respiratory failure characterized by rapid onset of widespread inflammation in the lungs. BCDA-04 is on a similar timeline with BCDA-03 and we are working towards FDA acceptance of the IND in 2021.

Recent Developments

Partner Agreement for Catheter Biotherapeutic Delivery Product Candidates

On February 17, 2021, the Company entered into an agreement with a leading international pharmaceutical company to assess the Helix™ Biotherapeutic Delivery System in preclinical testing. Under the terms of the agreement, the Company received a $500,000 up-front payment, a portion of which is creditable for BioCardia biotherapeutic delivery systems, support and training. The agreement includes a one-year option to negotiate a non-exclusive worldwide license for therapeutic delivery of certain cell types for cardiac indications.

Purchase Agreement with Lincoln Park

On March 29, 2021, we and Lincoln Park Capital Fund, LLC, (Lincoln Park) entered into a purchase agreement (the LPC Purchase Agreement) pursuant to which Lincoln Park purchased $2 million of shares of our common stock (373,832 shares) at a purchase price of $5.35 per share. Under the LPC Purchase Agreement, we have the right to sell to Lincoln Park shares of common stock having an aggregate value of up to $20 million, including the initial $2 million purchase, subject to certain significant limitations of the amount and timing of any such sales due to the terms and conditions set forth in the LPC Purchase Agreement.

In consideration for entering into the LPC Purchase Agreement, we agreed to issue an aggregate of 75,000 shares of common stock as a commitment fee. We also agreed to issue to Lincoln Park up to an aggregate of 50,000 additional shares of common stock as a further commitment fee based on a pro-rata percentage of the $20 million of common stock issued to Lincoln Park under the Purchase Agreement. On March 29, 2021, we issued 80,000 shares of common stock as commitment shares (which includes 5,000 commitment shares issued on a pro rata basis in respect of the initial purchase by Lincoln Park of $2 million of shares). We will not receive any cash proceeds from the issuance of any of the foregoing commitment shares.

The net proceeds under the LPC Purchase Agreement to us will depend on the frequency and prices at which shares of common stock are sold to Lincoln Park. Actual sales of shares of common stock to Lincoln Park under the LPC Purchase Agreement (beyond the initial purchase of $2 million of shares) and the amount of such net proceeds will depend on a variety of factors, including market conditions, the trading price of the common stock and determination by us as to other available and appropriate sources of funding for us. We expect to use the proceeds from this agreement for general corporate purposes and working capital.

Litigation Settlement

On March 12, 2021, we agreed to settle, pending final documentation and dismissal, the legal proceedings and any and all claims, counterclaims, actions and/or proceedings relating to or arising from the case captioned Boston Scientific Corp., et al., v. BioCardia Inc., Case No. 3:19-05645-VC, U.S.D.C., N. D. Cal. We expect the settlement will not result in any material benefit or liability to the Company. See Note 17 of our notes to the consolidated financial statements for additional information.

Financial Overview

Revenue

We currently have a portfolio of enabling and delivery products, from which we have generated modest revenue. Net product revenues include commercial sales of our Morph vascular access system in the US and EU and collaboration agreement revenues include revenue from partnering agreements with corporate and academic institutions. Under these partnering agreements, we provide our Helix biotherapeutic delivery system and customer training and support for use in preclinical and clinical studies.

Cost of Goods Sold

Cost of goods sold includes the costs of raw materials and components, manufacturing personnel and facility costs and other indirect and overhead costs associated with manufacturing our commercial enabling and delivery products, which generate net product revenue.

Research and Development Expenses

Our research and development expenses consist primarily of:

- salaries and related overhead expenses, which include share-based compensation and benefits for personnel in research and development functions;
- fees paid to consultants and contract research organizations, or CROs, including in connection with our preclinical studies and clinical trials and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial management and statistical compilation and analysis;
- costs related to acquiring and manufacturing clinical trial materials;
- costs related to compliance with regulatory requirements; and
- payments related to licensed products and technologies.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress of completion of specific tasks using information and data provided to us by our vendors and clinical sites. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and the services are received.

We plan to increase our research and development expenses for the foreseeable future as we continue the pivotal CardiAMP Heart Failure Trial, advance the pivotal CardiAMP Chronic Myocardial Ischemia Trial, further develop our autologous and allogeneic cell therapy candidates. We typically use our employee and infrastructure resources across multiple research and development programs, and accordingly, we have not historically allocated resources specifically to our individual programs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related costs for employees in executive, finance and administration, sales, corporate development and administrative support functions, including share-based compensation expenses and benefits. Other selling, general and administrative expenses include sales commissions, rent, accounting and legal services, obtaining and maintaining patents, the cost of consultants, occupancy costs, insurance premiums and information systems costs.

Other Income (Expense)

Other income and expense consist primarily of interest income we earn on our cash, cash equivalents and investments, changes in fair value of redemptive features embedded in convertible notes, loss on extinguishment of convertible notes, gain on extinguishment of Paycheck Protection Program note payable, and interest charges we incurred in periods during 2020 and 2019 when we had debt outstanding.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various judgements that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not clear from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations as well as the specific manner in which we apply those principles. The following discussion addresses what we believe to be the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

Research and Development—Clinical Trial Accruals

As part of the process of preparing our financial statements, we are required to estimate our expenses resulting from our obligations under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our clinical trial accrual is dependent upon the timely and accurate reporting of expenses of our CROs and other third-party vendors.

Our objective is to reflect the appropriate clinical trial expenses in our financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of completion of clinical trials, or the services completed. During the course of a clinical trial, we adjust the rate of clinical trial expense recognition if actual results differ from the estimates. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known at that time. Although we do not expect that our estimates will be materially different from amounts actually incurred, our understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting amounts that are too high or too low for any particular period. Through December 31, 2020, there had been no material adjustments to our prior period estimates of accrued expenses for clinical trials. However, due to the nature of estimates, we cannot provide assurance that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials.

Share-Based Compensation

We measure and recognize share-based compensation expense for equity awards to employees, directors and consultants based on fair value at the grant date. We use the Black-Scholes-Merton option-pricing model, or BSM, to calculate the fair value of stock options, which includes subjective assumptions such as the risk-free interest rate, the expected volatility in the value of the Company's common stock, and the expected term of the option. Restricted stock units (RSUs) are measured based on the fair market values of the underlying stock on the dates of grant. Share-based compensation expense recognized in the statements of operations is based on awards at the time of grant and is reduced for actual forfeitures at the time that the forfeitures occur. Compensation cost for employee share-based awards will be recognized over the vesting period of the applicable award on a straight-line basis.

Results of Operations

The table set forth below summarizes our results of operations for the years ended December 31, 2020 and 2019 (in thousands). The results of operations from 2019 compared to 2018 and related discussion can be found in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 9, 2020, and such results and related discussion are incorporated herein by reference.

	Years ended December 31,	
	2020	**2019**
Revenue:		
Net product revenue	$ 13	$ 182
Collaboration agreement revenue	132	528
Total revenue	145	710
Costs and expenses:		
Cost of goods sold	4	358
Research and development	9,809	8,562
Selling, general and administrative	5,861	6,003
Total costs and expenses	15,674	14,923
Operating loss	(15,529)	(14,213)
Other income (expense):		
Interest income	21	87
Gain on extinguishment of Paycheck Protection Program note payable	509	—
Gain on change in fair value of redemption feature embedded in convertible notes	—	52
Interest expense	(3)	(112)
Loss on extinguishment of convertible notes	—	(521)
Other expense	(2)	(2)
Total other income (expense)	525	(496)
Net loss	$ (15,004)	$ (14,709)

Revenue. Revenue for the year ended December 31, 2020 totaled $145,000 compared to $710,000 for the year ended December 31, 2019. The $565,000 decrease was primarily due to lower revenue generating partnership activities in 2020 coupled with reduced volumes of commercial catheter sales as we transition our commercial offerings to a limited launch of the Morph AVANCE™ and Morph DNA product families. We expect collaboration agreement revenues to increase in 2021 depending on progress in these existing collaborative programs and the initiation of new partnership relationships. Net product revenue is expected to be modest in 2021 and will be subject to customer demand, the availability of production resources for our new Morph product family members, and the timing of FDA clearance for market release of different models and sizes during the year.

Cost of Goods Sold. Cost of goods sold for the year ended December 31, 2020 totaled $4,000 compared to $358,000 for the year ended December 31, 2019, decreasing by $354,000 primarily due to the decrease in net product revenue. We expect cost of goods sold to increase modestly in 2021 relative to sales, depending on the timing and demand for our new Morph product family members and the associate production costs which will vary depending on volume.

Research and Development Expenses. Research and development expenses were approximately $9.8 million for the year ended December 31, 2020 compared to approximately $8.6 million for the year ended December 31, 2019, representing an increase of $1.2 million or 14%. Research and development in both periods focused on advancing our pivotal CardiAMP Heart Failure Trial and Chronic Myocardial Ischemia trials and development of our Neurokinin-1 Receptor Positive allogeneic cell therapies for cardiovascular and respiratory diseases. The $1.2 million increase in 2020 compared to 2019 was primarily due to cost of additional personnel and supporting systems to enhance enrollment and monitoring in our pivotal trials, accelerate development activities, and strengthen supporting functions. We expect research and development expenses to increase moderately as we continue enrolling in our pivotal trials, advance regulatory approvals for our therapies, and improve our cell processing, manufacturing capabilities and delivery platforms.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were approximately $5.9 million during the year end December 31, 2020 compared to approximately $6.0 million for the year ended December 31, 2019. The $142,000 decrease in 2020 compared to 2019, was primarily due to additional stock-based compensation expense related to the modification of certain stock option awards in 2019 that did not recur in 2020, partially offset by higher corporate expenses, including business insurance premiums and additional franchise taxes due related to prior financings. We expect selling, general and administrative expenses to decrease modestly in 2021 relative to 2020.

Other Income (Expense). In 2020, Other income (expense) consisted primarily of interest expense and the gain on extinguishment associated with the Paycheck Protection Program loan obtained on May 1, 2020 and forgiven on November 7, 2020. In 2019, Other income (expense) consisted primarily of amounts recognized in relation to the accounting for the convertible notes, including a gain on change in fair value of the embedded redemption feature of $52,000, interest expense associated with the accretion of the debt discount of $104,000, and a loss upon extinguishment of $521,000. Interest income of $21,000 and $87,000 was earned on cash and cash equivalents for the years ended December 31, 2020 and 2019, respectively.

Liquidity and Capital Resources

We have incurred net losses each year since our inception and as of December 31, 2020, we had an accumulated deficit of approximately $116.1 million. We anticipate that we will continue to incur net losses for at least the next several years.

We have funded our operations principally through the sales of equity and convertible debt securities as well as the cash acquired through the Merger. As of December 31, 2020, we had cash and cash equivalents of approximately $21.4 million.

The following table shows a summary of our cash flows for the periods indicated (in thousands):

	Years ended December 31,	
	2020	2019
Net cash provided by (used in):		
Operating activities	$ (12,357)	$ (9,445)
Investing activities	(32)	(146)
Financing activities	28,211	9,818
Net increase in cash and cash equivalents	$ 15,822	$ 227

Cash Flows from Operating Activities. Cash used in operating activities for the year ended December 31, 2020 totaled approximately $12.4 million, which is the sum of (i) our net loss of $15.0 million, adjusted for non-cash income and expenses totaling $3.0 million (share-based compensation, gain on extinguishment of the Paycheck Protection Program note payable, reduction in the carrying amount of right-of-use assets and depreciation), and (ii) changes in operating assets and liabilities of approximately $367,000. Cash used in operating activities for the year ended December 31, 2019 totaled approximately $9.4 million, which is the sum of (i) our net loss of $14.7 million, adjusted for non-cash income and expenses totaling $3.9 million (share-based compensation, loss on extinguishment of convertible notes, reduction in the carrying amount of right-of-use assets and depreciation), and (ii) changes in operating assets and liabilities of approximately $1.4 million.

The increase in cash used for operating activities of $2.9 million in 2020 compared to 2019 related primarily to increased spending to advance our allogeneic pivotal trials and therapeutic development programs coupled with decreases in advance payments from a customer and legal fees paid that have not yet been reimbursed by a related party under the Litigation Funding Agreement discussed in the notes to the financial statements. We expect net cash used in operating activities to remain relatively consistent in 2021.

Cash Flows from Investing Activities. Net cash used in investing activities of $32,000 and $146,000 during the years ended December 31, 2020, and 2019, respectively consists of purchases of property and equipment, primarily lab equipment and related infrastructure.

Cash Flows from Financing Activities. Net cash provided by financing activities during the year ended December 31, 2020 consisted of proceeds from sales of common stock totaling approximately $27.9 million (net of issuance costs) and proceeds from the Paycheck Protection note payable totaling $506,000, partially offset by tax withholding-related payments on the settlement of restricted unit awards. Net cash provided by financing activities during the year ended December 31, 2019 totaled approximately $9.8 million and consisted of proceeds from the sale of common stock and related warrants and proceeds from convertible loans payable.

Future Funding Requirements

To date, we have generated modest revenue from sales of our approved products. We do not know when, or if, we will generate any revenue from our development stage biotherapeutic programs. We do not expect to generate any revenue from sales of our CardiAMP, CardiALLO or Neurokinin-1 Receptor Positive allogeneic therapeutic candidates unless and until we obtain regulatory approval. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our therapeutic candidates. In addition, subject to obtaining regulatory approval for any of our therapeutic candidates and companion diagnostic, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need additional funding in connection with our continuing operations.

As discussed in the notes to the financial statements, we raised approximately $17.6 million in December 2020 from the sale of common stock under registered direct offerings, and approximately $10.3 million in May 2020 from a public offering of common stock, net of fees, discounts and offering expenses. In April 2019, we raised approximately $8.8 million from a public offering of common stock and warrants, net of underwriting discounts, commissions and offering expenses. We use our sources of capital primarily for clinical development, pursuing regulatory approval and commercialization of our product candidates, including advancing our partnering programs with corporate and academic institutions.

In March 2021, we entered into the LPC Purchase Agreement with Lincoln Park. Pursuant to the terms of the LPC Purchase Agreement, Lincoln Park agreed to purchase from us up to $20.0 million of our common stock (subject to certain limitations) from time to time during the term of the LPC Purchase Agreement. Pursuant to the terms of the LPC Purchase Agreement, at the time we signed the LPC Purchase Agreement, we sold 373,832 shares of our common stock at a price of $5.35 per share pursuant to the LPC Purchase Agreement for gross proceeds of $2 million (and issued 80,000 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock, which consisted of 75,000 shares for Lincoln Park's initial commitment and 5,000 shares issued on a pro rata basis in respect of Lincoln Park's initial purchase of 373,832 shares). We may sell up to an additional $18 million of shares of our common stock from time to time at various prices pursuant to the terms of the LPC Purchase Agreement. See Note 19 of our notes to the consolidated financial statements for additional information.

Based upon our current operating plan, we believe that the cash and cash equivalents of $21.4 million as of December 31, 2020 are sufficient to fund our operations for at least the next 12 months from the date of issuance of these financial statements. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our therapeutic candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our therapeutic candidates.

Our future capital requirements will depend on many factors, including:

- the progress, costs, results and timing of our CardiAMP and CardiALLO autologous and Neurokinin-1 Receptor Positive allogeneic clinical trials and related development programs;
- FDA acceptance of our CardiAMP and CardiALLO allogeneic and Neurokinin-1 Receptor Positive allogeneic therapies for heart failure and for other potential indications;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the costs associated with securing, establishing and maintaining commercialization and manufacturing capabilities;
- the number and characteristics of product candidates that we pursue, including our product candidates in preclinical development;
- the ability of our product candidates to progress through clinical development successfully;
- our need to expand our research and development activities;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

- the general and administrative expenses related to being a public company;
- our need and ability to hire additional management and scientific, medical and sales personnel;
- the effect of competing technological and market developments; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

Until such time that we can generate meaningful revenue from the sales of approved therapies and products, if ever, we expect to finance our operating activities through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements, and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include conversion discounts or covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, or strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, products, or therapeutic candidates or to grant licenses on terms that may not be favorable to us.

Recent Accounting Pronouncements

See Note 2 of our notes to the consolidated financial statements for information regarding recent accounting pronouncements that are of significance or potential significance to us.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2020, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates or credit conditions.

We believe that the interest rate risk related to our accounts receivable is not significant. We manage the risk associated with these accounts through periodic reviews of the carrying value for non-collectability and establishment of appropriate allowances.

We operate primarily in the United States and are not exposed to foreign exchange risk with respect to recognized assets and liabilities. We do not enter into hedging transactions and do not purchase derivative instruments.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
BioCardia, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of BioCardia, Inc. and Subsidiary (the "Company") as of December 31, 2020, the related consolidated statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2020, and the related notes (collectively referred to as the "consolidated 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 the results of its operations and its cash flows for the year ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Share-based compensation

As discussed in Note 11 to the consolidated financial statements, on January 29, 2020, the Company repriced certain previously granted and still outstanding vested and unvested stock option awards.

Auditing management's recording of compensation under the modification involved significant judgment given the requirements of the applicable accounting literature.

To evaluate the appropriateness and accuracy of the recording of compensation by management, we examined the closing price on the date of repricing and the closing price of the Company's common stock for the preceding period, as determined by the Company's Board of Directors and approved by shareholders. We also reviewed the underlying accounting codifications for this accounting treatment applied by management. In addition, we evaluated the Company's disclosure in relation to this matter included in Note 11 to the financial statements.

Accrued research and development expenses – clinical costs

The Company recorded research and development expenses of $9.8 million for the year ended December 31, 2020. As described in Note 2, research and development costs are expensed as incurred. Research and development costs include fees paid to contract research organizations that conduct certain research and development activities on the Company's behalf and contract manufacturing organizations in connection with the production of materials for clinical trials.

Auditing the Company's research and development expenses for contract research organizations and contract manufacturing organizations and related accruals was challenging due to the complex nature of evaluating the completeness and accuracy of the expenses and accruals. Research and development expenses are recognized as the services are being performed by the vendors, which requires management to accurately monitor the activity at the vendors to determine the extent of unbilled services performed during the reporting period.

We obtained an understanding and evaluated the design over the Company's process used to determine the completeness and accuracy of the research and development expenses and related accruals for contract research organizations and contract manufacturing organizations, including management's controls to accurately monitor the activity at the vendors.

To test the completeness and accuracy of the contract research organization and contract manufacturing organization expenses and related accruals, our audit procedures included, among others, testing a sample of research and development expenses recorded during the period and evaluating the timing, amount and project coding of the expense recognition, and testing a sample of cash disbursements after period end to assess the completeness of the expense recognition.

/s/ PKF San Diego, LLP
PKF San Diego, LLP
(formerly PKF, LLP)

We have served as the Company's auditor since 2020.
San Diego, California
March 29, 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
BioCardia, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of BioCardia, Inc. and its subsidiary (the Company) as of December 31, 2019, the related consolidated statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2019, and the related notes (collectively, the consolidated 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, 2019, and the results of its operations and its cash flows for the year ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred net losses and negative cash flows from operations since its inception and had an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provide a reasonable basis for our opinion.

We served as the Company's auditor from 2012 to 2020

San Francisco, California
April 8, 2020

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 21,407	$ 5,585
Accounts receivable, net of allowance for doubtful accounts of $16 and $2 at December 31, 2020 and 2019, respectively	232	147
Inventory	—	4
Prepaid expenses and other current assets	401	642
Other receivable due from related party	618	—
Total current assets	22,658	6,378
Property and equipment, net	145	181
Operating lease right-of-use asset, net	567	1,065
Other assets	54	54
Total assets	$ 23,424	$ 7,678
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 746	$ 914
Accrued expenses and other current liabilities	2,205	2,561
Deferred revenue	683	—
Operating lease liability - current	614	528
Total current liabilities	4,248	4,003
Operating lease liability - noncurrent	—	614
Deferred revenue	—	691
Total liabilities	4,248	5,308
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 25,000,000 shares authorized as of December 31, 2020 and 2019, respectively; no shares issued and outstanding as of December 31, 2020 and 2019	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized as of December 31, 2020 and 2019, respectively; 16,297,381 and 6,825,183 shares issued and outstanding as of December 31, 2020 and 2019, respectively	16	7
Additional paid-in capital	135,234	103,433
Accumulated deficit	(116,074)	(101,070)
Total stockholders' equity	19,176	2,370
Total liabilities and stockholders' equity	$ 23,424	$ 7,678

See accompanying notes to consolidated financial statements.

BIOCARDIA, INC.
Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	Years ended December 31,	
	2020	2019
Revenue:		
Net product revenue	$ 13	$ 182
Collaboration agreement revenue	132	528
Total revenue	145	710
Costs and expenses:		
Cost of goods sold	4	358
Research and development	9,809	8,562
Selling, general and administrative	5,861	6,003
Total costs and expenses	15,674	14,923
Operating loss	(15,529)	(14,213)
Other income (expense):		
Interest income	21	87
Gain on extinguishment of Paycheck Protection Program note payable	509	—
Gain on change in fair value of redemption feature embedded in convertible notes	—	52
Interest expense	(3)	(112)
Loss on extinguishment of convertible notes	—	(521)
Other expense	(2)	(2)
Total other income (expense)	525	(496)
Net loss	$ (15,004)	$ (14,709)
Net loss per share, basic and diluted	$ (1.48)	$ (2.61)
Weighted-average shares used in computing net loss per share, basic and diluted	10,118,682	5,644,328

See accompanying notes to consolidated financial statements.

BIOCARDIA, INC.
Consolidated Statements of Stockholders' Equity
For the Years Ended December 31, 2020 and 2019
(In thousands, except share data)

	Common stock		Additional	Accumulated	
	Shares	Cost	paid-in capital	deficit	Total
Balance at December 31, 2018	4,845,697	$ 5	$ 90,148	$ (86,361)	$ 3,792
Reverse stock split fractional share true up	(494)	—	—	—	—
Restricted stock units vested and issued	27,426	—	—	—	—
Issuance of sale of stock and warrants, net of issuance costs of $1,259	1,741,667	2	9,194	—	9,196
Issuance of stock and warrants from conversion of convertible notes	210,887	—	1,204	—	1,204
Issuance of restricted stock units in lieu of 2018 cash bonus	—	—	165	—	165
Share-based compensation	—	—	2,722	—	2,722
Net loss	—	—	—	(14,709)	(14,709)
Balance at December 31, 2019	6,825,183	$ 7	$ 103,433	$ (101,070)	$ 2,370
Sale of common stock on June 19, 2020, net of issuance costs of $1,227	5,476,190	5	10,268	—	10,273
Sale of common stock on December 16, 2020, net of issuance costs of $673	1,789,474	2	7,825	—	7,827
Sale of common stock on December 18, 2020, net of issuance costs of $735	2,038,836	2	9,763	—	9,765
Restricted stock units vested and issued	26,172	—	—	—	—
Restricted stock units issued to settle management bonus obligations	71,624	—	232	—	232
Common stock grants to former directors to settle board compensation obligations	29,625	—	148	—	148
Restricted stock units issued to settle board compensation obligations	39,807	—	613	—	613
Exercise of common stock warrants	470	—	—	—	—
Share-based compensation	—	—	2,952	—	2,952
Net loss	—	—	—	(15,004)	(15,004)
Balance at December 31, 2020	16,297,381	$ 16	$ 135,234	$ (116,074)	$ 19,176

See accompanying notes to consolidated financial statements.

BIOCARDIA, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Years ended December 31,	
	2020	2019
Operating activities:		
Net loss	$ (15,004)	$ (14,709)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	68	111
Reduction in the carrying amount of right-of-use assets	498	440
Non-cash interest expense on convertible stockholder notes	3	112
Gain on change in fair value of redemption feature embedded in convertible notes	—	(52)
Loss on extinguishment of convertible notes	—	521
Gain on extinguishment of Paycheck Protection Program note payable	(509)	—
Share-based compensation	2,952	2,722
Changes in operating assets and liabilities:		
Accounts receivable	(85)	127
Inventory	4	137
Prepaid expenses and other current assets	241	(198)
Other receivable due from related party	(618)	—
Accounts payable	(168)	171
Accrued liabilities excluding accrued interest on convertible note	797	922
Deferred revenue	(8)	691
Operating lease liability - current	86	88
Operating lease liability - noncurrent	(614)	(528)
Net cash used in operating activities	(12,357)	(9,445)
Investing activities:		
Purchase of property and equipment	(32)	(146)
Net cash used in investing activities	(32)	(146)
Financing activities:		
Proceeds from sale of common stock and warrants	—	10,452
Issuance costs from sales of common stock and warrants	—	(1,259)
Proceeds from sale of common stock June 19, 2020	11,500	—
Proceeds from sale of common stock Dec 16, 2020	8,500	—
Proceeds from sale of common stock Dec 18, 2020	10,500	—
Issuance costs from sales of common stock	(2,635)	—
Proceeds from Paycheck Protection Program note payable	506	—
Tax withholding payments on settlement of restricted stock unit awards	(160)	—
Proceeds from convertible notes payable	—	625
Net cash provided by financing activities	28,211	9,818
Net change in cash and cash equivalents	15,822	227
Cash and cash equivalents at beginning of year	5,585	5,358
Cash and cash equivalents at end of year	$ 21,407	$ 5,585
Supplemental disclosure for noncash investing and financing activities:		
Restricted stock units issued to settle management bonus obligations	$ 391	$ -
Common stock grants to former directors to settle board compensation obligations	$ 148	$ -
Restricted stock units issued to settle board compensation obligations	$ 613	$ -
Conversion of interest payable to stock and warrants	$ —	$ 633
Issuance of restricted stock units in lieu of 2018 cash bonus	$ —	$ 165
Right-of-use asset obtained in exchange for lease obligation	$ —	$ 1,505
Cashless exercise of warrant	$ —	$ —

See accompanying notes to consolidated financial statements.

(1) Summary of Business

(a) Description of Business

BioCardia, Inc. (BioCardia or the Company), is a clinical-stage regenerative medicine company developing novel therapeutics for cardiovascular and respiratory diseases with significant unmet medical needs. The Company's lead therapeutic candidate is the CardiAMP® Cell Therapy System, which provides an autologous bone marrow derived cell therapy using a patient's own cells for treatment in two clinical indications: heart failure that develops after a heart attack and chronic myocardial ischemia. The Company's second therapeutic platform is the investigational culture expanded bone marrow derived allogeneic "off the shelf" Neurokinin-1 Receptor Positive mesenchymal stem cells for the treatment of cardiac and pulmonary disease. To date, the Company has devoted substantially all its resources to research and development efforts relating to its therapeutic candidates and biotherapeutic delivery systems including conducting clinical trials, developing manufacturing and sales capabilities, in-licensing related intellectual property, providing general and administrative support for these operations and protecting its intellectual property.

BioCardia also has three enabling device product lines: (1) the CardiAMP cell processing system; (2) the Helix biotherapeutic delivery system, or Helix; and (3) the Morph vascular access product line, or Morph. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions.

(2) Significant Accounting Policies

(a) Basis of Presentation and Consolidation

These consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP) and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All material intercompany accounts and transactions have been eliminated during the consolidation process.

(b) Liquidity

The Company has incurred net losses and negative cash flows from operations since its inception and had an accumulated deficit of $116.1 million as of December 31, 2020. Management expects operating losses and negative cash flows to continue through at least the next several years.

Cash and cash equivalents totaled $21.4 million on December 31, 2021, which management believes is sufficient to fund the Company's planned expenditures and meet its obligations for at least 12 months following the filing of this Form 10-K.

(c) Use of Estimates

The preparation of the financial statements in accordance with U.S. GAAP requires Company management to make certain estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant items subject to such estimates and assumptions include the useful lives of property and equipment, right-of-use assets and related liabilities, allowances for doubtful accounts and sales returns; inventory valuation, derivative instruments, clinical accruals, share-based compensation and the assumptions used for revenue recognition. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ materially from those estimates.

(d) Cash Equivalents

The Company classifies all highly liquid investments with an original maturity date of 90 days or less at the date of purchase as cash equivalents. The Company maintains its cash and cash equivalents with reputable financial institutions.

(e) Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company maintains its cash at reputable U.S. financial institutions, which at times, exceed federally insured limits of $250,000 per customer. On December 31, 2020, the Company's cash was held by one financial institution and the amount on deposit was in excess of FDIC insurance limits. The Company has not recognized any losses from credit risks on such accounts since inception. The Company believes it is not exposed to significant credit risk on cash and cash equivalents.

(f) Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are recorded at the invoiced amount and do not bear interest. The Company considers the creditworthiness of its customers but does not require collateral in advance of a sale. The Company evaluates collectability and maintains an allowance for doubtful accounts for estimated losses inherent in its accounts' receivable portfolio when necessary. The estimate is based on the Company's historical write-off experience, customer creditworthiness, facts, and circumstances specific to outstanding balances and payment terms. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. The allowance for doubtful accounts was $16,000 and $2,000 as of December 31, 2020 and 2019, respectively.

(g) Inventory

Inventory is stated at the lower of cost or net realizable value. Cost is determined using the average-cost method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The Company analyzes its inventory levels quarterly and writes down inventory that has become obsolete or has a cost basis in excess of its expected net realizable value or inventory quantities in excess of expected requirements. Excess requirements are determined based on comparison of existing inventories to forecasted sales, with consideration given to inventory shelf life. Expired inventory is disposed of and the related costs are recognized in cost of goods sold.

(h) Property and Equipment, Net

Property and equipment, net, are carried at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets, as described in the table below. Maintenance and repairs are expensed as incurred. When assets are retired or otherwise disposed of, the cost and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is reflected in the accompanying consolidated statements of operations.

Asset	Estimated useful lives (in years)
Computer equipment and software	3
Laboratory and manufacturing equipment	3
Furniture and fixtures	3
Leasehold improvements	5 years or lease term, if shorter

(i) Right-of-Use Assets

Operating lease right-of-use asset and liabilities - The Company will determine if an arrangement is a lease at the inception of the arrangement. All leases are assessed for classification as an operating lease or finance lease. The Company will recognize a lease liability and a right-of-use (ROU) asset for all leases, including operating leases, with a term greater than 12 months. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease.

The Company's lease liabilities are recognized at the applicable lease commencement date based on the present value of the lease payments required to be paid over the lease term. Variable lease payments are expensed as incurred and are not included the computation of the lease liability. The lease liability discount rate is generally the Company's incremental borrowing rate unless the lessor's rate implicit in the lease is readily determinable, in which case the lessor's implicit rate is used.

The Company's ROU assets are also recognized at the applicable lease commencement date. The ROU asset equals the carrying amount of the related lease liability, adjusted for any lease payments made prior to lease commencement and lease incentives provided by the lessor, if any. The Company reduces a ROU asset, and the periodic reduction is the difference between the straight-line total lease cost for the period (including reduction of initial direct costs) and the periodic accretion of the lease liability using the effective interest method.

The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that it will exercise any such options. Operating lease cost for lease payments is recognized on a straight-line basis over the lease term.

The Company's lease contracts often include lease and non-lease components. The Company has elected the practical expedient offered by the standard to not separate lease from non-lease components and accounts for them as a single lease component.

The Company has elected not to recognize ROU assets and lease liabilities for leases with a term of twelve months or less. Lease cost for short-term leases is recognized on a straight-line basis over the lease term.

(j) Long-lived Assets

Impairment assessment of long-lived assets - The carrying value of long-lived assets, including property and equipment and operating lease right-of-use assets, is reviewed for impairment whenever events or changes in circumstances indicate that the asset may not be recoverable. An impairment loss is recognized when the total of estimated future undiscounted cash flows, expected to result from the use of the asset and its eventual disposition, are less than its carrying amount. Impairment, if any, would be assessed using discounted cash flows or other appropriate measures of fair value. Through December 31, 2020, there have been no such impairment losses.

(k) Clinical Trial Accruals

As part of the process of preparing its consolidated financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiation and may result in payment flows that do not match the periods over which materials or services are provided by the vendor under the contracts. The Company's objective is to reflect the clinical trial expenses in its consolidated financial statements by matching those expenses with the period in which the services and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company makes estimates of its accrued expenses as of each balance sheet date in its consolidated financial statements based on the facts and circumstances known at that time. Although, the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services relative to the actual status and timing of services performed may vary and may result in reported amounts that differ from the actual amounts incurred.

(l) Derivatives

The Company accounts for its derivative instruments as either assets or liabilities on the consolidated balance sheets and measures them at fair value. Derivatives are adjusted to fair value through other (expense) income, net, in the consolidated statements of operations. Derivatives settled in cash or with another financial instrument are reflected in the consolidated statements of cash flows in the same section as the related items.

(m) Revenue Recognition

Net product revenue – BioCardia currently has a portfolio of enabling and delivery products. Revenue from product sales is recognized generally upon shipment to the end customer, which is when control of the product is deemed to be transferred. Product sale transactions are evidenced by customer purchase orders, customer contracts, invoices and/or related shipping documents.

Collaboration agreement revenue – Collaboration agreement revenue is income from agreements under partnering programs with corporate and academic institutions, wherein the Company provides biotherapeutic delivery systems and customer training and support for their use in clinical trials and studies. These programs provide additional clinical data, intellectual property rights and opportunities to participate in the development of combination products for the treatment of cardiac disease.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract.

The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success. This evaluation is subjective and requires the Company to make judgments about the promised goods and services and whether those goods and services are separable from other aspects of the contract. Further, determining the stand-alone selling price for performance obligations requires significant judgment, and when an observable price of a promised good or service is not readily available, the Company considers relevant assumptions to estimate the stand-alone selling price, including, as applicable, market conditions, development timelines, probabilities of technical and regulatory success, reimbursement rates for personnel costs, forecasted revenues, potential limitations to the selling price of the product and discount rates.

The Company applies judgment in determining whether a combined performance obligation is satisfied at a point in time or over time, and, if over time, concluding upon the appropriate method of measuring progress to be applied for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, as estimates related to the measure of progress change, related revenue recognition is adjusted accordingly. Changes in the Company's estimated measure of progress are accounted for prospectively as a change in accounting estimate. The Company recognizes collaboration revenue by measuring the progress toward complete satisfaction of the performance obligation using an input measure. The Company will re-evaluate the estimate of expected costs to satisfy the performance obligation each reporting period and make adjustments for any significant changes.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company's consolidated balance sheets. If the related performance obligation is expected to be satisfied within the next twelve months, it will be classified in current liabilities. The Company receives payments from its customers as established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. The Company does not assess whether a contract with a customer has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less. On December 31, 2020, deferred revenue totaled $683,000, consisting of future service revenues of approximately $183,000 and future license fee revenues of $500,000, to be recognized at a point in time before July 2021.

Multiple contracts with the same customer - When two or more contracts are entered into with the same customer at or near the same time, the Company evaluates the contracts to determine whether the contracts should be accounted for as a single arrangement. Contracts are combined and accounted for as a single arrangement if one or more of the following criteria are met: (i) the contracts are negotiated as a package with a single commercial objective; (ii) the amount of consideration to be paid in one contract depends on the price or performance of the other contract; or (iii) the goods or services promised in the contracts (or some goods or services promised in each of the contracts) are a single performance obligation.

Contract costs - The Company recognizes as an asset the incremental costs of obtaining a contract with a customer if the costs are expected to be recovered. The Company has elected a practical expedient wherein it recognizes the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset that it otherwise would have recognized is one year or less. To date, the Company has not incurred any material incremental costs of obtaining a contract with a customer.

Contract modifications - Contract modifications, defined as changes in the scope or price (or both) of a contract that are approved by the parties to the contract, such as a contract amendment, exist when the parties to a contract approve a modification that either creates new or changes existing enforceable rights and obligations of the parties to the contract. Depending on facts and circumstances, the Company accounts for a contract modification as one of the following: (i) a separate contract; (ii) a termination of the existing contract and a creation of a new contract; or (iii) a combination of the preceding treatments. A contract modification is accounted for as a separate contract if the scope of the contract increases because of the addition of promised goods or services that are distinct and the price of the contract increases by an amount of consideration that reflects the Company's stand-alone selling prices of the additional promised goods or services. When a contract modification is not considered a separate contract and the remaining goods or services are distinct from the goods or services transferred on or before the date of the contract modification, the Company accounts for the contract modification as a termination of the existing contract and a creation of a new contract. When a contract modification is not considered a separate contract and the remaining goods or services are not distinct, the Company accounts for the contract modification as an add-on to the existing contract and as an adjustment to revenue on a cumulative catch-up basis.

(n) Shipping Costs

Costs incurred for the shipping of products to customers totaled approximately $0 and $6,000 for the years ended December 31, 2020 and 2019, respectively, and are included in cost of goods sold in the accompanying consolidated statements of operations.

(o) Product Warranties

The Company provides a standard warranty of serviceability on all its products for the duration of the product's shelf life, which is two years for Helix and Morph products currently. Estimated future warranty costs, if any, are accrued and charged to costs of goods sold in the period that the related revenue is recognized. Historical data and trends of product reliability and costs of repairing or replacing defective products are considered. Due to the low historical warranty claims experience, a general warranty accrual has not been required or recorded as of December 31, 2020 and 2019.

(p) Research and Development

The Company's research and development costs are expensed as incurred. Research and development expense include the costs of basic research activities as well as other research, engineering, and technical effort required to develop new products or services or make significant improvement to an existing product or manufacturing process. Research and development costs also include pre-approval regulatory and clinical trial expenses and support costs for collaborative partnering programs wherein the Company provides biotherapeutic delivery systems and customer training and support for their use in clinical trials and studies. The Company's research and development costs consist primarily of:

- Salaries, benefits and other personnel-related expenses, including share-based compensation;
- Fees paid for services provided by clinical research organizations, research institutions, consultants and other outside service providers;
- Costs to acquire and manufacture materials used in research and development activities and clinical trials;
- Laboratory consumables and supplies;
- Facility-related expenses allocated to research and development activities;
- Fees to collaborators to license technology; and
- Depreciation expense for equipment used for research and development and clinical purposes.

(q) Cost of Goods Sold

Cost of goods sold includes the costs of raw materials and components, manufacturing personnel and facility costs and other indirect and overhead costs associated with manufacturing the commercial enabling and delivery products, which generate net product revenue.

(r) Share-Based Compensation

The Company measures and recognizes share-based compensation expense for equity awards to employees, directors and consultants based on fair value at the grant date. The Company uses the Black-Scholes-Merton (BSM) option pricing model to calculate fair value of its stock option grants. The compensation cost for restricted stock awards is based on the closing price of the Company's common stock on the date of grant. Share-based compensation expense recognized in the consolidated statements of operations is based on the period the services are performed and recognized as compensation expense on a straight-line basis over the requisite service period. The Company accounts for forfeitures as they occur.

Measurement of nonemployee awards - The measurement of equity-classified nonemployee awards is fixed at the grant date, and the Company may use the expected term to measure nonemployee options or elect to use the contractual term as the expected term, on an award-by-award basis. This differs from the guidance in Accounting Standards Codification (ASC) 505-50 that requires the use of the contractual term. Forfeitures of nonemployee awards will be recognized as they occur.

The BSM option pricing model requires the input of subjective assumptions, including the risk-free interest rate, the expected volatility in the value of the Company's common stock, and the expected term of the option. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, the share-based compensation expense could be materially different in the future. These assumptions are estimated as follows:

Risk-free Interest Rate

The risk-free interest rate assumption is based on the zero-coupon U.S. Treasury instruments appropriate for the expected term of the stock option grants.

Expected Volatility

The Company has limited historical data of its own to utilize in determining expected volatility. As such the Company based the volatility assumption on a combined weighted average of the Company's own historical data and that of a selected peer group. The peer group was developed based on companies in the biotechnology and medical device industries whose shares are publicly traded.

Expected Term

The expected term represents the period of time that options are expected to be outstanding. As the Company does not have sufficient historical experience for determining the expected term of the stock options awards granted, the expected life is determined using the simplified method, which is an average of the contractual terms of the option and its ordinary vesting period.

(s) Income Taxes

The Company accounts for income taxes based on the asset and liability method whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets, liabilities, operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized.

In evaluating the ability to recover its deferred income tax assets, the Company considers all available positive and negative evidence, including its operating results, forecasts of future taxable income, and ongoing tax planning. In the event the Company was to determine that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, it would make an adjustment to the valuation allowance, which would reduce the provision for income taxes. Conversely, in the event that all or part of the net deferred tax assets are determined not to be realizable in the future, an adjustment to the valuation allowance would be charged to earnings in the period such determination is made.

The Company recognizes and measures benefits for uncertain tax positions using a two-step approach. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that the tax position will be sustained upon audit, including resolution of any related appeals or litigation processes. For tax positions that are more likely than not to be sustained upon audit, the second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon settlement. Significant judgment is required to evaluate uncertain tax positions. The Company evaluates its uncertain tax positions quarterly. Evaluations are based upon a number of factors, including the technical merits of the tax position, changes in facts or circumstances, changes in tax law, interactions with tax authorities during the course of audits, and effective settlement of audit issues. The Company's policy is to recognize interest and penalties related to unrecognized tax benefits as a component of income tax expense in the consolidated statements of operations and accrued interest and penalties within accrued liabilities in the consolidated balance sheets. No such interest and penalties have been recorded to date.

(t) Fair Value of Financial Instruments

The Company applies fair value accounting for all financial assets and liabilities and nonfinancial assets and liabilities that are required to be recognized or disclosed at fair value in the consolidated financial statements. The Company defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Where observable prices or inputs are not available, valuation models are applied. These valuation techniques involve some level of management estimation and judgment, the degree of which is dependent on the price transparency for the instruments or market and the instruments complexity.

The Company's financial assets and liabilities consist principally of cash and cash equivalents, accounts receivable, and accounts payable. The fair value of the Company's cash equivalents is determined based on quoted prices in active markets for identical assets. Cash in the Company's operating bank accounts represents the difference between cash in the money market accounts and total cash and cash equivalents reported on the consolidated balance sheets. The recorded values of the Company's accounts receivable and accounts payable approximate their current fair values due to the relatively short-term nature of these accounts.

(u) Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Common stock equivalents are comprised of restricted stock units, warrants to purchase common stock and options outstanding under the stock option plans. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding since the effects of potentially dilutive securities are antidilutive due to the net loss position.

(v) Recent Accounting Pronouncements

In October 2020, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2020-10—*Codification Improvements.* For public business entities, the amendments in this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The amendments in this update do not change U.S. GAAP and, therefore, are not expected to result in a significant change in practice. Section A was removed from the final update of ASU 2020-10. Section B of this update contains amendments that improve the consistency of the Codification by including all disclosure guidance in the appropriate Disclosure Section (Section 50). Section C of this update contains Codification improvements that vary in nature. Management does not expect that adoption of this guidance will have a significant impact on the Company's financial statements.

In March 2020, the Securities and Exchange Commission (SEC) adopted amendments to change the definitions of *accelerated filer* and *large accelerated filer* to provide relief to smaller reporting companies. The amendments in SEC Release No. 34-88365 to Rule 12b-2 of the Securities Exchange Act of 1934 provide that smaller reporting companies with up to $700 million in public float and less than $100 million in annual revenues in their most recently completed fiscal year are excluded from the definitions and as such are now designated as non-accelerated filers, in addition to all entities with less than $75 million in public float. Management does not expect that adoption of this guidance will have a significant impact on the Company's financial statements.

In December 2019, the FASB issued ASU 2019-12 Income Taxes *(Topic 740): Simplifying the Accounting for Income Taxes*, which removes certain exceptions for intra period allocations, recognizing deferred taxes for investments and calculating income taxes in interim periods. This ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. The guidance is effective for the Company for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. Management does not expect that adoption of this guidance will have a significant impact on the Company's financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses *(Topic 326): Measurement of Credit Losses on Financial Instruments*, an amendment which modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. Accordingly, these financial assets will be presented at the net amount expected to be collected. The amendment also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. For smaller reporting companies the guidance is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. Management does not expect that adoption of this guidance will have a significant impact on the Company's financial statements.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, and the American Institute of Certified Public Accountants did not or are not believed by management to have a material impact on the Company's financial statement presentation or disclosures.

(3) Fair Value Measurements

The fair value of financial instruments reflects the amounts that the Company estimates to receive in connection with the sale of an asset or paid in connection with the transfer of a liability in an orderly transaction between market participants at the measurement date (exit price). The Company follows a fair value hierarchy that prioritizes the use of inputs used in valuation techniques into the following three levels:

Level 1 – quoted prices in active markets for identical assets and liabilities

Level 2 – observable inputs other than quoted prices in active markets for identical assets and liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities

Level 3 – unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities

The following table sets forth the fair value of the financial assets measured on a recurring basis as of December 31, 2020 and 2019 and indicates the fair value hierarchy utilized to determine such fair value (in thousands).

	As of December 31, 2020			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds	$ 20,662	$ -	$ -	$ 20,662
Cash in checking accounts	-	-	-	745
Total cash and cash equivalents	$ 20,662	$ —	$ —	$ 21,407

	As of December 31, 2019			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds	$ 4,637	$ -	$ -	$ 4,637
Cash in checking accounts	-	-	-	948
Total cash and cash equivalents	$ 4,637	$ —	$ —	$ 5,585

(4) Inventories

Inventories are stated at the lower of cost or net realizable value using the average cost method. Inventories consist of the following (in thousands):

	December 31,	
	2020	2019
Raw materials	$ —	$ —
Work in process	—	—
Finished goods	—	4
Total	$ —	$ 4

Write downs for excess or expired inventory are based on management's estimates of forecasted usage of inventories and are included in cost of goods sold. A significant change in the timing or level of demand for certain products as compared to forecasted amounts may result in recording additional write downs for excess or expired inventory in the future. Charges to cost of goods sold for inventory write-downs, reserve adjustments, scrap, shrinkage and expired inventories totaled approximately $2,000 and $36,000 for the years ended December 31, 2020, and 2019, respectively.

(5) Property and Equipment, Net

Property and equipment, net consist of the following (in thousands):

	December 31,	
	2020	2019
Computer equipment and software	$ 159	$ 132
Laboratory and manufacturing equipment	550	550
Furniture and fixtures	59	55
Leasehold improvements	332	332
Construction in progress	70	69
Property and equipment, gross	1,170	1,138
Less accumulated depreciation	(1,025)	(957)
Property and equipment, net	$ 145	$ 181

Depreciation expense totaled approximately $68,000 and $111,000 for the years ended December 31, 2020 and 2019, respectively. All of the Company's property and equipment is located in the United States.

(6) Operating Lease Right-of-Use Assets, Net

The Company determines if an arrangement is a lease at inception by assessing whether it conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company's operating lease, which expires in December 2021, is related to a property lease for its laboratory and corporate offices. BioCardia's lease agreement does not contain any material residual guarantees or material restrictive covenants, nor does it contain an additional lease extension.

ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. The Company's lease does not provide an implicit rate. The Company used an adjusted historical incremental borrowing rate, based on the information available at the approximate lease commencement date, to determine the present value of lease payments. The net lease asset was adjusted for deferred rent, lease incentives, and prepaid rent. Variable rent expense is made up of expenses for common area maintenance and shared utilities and were not included in the determination of the present value of lease payments. The Company has no finance leases.

The components of lease expense for the year ended December 31, 2020 and 2019, respectively, was as follows (in thousands, except years and percentages):

	December 31,	
	2020	2019
Straight-line rent expense recognized for operating lease	$ 601	$ 601
Variable rent expense recognized for operating lease	395	264
Total rent expense	$ 996	$ 865
Weighted average remaining lease term (in years)	1.0	2.0
Weighted average discount rate	12.05%	12.05%

Supplemental cash flow information related to the operating lease was as follows (in thousands):

	December 31,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities	$ 630	$ 612
Cash lease expense (imputed interest expense component of net income)	$ 103	$ 161

Future minimum lease payments under the operating lease as of December 31, 2020 are as follows (in thousands):

For the years ending December 31,	
2021	$ 649
2022	—
2023	—
Thereafter	—
Total undiscounted lease payments	649
Less imputed interest	35
Total operating lease liabilities	$ 614

(7) Collaborative Agreements

The Company has entered into various collaborations related to clinical development. These agreements allow partners to utilize the Company's enabling biotherapeutic delivery systems, including training and support during clinical and preclinical delivery of biotherapeutics. Under the terms of these agreements, the Company typically receives a use fee and payments for the systems and services provided. The Company gains access to certain data generated by its partners for use in its own product development efforts and also receives nonexclusive patent rights to any partner discovered BioCardia technology improvement inventions. Revenue from collaborative agreements is recognized in the Consolidated Statements of Operations in the line "Collaboration agreement revenue."

(8) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2020	2019
Accrued expenses	$ 87	$ 10
Accrued salaries and employee benefits	961	652
Accrued director compensation	—	648
Accrued clinical trial costs	452	519
Grant liability	615	630
Customer deposits	90	102
Total	$ 2,205	$ 2,561

(9) Note payable under Paycheck Protection Program

On May 1, 2020, BioCardia Lifesciences, Inc. (the Borrower), a wholly owned subsidiary of BioCardia, Inc. (the Company), entered into a promissory note (the Note) with Silicon Valley Bank (the Lender) evidencing an unsecured loan in the aggregate principal amount of $506,413 pursuant to the Paycheck Protection Program (the PPP) of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) administered by the U.S. Small Business Administration. All the funds under the Note were disbursed to the Borrower on May 1, 2020.

In accordance with the requirements of the CARES Act, the Borrower used the proceeds from the Note in accordance with the requirements of the PPP to cover certain qualified expenses, including payroll costs, rent and utility costs. Interest accrued on the Note at the rate of 1.00% per annum. The Borrower may apply for forgiveness of amount due under the Note, in an amount equal to the sum of qualified expenses under the PPP, which include payroll costs, rent obligations, and covered utility payments incurred during the eight weeks following disbursement under the Note. On June 5, 2020, the Paycheck Protection Flexibility Act extended the period for qualifying expenses from eight weeks to an optional twenty-four-week period.

Subject to any forgiveness under the PPP, the Note would have matured two years following the date of issuance of the Note and include a period for the first six months during which time required payments of interest and principal would be deferred. On October 7, 2020, the Company applied for forgiveness of the note payable with the Lender. That application for forgiveness of $506,000 and related interest payable of $3,000 was approved in its entirety on November 2, 2020. Accordingly, $509,000 is presented as a gain on extinguishment of Paycheck Protection Program note payable in the accompanying consolidated statements of operations for the year ended December 31, 2020.

(10) Stockholders' Equity

$10.5 Million Registered Direct Offering - On December 15, 2020, the Company entered into a securities purchase agreement with certain institutional investors (the December 15 Purchase Agreement) for the sale of an aggregate of 2,038,836 shares (the December 15 Shares) of the Company's common stock, $0.001 par value per share (the Common Stock), at a price to the public of $5.15 per share (the December 15 Registered Offering) share for gross proceeds of approximately $10.5 million before deducting the fees of A.G.P./Alliance Global Partners, which acted as placement agent, and related offering expenses. The Company paid the placement agent a cash fee equal to 7.0% of the gross proceeds generated from the sale of the December 15 Shares. On December 18, 2020, BioCardia concluded the Purchase Agreement with the purchasers of the December 15 Shares. The Company intends to use the net proceeds for working capital and general corporate purposes, which include, but are not limited to, completing enrollment in the ongoing CardiAMP Cell Therapy pivotal trial for the treatment of heart failure, the funding of clinical development and pursuing regulatory approval for BioCardia's product candidates. After deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, BioCardia realized net proceeds of approximately $9.8 million. The December 15 Offering was made pursuant to a Registration Statement on Form S-3, which was filed by the Company with the Securities and Exchange Commission on October 9, 2020, and declared effective on October 20, 2020, as supplemented by a prospectus supplement dated December 15, 2020.

$8.5 Million Registered Direct Offering - On December 14, 2020, the Company entered into a securities purchase agreement with certain institutional investors (the December 14 Purchase Agreement) for the sale of an aggregate of 1,789,474 shares (the December 14 Shares) of the Company's common stock, $0.001 par value per share (the Common Stock), at a price to the public of $4.75 per share (the December 14 Registered Offering) for gross proceeds of approximately $8.5 million before deducting the fees of A.G.P./Alliance Global Partners, which acted as placement agent, and related offering expenses. The Company paid the placement agent a cash fee equal to 7.0% of the gross proceeds generated from the sale of the December 14 Shares and reimbursed the Placement Agent for certain of its expenses in an amount not to exceed $40,000. On December 16, 2020, BioCardia concluded the Purchase Agreement with the purchasers of the December 14 Shares. The Company intends to use the net proceeds for working capital and general corporate purposes, which include, but are not limited to, completing enrollment in the ongoing CardiAMP Cell Therapy pivotal trial for the treatment of heart failure, the funding of clinical development and pursuing regulatory approval for BioCardia's product candidates. After deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, BioCardia realized net proceeds of approximately $7.8 million. The December 14 Offering was made pursuant to a Registration Statement on Form S-3, which was filed by the Company with the Securities and Exchange Commission on October 9, 2020, and declared effective on October 20, 2020, as supplemented by a prospectus supplement dated December 14, 2020.

2020 Public Offering on Form S-1 Registration Statement - In May 2020, the Company submitted a Form S-1 Registration Statement (S-1) to the SEC, which was subsequently amended. On June 17, 2020, the Company entered into an underwriting agreement with A.G.P./Alliance Global Partners, as representative of the several underwriters named therein, relating to a firm commitment underwritten public offering pursuant to the S-1, of 4,762,000 shares of common stock, par value of $0.001 per share. The offering price to the public was $2.10 per share. The underwriters were granted a 45-day option to purchase up to 714,190 additional shares of common stock to cover over-allotments. Such option was exercised in full on June 18, 2020. The closing of the offering occurred on June 19, 2020. After deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, BioCardia realized net proceeds of approximately $10.3 million.

On June 8, 2020, the Company issued 29,625 shares of common stock to two former Board members to settle in lieu of cash their accrued board compensation liability of approximately $148,000.

Public Offering on Form S-1 Registration Statement - In April 2019, the Company submitted a Form S-1 Registration Statement (S-1) to the SEC, which was subsequently amended. On August 2, 2019, the Company entered into an underwriting agreement with Maxim Group LLC, as representative of the several underwriters named therein, relating to a firm commitment underwritten public offering pursuant to the S-1, of 1,666,667 units consisting of one share of common stock, par value of $0.001 per share, and a warrant to purchase one share of common stock. The offering price to the public was $6.00 per unit. The warrants, which are equity classified, are immediately exercisable for shares of common stock at a price of $6.30 per share and expire five years from the date of issuance. In addition, the underwriters were granted 11,958 warrants exercisable at a per warrant exercise price of $6.60 as part of their compensation. The underwriters were granted a 45-day option to purchase up to 250,000 additional shares of common stock, and/or 250,000 additional warrants to cover over-allotments, if any. The closing of the offering occurred on August 6, 2019. After deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, BioCardia realized net proceeds of approximately $8.8 million. On September 4, 2019, the underwriters exercised the over-allotment and purchased 75,000 shares of common stock and 250,000 warrants for net proceeds of approximately $420,000, after deducting underwriting discounts of approximately $32,000.

Up List to Nasdaq - On August 2, 2019, the Company's common stock and warrants to purchase common stock began trading on the Nasdaq Capital Market. Previously, the common stock was quoted on the OTCQB Marketplace (OTCQB) under the symbol, "BCDA." "BCDA" and "BCDAW" are the trading symbols for the Company's common stock and warrants to purchase common stock, respectively, on the Nasdaq Capital Market.

Convertible Note Financing - On July 5, 2019, BioCardia entered into a note purchase agreement pursuant to which the Company issued on such date $625,000 in aggregate principal amount of convertible promissory notes to accredited investors, a portion of which were certain of the Company's officers and directors and a principal stockholder (or their respective affiliates). The notes accrued 14.0% simple interest and mature six months from the issue date, on January 5, 2020. If at any time prior to the maturity date, the Company closes a public stock offering for the purpose of raising capital in which the Company's common stock is listed or quoted on the New York Stock Exchange, the Nasdaq Global Select Market, the Nasdaq Global Market or the Nasdaq Capital Market, the outstanding principal and interest would automatically convert into the securities offered in the financing at a unit price equal to a 50% discount to the qualified financing price. The convertible notes conversion features were determined to be an embedded derivative requiring bifurcation and separate accounting at estimated fair value. The fair value of the derivative was treated as a discount on the notes, which is subject to accretion over the term of the note. The change in fair value of the derivative liability was approximately $52,000. The loss on extinguishment of the convertible notes approximated $521,000. Interest expense on the notes for the year ended December 31, 2019 totaled $112,000 and included $104,000 of accretion of the discount.

Upon the closing of the Company's public offering of units on August 6, 2019 the unpaid principal and interest on the convertible notes totaling approximately $633,000, converted into 210,887 units, each unit consisting of one share of common stock and a warrant to purchase one share of common stock, at a conversion price of $3.00 per unit. Holders of the convertible notes had the option of converting the notes into units of one share of common stock and a warrant at a unit price of $8.00 prior to the automatic conversion in the Company's public offering. The warrants have the same terms, including exercise price and expiration date, as the warrants issued in the public offering.

Reverse Stock Split - On June 6, 2019, the Company effected a 1-for-9 reverse stock split of the Company's common stock. Neither the par value nor the authorized number of shares was adjusted as a result of the reverse stock split. All issued and outstanding common stock, warrants, stock options, restricted stock units and per share amounts contained in the accompanying consolidated financial statements and notes to the consolidated financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presented.

Sales of Unregistered Common Stock and Warrants - On December 24, 2018, the Company entered into a Securities Purchase Agreement with entities affiliated with BioCardia's existing investors (the "Investors"), relating to an offering and sale of an aggregate of 592,592 shares (as adjusted) of the Company's common stock at a purchase price of $6.75 per share (as adjusted), and warrants to purchase up to one-half of the number of shares of common stock sold to an Investor, up to an aggregate for all Investors of 296,296 shares (as adjusted) of common stock, for aggregate net proceeds of $3.8 million net of $200,000 expenses. The warrants are exercisable immediately for cash and, because six months have passed, are also exercisable on a cashless basis until an effective registration statement has been filed registering the resale of the shares issuable upon exercise of the warrants. As of December 31, 2020, no effective registration statement had been filed. Warrants can be settled in unregistered shares. The warrants have an exercise price of $6.75 per share and will expire on December 24, 2023. The issued warrants are stand-alone financial instruments and were equity classified in additional paid-in capital in accordance with U.S. GAAP.

Warrants – Set forth below is a table of activity of warrants for common stock and the related weighted average exercise price per warrant.

	Number of Common Stock Warrants	Weighted Average Exercise Price
Balance, December 31, 2019	2,435,807	$ 6.36
Warrants for common stock sold	—	—
Warrants for common stock exercised	(11,083)	6.60
Balance, December 31, 2020	2,424,724	$ 6.36

On December 24, 2020, a warrant holder exercised 11,083 warrants for common stock using cashless exercise provisions, resulting in the issuance of 470 shares of common stock.

(11) Share-Based Compensation

BioCardia Lifesciences adopted, and the BioCardia Lifesciences shareholders approved, the 2002 Stock Plan in 2002 (the "2002 Plan"), and the Company assumed the 2002 Plan in the Merger. The Company has not granted or does not intend to grant any additional awards under the 2002 Plan following the Merger. In 2016, BioCardia Lifesciences adopted, and the BioCardia Lifesciences shareholders approved, the 2016 Equity Incentive Plan (the "2016 Plan"), and the Company assumed the 2016 Plan in the Merger. BioCardia has granted awards, including incentive stock options and non-qualified stock options, under the 2016 Plan following the Merger. Under the 2002 Plan and the 2016 Plan, the number of shares, terms, and vesting periods are determined by the Company's board of directors or a committee thereof on an option-by-option basis. Options generally vest ratably over service periods of four years and expire ten years from the date of grant. The per share exercise price shall be no less than the fair market value on the date of grant. Compensation cost for employee share-based awards is based on the grant-date fair value and is recognized over the vesting period of the applicable award on a straight-line basis. The number of shares reserved for issuance or transfer pursuant to awards under the 2016 Plan will be increased by (i) the number of shares represented by awards outstanding under 2016 Plan that are returned to the plan because they are either forfeited or lapse unexercised or that are repurchased for the original purchase price thereof, (ii) if approved by the Administrator of the 2016 Plan, an annual increase on the first day of each fiscal year equal to the lessor of (A) 4% of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year; (B) 268,997 shares (1,000,000 shares effective January 1, 2021). As of December 31, 2020, 160,020 shares have been authorized and available for awards under the 2016 Plan.

The Company recognizes in the consolidated statements of operations the grant-date fair value of stock options and other equity-based compensation. Share-based compensation expense for the years ended December 31, 2020 and 2019 was recorded as follows (in thousands):

	Years ended December 31,	
	2020	2019
Cost of goods sold	$ -	$ 191
Research and development	1,369	1,115
Selling, general and administrative	1,583	1,416
Total stock-based compensation	$ 2,952	$ 2,722

On January 29, 2020 (the "repricing date"), the Company's Board of Directors repriced certain previously granted and still outstanding vested and unvested stock option awards held by employees, executives, and certain service providers of the Company; as a result, the exercise price was lowered to $5.32 per share. No other terms of the repriced stock options were modified, and the repriced stock options will continue to vest according to their original vesting schedules and will retain their original expiration dates. As a result of the repricing, 515,036 vested and unvested stock options outstanding with original exercise prices ranging from $10.05 to $97.21, were repriced.

The repricing on January 29, 2020 resulted in incremental stock-based compensation expense of $569,000, of which $412,000 related to vested employee stock option awards and was expensed on the repricing date, and $157,000 related to unvested stock option awards and is being amortized on a straight-line basis over the approximately three year remaining weighted average vesting period of those awards.

The following table summarizes activity under the Company's stock option plans, including the 2002 Plan and the 2016 Plan and related information (in thousands, except share and per share amounts and term):

	Options outstanding			
	Number of shares	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Balance, December 31, 2019	821,464	$ 18.99	7.6	$ -
Stock options granted	342,232	3.10		
Stock options exercised	—	—		
Stock options cancelled	(49,390)	12.79		
Balance, December 31, 2020	1,114,306	$ 5.89	7.5	$ 177.1
Options exercisable December 31, 2020	615,470	$ 7.51	6.3	$ 15.6
Options vested and expected to vest	1,114,306	$ 5.89	7.5	$ 177.1

The aggregate intrinsic value represents the difference between the total pre-tax value (i.e., the difference between the Company's stock price and the exercise price) of stock options outstanding as of December 31, 2020, based on the Company's common stock closing price of $3.46 per share, which would have been received by the option holders had all their in-the-money options been exercised as of that date.

The total intrinsic value of options exercised during the years ended December 31, 2020 and 2019 was zero in both years. The weighted average grant-date BSM fair value of options granted during the years ended December 31, 2020 and 2019 was $1.73 and $3.87 per share, respectively.

Employee, Director and Non-employee Share-Based Compensation

During the years ended December 31, 2020 and 2019, the Company granted stock options to certain employees, non-employee directors and non-employees to purchase 342,232 and 254,785 shares of common stock, respectively. The fair value of each option grant was estimated on the date of the grant using the BSM option pricing model with the following assumptions:

	Years ended December 31,	
	2020	2019
Risk-free interest rate	0.4 - 1.6%	1.40 - 2.14%
Volatility	107 - 112%	74 - 94%
Dividend yield	None	None
Expected term (in years)	6.25 - 10.0	6.25 - 10.0

Unrecognized share-based compensation for employees, non-employee directors and non-employee options granted through December 31, 2020 is approximately $2.1 million to be recognized over a remaining weighted average service period of 2.2 years.

Share-Based Compensation (RSUs)

During the years ended December 31, 2020 and 2019, respectively, the Company granted to certain members of management 113,976 and 34,713 restricted stock units, or RSUs in lieu of paying bonuses. The fair value of each RSU is estimated on the closing market price of the Company's common stock on the grant date.

During the year ended December 31, 2020, the Company granted 122,977 RSUs to board members to settle $613,000 of board compensation earned from April 2018 to March 30, 2020. The associated compensation expense was recognized when earned. During the year ended December 31, 2020, the Company granted 69,321 RSUs to board members and recognized approximately $190,000 in stock compensation expense for board service from April 1, 2020 to December 31, 2020. The RSUs were granted on a quarterly basis and were calculated based on $92,500 divided by the greater of $4 or the closing share price of the Company's common stock on the last trading day of the fiscal quarter. These RSUs represent a contingent right to receive one share of common stock, but for which delivery of the stock will occur on the earlier of the two-year anniversary of the grant, the board member's separation from the Company, a change in control as defined by the 2016 Equity Incentive Plan or the board member's death.

The following table summarizes the activity for RSUs during the year ended December 31, 2020:

	Number of shares	Weighted average grant date fair values per share
Balance, December 31, 2019	36,981	$ 10.56
RSUs granted	381,094	3.93
RSUs vested and settled	(137,603)	5.48
RSUs forfeited	(56,161)	3.75
Balance, December 31, 2020	224,311	$ 4.12

RSUs vested and settled are converted into the Company's common stock on a one-for-one basis. RSUs are generally subject to forfeiture if employment terminates prior to the release of vesting restrictions. Of the 224,311 RSUs outstanding on December 31, 2020, 216,111 RSUs are vested and have not been settled and 8,200 have not yet vested. The related compensation expense, which is based on the grant date fair value of the Company's common stock multiplied by the number of units granted, is recognized ratably over the period during which the vesting restrictions lapse. Unrecognized share-based compensation for RSUs granted through December 31, 2020 was approximately $37,000 to be recognized over a remaining weighted average service period of 2.3 years.

(12) Concentrations

Most of the Company's customers are located in the United States. Two customers accounted for approximately 70% and 16% of total revenues in 2020. Two customers accounted for approximately 43% and 25% of total revenues in 2019. Three customers accounted for approximately 22%, 18% and 11% of accounts receivable on December 31, 2020. One customer accounted for 15% of accounts receivable on December 31, 2019.

(13) Net Loss per Share

The following table sets forth the computation of the basic and diluted net loss per share for the years ended December 31, 2020 and 2019 (in thousands, except share and per share data):

	Years ended December 31,	
	2020	2019
Numerator:		
Net loss	$ (15,004)	$ (14,709)
Denominator:		
Weighted average shares used to compute net loss per share, basic and diluted	10,118,682	5,644,328
Net loss per share, basic and diluted	$ (1.48)	$ (2.61)

The following weighted-average outstanding common stock equivalents were excluded from the computation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	At December 31,	
	2020	2019
Stock options to purchase common stock	1,114,306	821,464
Unvested restricted stock units	8,200	36,981
Common stock warrants	2,424,724	2,435,808
Total	3,547,230	3,294,253

(14) Income Taxes

The Company's provision for income taxes for the years ended December 31, 2020 and 2019 was $0 for both years.

The provision for income taxes differs from the amount which would result by applying the federal statutory income tax rate to pre-tax loss for the years ended December 31, 2020 and 2019. The reconciliation of the provision computed at the federal statutory rate to the Company's provision (benefit) for income taxes was as follows (in thousands):

	Years ended December 31,	
	2020	2019
Tax at federal statutory rate	$ (3,151)	$ (3,089)
State, net of federal benefit	(449)	(414)
Research and development credit	(276)	(225)
Share-based compensation	649	446
PPP Note forgiveness	(107)	-
Other	2	5
Change in valuation allowance	3,332	3,277
Total provision for income taxes	$ —	$ -

Deferred income taxes reflect the net tax effects of temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes as well as net operating loss and tax credit carryforwards, net of any adjustment for unrecognized tax benefits. The components of the net deferred income tax assets as of December 31, 2020 and 2019 were as follows (in thousands):

	Years ended December 31,	
	2020	2019
Accrued compensation	$ 225	$ 148
Inventory adjustments	335	297
Depreciation and amortization	90	98
Share-based compensation	686	744
Net operating loss and tax credit carryforwards	26,931	23,809
Other	173	11
Gross Deferred Tax Asset	28,440	25,107
Valuation Allowance	(28,440)	(25,107)
Net deferred tax asset	$ -	$ -

The Company has approximately $91.5 million and $62.7 million of federal and state net operating loss (NOL) carryforwards, respectively, as of December 31, 2020. For tax reporting purposes, operating loss carryforwards are available to offset future taxable income; such carryforwards expire in varying amounts beginning in 2022 and 2028 for federal and state purposes, respectively, with 2020, 2019, and 2018 federal NOLs having no expiration date. Under current federal and California law, the amounts of and benefits from net operating losses carried forward may be impaired or limited in certain circumstances. Events which may cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50% over a three-year period.

Generally, utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by section 382, which discusses limitations on NOL carryforwards and certain built-in losses following ownership changes, and section 383, which discusses, special limitations on certain excess credits, etc., of the Internal Revenue Code (IRC) of 1986, as amended and similar state provisions. Accordingly, the Company's ability to utilize net operating loss carryforwards and tax credit carryforwards may be limited, potentially significantly, as the result of such an "ownership change." The Company has not yet performed a comprehensive study to determine if it has undergone any ownership changes. If the Company is able to potentially utilize its net operating loss carryforwards and tax credit carryforwards, it will perform a comprehensive section 382 and 383 study to determine what, if any, limitation on its ability to utilize its NOLs exists.

As of December 31, 2020, the Company has federal and state research and development credits of approximately $2.8 million and $2.1 million available to offset future federal and state income taxes, respectively. The federal tax credit carryforward expires beginning in 2028. The state credit carryforwards have no expiration.

The Company does not believe that these assets are realizable on a more likely than not basis; therefore, the net deferred tax assets have been fully offset by a valuation allowance. The Company did not have deferred tax liabilities as of December 31, 2020 or 2019. The net increase in the total valuation allowance for the year ending December 31, 2020 is $3.3 million, primarily from the net operating losses generated. The net increase in the total valuation allowance for the year ending December 31, 2019 is $3.2 million, primarily from the net operating losses generated. No liability related to uncertain tax positions is reported in the financial statements.

The aggregate changes in the balance of gross unrecognized tax benefits were as follows (in thousands):

	Years ended December 31,	
	2020	2019
Balance, beginning of year	$ 1,046	$ 891
Additions based on tax positions related to the current year	189	155
Balance, end of year	$ 1,235	$ 1,046

Recognition of approximately $895,000 and $753,000 of unrecognized tax benefits would impact the effective rate at December 31, 2020 and 2019 respectively, if recognized. Increases in 2020 and 2019 relate to increased research and development activity.

On May 1, 2020, the Company received loan proceeds in the amount of approximately $506,413 under the Paycheck Protection Program. The PPP, established as part of the CARES Act, provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loans and accrued interest are forgivable after eight weeks as long as the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels.

The Consolidated Appropriations Act, 2021, P.L. 116-260, enacted on Dec. 27, 2020, resolved the issue of whether taxpayers can take deductions for expenses paid with forgiven PPP loans. The act clarified that gross income does not include any amount that would otherwise arise from the forgiveness of a PPP loan. It also clarified that deductions are allowed for otherwise deductible expenses paid with the proceeds of a PPP loan that is forgiven and that the tax basis and other attributes of the borrower's assets will not be reduced as a result of the loan forgiveness.

The Company applied for and received a PPP loan for $506,413 during 2020. The Company was approved for forgiveness on the entire loan balance and related interest payable of $3,000 on November 2, 2020.

The Company is subject to U.S. federal, California, Colorado, Florida and North Carolina income taxes. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company was incorporated in 2002 and is subject to U.S. federal, state, and local tax examinations by tax authorities for all prior years.

(15) Contingencies and Uncertainties

Contingencies - The Company may be subject to various claims, complaints, and legal actions that arise from time to time in the normal course of business. Management is not aware of any current legal or administrative proceedings that are likely to have an adverse effect on the Company's business, financial position, results of operations, or cash flows.

Uncertainties - The results for the year ended December 31, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or for any other interim period or for any other future year, particularly in light of the novel coronavirus pandemic, or COVID-19, and its impact on domestic and global economies. To limit the spread of COVID-19, governments have taken various actions including the issuance of stay-at-home orders and social distancing guidelines, causing some businesses to suspend operations and/or experience a reduction in demand for many products from direct or ultimate customers. Accordingly, businesses have adjusted, reduced or suspended operating activities and are continuing to adapt to these changing actions and guidelines.

Beginning March 17, 2020, substantially all of the Company's workforce began working from home. On April 6, 2020, manufacturing operations resumed at the Company's facilities, with a number of other staff continuing to work from home. While the direct effects of the stay-at-home orders and BioCardia's work-from-home policies have been largely mitigated during the year ended December 31, 2020, the overall impact of the pandemic resulted in disruption to the Company's business and in delays in the Company's development programs and regulatory and commercialization timelines. The overall magnitude of the continuing impact will depend, in part, on the length and severity of changing restrictions and other limitations on BioCardia's ability to conduct the Company's business. BioCardia's future research and development expenses and general and administrative expenses may vary significantly if the Company experiences an increased impact from COVID-19 on the costs and timing associated with the conduct of BioCardia's clinical trials and other related business activities.

As the outbreak continues to mutate and spread, it may affect the Company's operations and those of third parties on which the Company relies, including causing disruptions in the supply of the Company's product candidates and the conduct of current and planned preclinical and clinical studies. BioCardia may need to limit operations and may experience limitations in employee resources. There are risks that the COVID-19 outbreak may be more difficult to contain if the outbreak reaches a larger population or broader geography, in which case the risks described herein could be elevated significantly. The extent to which the coronavirus impacts the Company's results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Additionally, while the potential economic impact brought by, and the duration of, a coronavirus pandemic is difficult to assess or predict, the impact of the coronavirus on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity, and the Company's ability to complete its preclinical and clinical studies on a timely basis, or at all. The Company was successful in raising additional funding in 2020 (See Note 10). However, the ultimate impact of coronavirus is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business, financing, preclinical and clinical trial activities or the global economy as a whole. However, these effects could have a material, adverse impact on the Company's liquidity, capital resources, operations and business and those of the third parties on which BioCardia relies.

(16) Grant Funding

In June 2016, the Company entered into a grant agreement with Maryland Technology Development Corporation (TEDCO). TEDCO was created by the Maryland State Legislature in 1998 to facilitate the transfer and commercialization of technology from Maryland's research universities and federal labs into the marketplace. TEDCO administers the Maryland Stem Cell Research Fund to promote State funded stem cell research and cures through financial assistance to public and private entities operating within the State. Under the agreement, TEDCO has agreed to provide the Company an amount not to exceed $750,000 to be used solely to finance the costs to conduct the research project entitled "Heart Failure Trial" over a period of three years. This agreement has been extended for another year to June 2021.

As of December 31, 2020, the Company has received approximately $750,000 under the grant which is accounted for as a reduction to research and development expenses as the related qualifying costs are incurred. Approximately $135,000 of the qualifying costs had been incurred as of December 31, 2020. The remaining $615,000 was recorded as grant liability on the consolidated balance sheet at December 31, 2020. The amount is recorded as a liability as the amounts are refundable, should a default by the Company, as defined in the agreement, occur prior to incurring the qualifying costs.

(17) Related Party Transactions

Litigation Funding Agreement

On April 9, 2020, BioCardia, Inc. entered into a Litigation Funding Agreement (the Funding Agreement) with BSLF, L.L.C. (the Funder), an entity owned and controlled by Andrew Blank, Chair of BioCardia's board of directors, for the purpose of funding the Company's currently pending legal proceedings and any and all claims, actions and/or proceedings relating to or arising from the case captioned Boston Scientific Corp., et al., v. BioCardia Inc., Case No. 3:19-05645-VC, U.S.D.C., N. D. Cal (the Litigation). BioCardia seeks imposition of constructive trusts both on the patents naming Ms. Sarna as an inventor and the proceeds received from the sale of nVision to Boston Scientific, as well as damages, including unjust enrichment damages measured by the proceeds received from the sale of nVision to Boston Scientific.

Under the terms of the Funding Agreement, the Funder agreed to fund the legal fees and costs incurred by the Company in connection with the Litigation on and after March 1, 2020 on a non-recourse basis. The Company agreed to repay the Funder from any proceeds arising from the Litigation (the Litigation Proceeds), (i) any taxes paid by or imposed upon Funder (other than taxes imposed upon Funder as a consequence of Funder's income) with respect to the claims, the litigation proceeds or as a consequence of any settlement in connection with the Litigation, if any, plus (ii) an amount, without reduction, set-off or counterclaim, equal to the amount actually paid by the Funder pursuant to the Funding Agreement (the Actual Funding Amount) plus (iii) the greater of:

50% of the remaining Litigation Proceeds, up to three times the Actual Funding Amount; or

30% of the remaining Litigation Proceeds.

Although the Company is required under the terms of the Funding Agreement to consult with the Funder regarding any settlement in connection with the Litigation and to allow Funder to participate in any real-time settlement negotiations, the Company has the sole and exclusive right to settle on whatever terms it deems acceptable.

The Funding Agreement may be terminated by Funder upon ten days' written notice to the Company. Funder is obligated to fund only the fees and costs incurred in the Litigation through the end of the month in which the termination notice was served. BioCardia may terminate the agreement upon ten days' written notice to Funder from and after a failure by Funder to fulfill its obligations under the Funding Agreement if such failure or material breach is continuing at the end of such ten-day period. Under the terms of the agreement, the total due from the related party as of December 31, 2020 is approximately $618,000.

On March 12, 2021, the Company agreed to settle the Litigation, which is pending final documentation and dismissal. The Company expects the settlement will not result in any material benefit or liability to the Company.

OPKO

BioCardia, Inc. and OPKO Health, Inc. (OPKO) previously entered into a consulting agreement dated August 19, 2016, between the Company and OPKO (the Consulting Agreement). The chairman and chief executive officer of OPKO is a beneficial owner of more than 5% of the outstanding shares of the Company's common stock.

Pursuant to the terms of the Consulting Agreement, OPKO was to provide advisory services to the Company in support of strategic transactions, financings and other matters as agreed between the parties from time to time. Also, in August 2016, the Company granted OPKO a ten-year option to purchase 46,553 shares of common stock, with a 4-year vesting period and an exercise price of $16.20 per share, to OPKO as consideration for consulting services to be provided under the Consulting Agreement. The term of the Consulting Agreement was initially for four years and was to have been automatically renewed for successive one-year periods.

Effective August 29, 2019, the Company and OPKO mutually agreed to terminate the Consulting Agreement without penalty or payment of any kind as the services under the Consulting Agreement were no longer necessary. In connection with the termination of the Consulting Agreement, OPKO's option grant was amended such that it is unaffected by the termination of the Consulting Agreement and will continue to vest and remain outstanding for the remainder of its ten-year term unless earlier exercised. As a result of this modification of the option grant, all future unrecognized stock-based compensation expense was remeasured and recognized in August 2019. BioCardia recorded $225,000 expense (of which $167,000 pertains to the option modification) in share-based compensation expense related to the OPKO stock option in selling, general and administrative expense during the year ended December 31, 2019.

Convertible Note Financing

On July 5, 2019, BioCardia entered into a note purchase agreement pursuant to which the Company issued on such date $625,000 in aggregate principal amount of convertible promissory notes to accredited investors, a portion of which were certain of the Company's officers and directors and a principal stockholder (or their respective affiliates). See note 10 above.

(18) Employee Benefit Plans

The Company's U.S. employees are eligible to participate in a retirement and savings plan that qualifies under Section 401(k) of the IRC. Participating employees may contribute up to 75% of their pretax salary, but not more than statutory limits. The Company made matching contributions of $26,000 and $25,000 during the years ended December 31, 2020 and 2019, respectively.

(19) Subsequent Events

On February 17, 2021, the Company entered into an agreement with a leading international pharmaceutical company to assess the Helix™ Biotherapeutic Delivery System in preclinical testing. Under the terms of the agreement, the Company received a $500,000 up-front payment, a portion of which is creditable for BioCardia biotherapeutic delivery systems, support and training. The agreement includes a one-year option to negotiate a non-exclusive worldwide license for therapeutic delivery of certain cell types for cardiac indications.

On March 29, 2021, the Company and Lincoln Park Capital Fund, LLC, (Lincoln Park) entered into a purchase agreement pursuant to which Lincoln Park purchased $2 million of shares of the Company's common stock (373,832 shares) at a purchase price of $5.35 per share. Under the purchase agreement, the Company has the right to sell to Lincoln Park shares of common stock having an aggregate value of up to $20 million, including the initial $2 million purchase, subject to certain significant limitations of the amount and timing of any such sales due to the terms and conditions set forth in the purchase agreement.

In consideration for entering into the purchase agreement with Lincoln Park, the Company agreed to issue an aggregate of 75,000 shares of common stock as a commitment fee. In addition, the Company agreed to issue to Lincoln Park up to an aggregate of 50,000 additional shares of common stock as a further commitment fee based on a pro-rata percentage of the $20 million of common stock issued to Lincoln Park under the Purchase Agreement as Purchase Shares (as such term is defined in the purchase agreement with Lincoln Park). On March 29, 2021, the Company issued 80,000 shares of common stock as commitment shares (which includes 5,000 commitment shares issued on a pro rata basis in respect of the initial purchase by Lincoln Park of $2 million of shares). The Company will not receive any cash proceeds from the issuance of any of the foregoing commitment shares.

The net proceeds under the purchase agreement to the Company will depend on the frequency and prices at which shares of common stock are sold to Lincoln Park. Actual sales of shares of common stock to Lincoln Park under the purchase agreement and the amount of such net proceeds will depend on a variety of factors, including market conditions, the trading price of the common stock and determination by the Company as to other available and appropriate sources of funding for the Company. The Company expects to use the proceeds from this agreement for general corporate purposes and working capital.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

As previously reported on our Current Report on Form 8-K, filed on November 13, 2020, the Audit Committee (the Audit Committee) of the Company approved the dismissal of KPMG LLP (KPMG), which was then serving as the Company's independent registered public accounting firm. KPMG was dismissed on November 9, 2020 as the Company's independent registered public accounting firm, effective upon completion of their review of the Company's unaudited consolidated financial statements as of and for the three and nine months ended September 30, 2020. On November 9, 2020, the Audit Committee approved the appointment of PKF, LLP as the Company's new independent registered public accounting firm, effective November 11, 2020. Effective December 1, 2020, PKF, LLP changed its name to PKF San Diego, LLP.

During the two fiscal years ended December 31, 2019 and 2018 and the subsequent interim period through November 9, 2020, there were no: (1) disagreements with KPMG LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to their satisfaction, would have caused them to make reference in connection with their opinion to the subject matter of the disagreement, or (2) reportable events, except that KPMG LLP advised BioCardia, Inc. of the following material weakness: a lack of sufficient technical resources to appropriately perform effective and timely review of the accounting for and disclosure of complex non-routine transactions, including the adoption of new accounting standards.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as our controls are designed to do, and management necessarily was required to apply its judgment in evaluating the risk related to controls and procedures.

In connection with the preparation of this Annual Report on Form 10-K, as of December 31, 2020, an evaluation was performed under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2020, our disclosure controls and procedures were, in design and operation, effective.

Changes in Internal Control over Financial Reporting

Other than those noted below under the section titled "Previously Identified Material Weaknesses in Internal Control Over Financial Reporting," there were no changes to our internal control over financial reporting identified in connection with the evaluation required by rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the year ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

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

Management assessed our internal control over financial reporting as of December 31, 2020. Management based its assessment on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2020 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external reporting purposes in accordance with U.S. GAAP. We reviewed the results of management's assessment with the Audit Committee of our Board of Directors.

Previously Identified Material Weaknesses in Internal Control Over Financial Reporting

We previously identified a material weakness in internal control over financial reporting as of September 30, 2019 and for the year ended December 31, 2019. The material weakness resulted from a lack of sufficient technical resources to appropriately perform effective and timely review of the accounting for and disclosure of complex non-routine transactions, including the adoption of new accounting standards. This material weakness was remediated as of December 31, 2020.

We have implemented measures designed to improve our internal control over financial reporting and remediate the material weakness, including the following:

- we enhanced our control processes for identifying and reviewing non-routine transactions, including formalized reviews of these transactions by senior accounting management and more robust documentation of the related conclusions and required accounting; and

- we have engaged external consultants to provide expertise and assistance sufficient to evaluate, resolve and document the accounting for complex non-routine transactions.

Inherent Limitations on Effectiveness of Controls

Our management, including the CEO and CFO, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well-designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of the effectiveness of controls to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Proxy Statement for our 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2020.

We have adopted a Code of Business Conduct and Ethics that applies to all our (1) officers, (2) employees (including our principal executive officer, principal financial officer, principal accounting officer or controller and other employees who perform financial or accounting functions), and (3) agents and representatives, including our independent directors and consultants, who are not employees of ours, with regard to their BioCardia-related activities. Our code of business conduct and ethics is available on our website at www.biocardia.com under the heading "Corporate Governance" under the section titled "Investors". We will post on this section of our website any amendment to our code of business conduct and ethics, as well as any waivers of our code of business conduct and ethics, that are required to be disclosed by the rules of the SEC.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement for our 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2020.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our Proxy Statement for our 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2020.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our Proxy Statement for our 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2020.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for our 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2020.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Documents filed as part of this report are as follows:

1. Consolidated Financial Statements:

Our Consolidated Financial Statements are listed in the "Index to Financial Statements" of BioCardia, Inc. in Part II, Item 8 of this Annual Report on Form 10-K.

2. Financial Statement Schedules

All financial statement schedules have been omitted because they are not required, not applicable, or the required information is included in the financial statements or notes thereto included in this Annual Report on Form 10-K.

3. Exhibits

The documents listed in the Exhibit Index of this Annual Report on Form 10-K are incorporated by reference or are filed with this report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

EXHIBIT INDEX

Exhibit Number	Description
2.1(1)	Agreement and Plan of Merger dated August 22, 2016
2.2(2)	First Amendment to Agreement and Plan of Merger dated October 21, 2016
3.1(3)	Amended and Restated Certificate of Incorporation, as amended May 6, 2019
3.2(4)	Amended and Restated Bylaws
4.1(5)	Specimen common stock certificate
4.2(6)#	BioCardia 2002 Stock Plan, as amended
4.3(7)#	Form of Stock Option Agreement under BioCardia 2002 Stock Plan
4.4*#	BioCardia 2016 Equity Incentive Plan, as amended
4.5(8)#	Form of Stock Option Agreement under BioCardia 2016 Equity Incentive Plan
4.6(9)#	Form of Restricted Stock Unit Agreement under BioCardia 2016 Equity Inventive Plan
4.7(10)#	Form of Warrant for Common Stock Purchase Warrants issued December 24, 2018
4.8(11)	Form of Common Stock Purchase Warrant
4.9(12)	Form of Representative's Warrant
4.10(13)	Description of Registered Securities
4.11(14)#	Form of Director Restricted Stock Unit Agreement under the BioCardia 2016 Equity Incentive Plan
4.12(15)	Registration Rights Agreement, dated March 29, 2021, between the Company and Lincoln Park Capital Fund, LLC.
10.1(16)#	Form of Indemnification Agreement for directors and executive officers
10.2(17)#	Form of Change of Control and Severance Agreement with each executive officer.
10.3(18)	Lease Agreement, dated September 29, 2008, by and between the Company and ARE-San Francisco No. 29, LLC.
10.4(19)	First Amendment to Lease, dated May 31, 2010, by and between the Company and ARE-San Francisco No. 29, LLC.
10.5(20)	Second Amendment to Lease, dated May 29, 2013 by and between the Company and ARE-San Francisco No. 29, LLC.
10.6(21)	Third Amendment to Lease, dated November 4, 2016, by and between the Company and ARE-San Francisco No. 29, LLC.
10.7(22) †	License and Distribution Agreement, dated October 30, 2012, by and between the Company and Biomet Biologics, LLC, as amended.
10.8(23)	Form of Warrant Agreement
10.9(24)	Litigation Funding Agreement dated April 9, 2020, between BSLF, L.L.C. and the Company.
10.11(25)	Consulting Agreement dated February 15, 2021, between the Company and Henricus Duckers, M.D., Ph.D., FESC
10.12(26)	Purchase Agreement, dated March 29, 2021, between the Company and Lincoln Park Capital Fund, LLC.
16.1(27)	Letter from KPMG LLP to the Securities and Exchange Commission dated November 12, 2020.
21.1*	Subsidiaries of the Company
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of PKF San Diego, LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (see page 106 of this Annual Report on Form 10-K).
31.1*	Certification of Principal Executive Officer.
31.2*	Certification of Principal Financial Officer.
32.1**	Certification of Principal Executive Officer Pursuant to Rule 13a-14(b) and Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Title 18, United States Code).
32.2**	Certification of Principal Financial Officer Pursuant to Rule 13a-14(b) and Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Title 18, United States Code).
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase.
101.LAB*	XBRL Taxonomy Extension Label Linkbase.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase.

† Confidential treatment has been granted with respect to certain portions of this Exhibit.
# Indicates management contract or compensatory plan or arrangement.
* Filed herewith.
** Furnished herewith.

(1) Previously filed as Exhibit 2.1 to the Current Report on Form 8-K filed by us on August 25, 2016.
(2) Previously filed as Exhibit 2.2 to the Current Report on Form 8-K filed by us on October 27, 2016.
(3) Previously filed as Exhibit 3.1 to the Quarterly Report on Form 10-Q filed by us on August 14, 2019.
(4) Previously filed as Exhibit 3.2 to the Current Report on Form 8-K filed by us on April 11, 2017.
(5) Previously filed as Exhibit 4.1 to the Current Report on Form 8-K filed by us on October 27, 2016.
(6) Previously filed as Exhibit 10.1 to the Current Report on Form 8-K filed by us on October 27, 2016.
(7) Previously filed as Exhibit 4.3 to the registration statement on Form S-8 filed by us on February 8, 2017.
(8) Previously filed as Exhibit 4.7 to the registration statement on Form S-8 filed by us on February 8, 2017.
(9) Previously filed as Exhibit 4.8 to the registration statement on Form S-8 filed by us on February 8, 2017.
(10) Previously filed as Exhibit 4.1 to the Current Report on Form 8-K filed by us on December 27, 2018.
(11) Previously filed as Exhibit 4.1 to the Current Report on Form 8-K filed by us on August 7, 2019.
(12) Previously filed as Exhibit 4.10 to Amendment No. 3 to the registration statement on Form S-1 filed by us on July 23, 2019.
(13) Previously filed as Exhibit 4.10 to the Annual Report on Form 10-K filed by us on April 9, 2020.
(14) Previously filed as Exhibit 4.1 to the Current Report on Form 8-K filed by us on May 15, 2020.
(15) Previously filed as Exhibit 10.2 to the Current Report on Form 8-K filed by us on March 29, 2021.
(16) Previously filed as Exhibit 10.4 to the Current Report on Form 8-K filed by us on October 27, 2016.
(17) Previously filed as Exhibit 10.2 to the Annual Report on Form 10-K filed by us on March 30, 2017.
(18) Previously filed as Exhibit 10.5 to the Current Report on Form 8-K filed by us on October 27, 2016.
(19) Previously filed as Exhibit 10.6 to the Current Report on Form 8-K filed by us on October 27, 2016.
(20) Previously filed as Exhibit 10.7 to the Current Report on Form 8-K filed by us on October 27, 2016.
(21) Previously filed as Exhibit 10.6 to the Annual Report on Form 10-K filed by us on March 30, 2017.
(22) Previously filed as Exhibit 10.8 to the Current Report on Form 8-K filed by us on October 27, 2016.
(23) Previously filed as Exhibit 10.1 to the Current Report on Form 8-K filed by us on August 7, 2019.
(24) Previously filed as Exhibit 10.1 to the Current Report on Form 8-K filed by us on April 14, 2020.
(25) Previously filed as Exhibit 10.1 to the Current Report on Form 8-K filed by us on May 8, 2020.
(26) Previously filed as Exhibit 10.1 to the Current Report on Form 8-K filed by us on March 29, 2021.
(27) Previously filed as Exhibit 16.1 to the Current Report on Form 8-K filed by us on November 13, 2020.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIOCARDIA INC.

By: /s/ Peter Altman, Ph.D.
Peter Altman, Ph.D.
President and Chief Executive Officer

Date: March 29, 2021

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Peter Altman and David McClung, and each of them, his true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Peter Altman, Ph.D. (Peter Altman, Ph.D.)	President and Chief Executive Officer and Director *(Principal Executive Officer)*	March 29, 2021
/s/ David McClung (David McClung)	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 29, 2021
/s/ Andrew Blank (Andrew Blank)	Chairman of the Board	March 29, 2021
/s/ Jim Allen (Jim Allen)	Director	March 29, 2021
/s/ Richard Krasno, Ph.D. (Richard Krasno, Ph.D.)	Director	March 29, 2021
/s/ Krisztina Zsebo, Ph.D. (Krisztina Zsebo, Ph.D.)	Director	March 29, 2021
/s/ Jay M. Moyes (Jay M. Moyes)	Director	March 29, 2021
/s/ Simon H. Stertzer, M.D. (Simon H. Stertzer, M.D.)	Director	March 29, 2021

BIOCARDIA, INC.

2016 EQUITY INCENTIVE PLAN

(as amended effective December 22, 2020 (the "Effective Date")

1. Purposes of the Plan. The purposes of this Plan are:

- to attract and retain the best available personnel for positions of substantial responsibility,
- to provide additional incentive to Employees, Directors and Consultants, and
- to promote the success of the Company's business.

The Plan permits the grant of Incentive Stock Options, Nonstatutory Stock Options, Restricted Stock, Restricted Stock Units, Stock Appreciation Rights, Performance Units and Performance Shares.

2. Definitions. As used herein, the following definitions will apply:

(a)" Administrator" means the Board or any of its Committees as will be administering the Plan, in accordance with Section 4 of the Plan.

(b)" Applicable Laws" means the requirements relating to the administration of equity-based awards under U.S. state corporate laws, U.S. federal and state securities laws, the Code, any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws of any foreign country or jurisdiction where Awards are, or will be, granted under the Plan.

(c)" Award" means, individually or collectively, a grant under the Plan of Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, Performance Units or Performance Shares.

(d)" Award Agreement" means the written or electronic agreement setting forth the terms and provisions applicable to each Award granted under the Plan. The Award Agreement is subject to the terms and conditions of the Plan.

(e)" Board" means the Board of Directors of the Company.

(f)" Change in Control" means the occurrence of any of the following events:

(i) A change in the ownership of the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than fifty percent (50%) of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection, the acquisition of additional stock by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the stock of the Company will not be considered a Change in Control; or

(ii) A change in the effective control of the Company which occurs on the date that a majority of members of the Board is replaced during any twelve (12) month period by Directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this clause (ii), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change in Control; or

(iii) A change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions; provided, however, that for purposes of this subsection (iii), the following will not constitute a change in the ownership of a substantial portion of the Company's assets: (A) a transfer to an entity that is controlled by the Company's stockholders immediately after the transfer, or (B) a transfer of assets by the Company to: (1) a stockholder of the Company (immediately before the asset transfer) in exchange for or with respect to the Company's stock, (2) an entity, fifty percent (50%) or more of the total value or voting power of which is owned, directly or indirectly, by the Company, (3) a Person, that owns, directly or indirectly, fifty percent (50%) or more of the total value or voting power of all the outstanding stock of the Company, or (4) an entity, at least fifty percent (50%) of the total value or voting power of which is owned, directly or indirectly, by a Person described in this subsection (iii)(B)(3). For purposes of this subsection (iii), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this definition, persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company.

Notwithstanding the foregoing, a transaction will not be deemed a Change in Control unless the transaction qualifies as a change in control event within the meaning of Code Section 409A, as it has been and may be amended from time to time, and any proposed or final Treasury Regulations and Internal Revenue Service guidance that has been promulgated or may be promulgated thereunder from time to time.

Further and for the avoidance of doubt, a transaction will not constitute a Change in Control if: (i) its sole purpose is to change the state of the Company's incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

(g)" Code" means the Internal Revenue Code of 1986, as amended. Reference to a specific section of the Code or regulation thereunder will include such section or regulation, any valid regulation promulgated under such section, and any comparable provision of any future legislation or regulation amending, supplementing or superseding such section or regulation.

(h)" Committee" means a committee of Directors or of other individuals satisfying Applicable Laws appointed by the Board, or a duly authorized committee of the Board, in accordance with Section 4 hereof.

(i)" Common Stock" means the common stock of the Company.

(j)" Company" means BioCardia, Inc., a Delaware corporation, or any successor thereto.

(k)" Consultant" means any natural person, including an advisor, engaged by the Company or a Parent or Subsidiary to render bona fide services to such entity, provided the services (i) are not in connection with the offer or sale of securities in a capital-raising transaction, and (ii) do not directly promote or maintain a market for the Company's securities.

(l)" Director" means a member of the Board.

(m)" Disability" means total and permanent disability as defined in Section 22(e)(3) of the Code, provided that in the case of Awards other than Incentive Stock Options, the Administrator in its discretion may determine whether a permanent and total disability exists in accordance with uniform and non-discriminatory standards adopted by the Administrator from time to time.

(n)" Employee" means any person, including Officers and Directors, employed by the Company or any Parent or Subsidiary of the Company. Neither service as a Director nor payment of a director's fee by the Company will be sufficient to constitute "employment" by the Company.

(o)" Exchange Act" means the Securities Exchange Act of 1934, as amended.

(p)" Exchange Program" means a program under which (i) outstanding Awards are surrendered or cancelled in exchange for awards of the same type (which may have higher or lower exercise prices and different terms), awards of a different type, and/or cash, (ii) Participants would have the opportunity to transfer any outstanding Awards to a financial institution or other person or entity selected by the Administrator, and/or (iii) the exercise price of an outstanding Award is increased or reduced. The Administrator will determine the terms and conditions of any Exchange Program in its sole discretion.

(q)" Fair Market Value" means, as of any date, the value of Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or a national market system, including without limitation the New York Stock Exchange, the NASDAQ Global Select Market, the NASDAQ Global Market or the NASDAQ Capital Market of The NASDAQ Stock Market, its Fair Market Value will be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on such exchange or system on the day of determination, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable;

(ii) If the Common Stock is regularly quoted by a recognized securities dealer but selling prices are not reported, the Fair Market Value of a Share will be the mean between the high bid and low asked prices for the Common Stock on the date of determination (or, if no bids and asks were reported on that date, as applicable, on the last trading date such bids and asks were reported), as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable; or

(iii) In the absence of an established market for the Common Stock, the Fair Market Value will be determined in good faith by the Administrator.

(r)" Fiscal Year" means the fiscal year of the Company.

(s)" Incentive Stock Option" means an Option that by its terms qualifies and is intended to qualify as an incentive stock option within the meaning of Section 422 of the Code.

(t)" Inside Director" means a Director who is an Employee.

(u)" Nonstatutory Stock Option" means an Option that by its terms does not qualify or is not intended to qualify as an Incentive Stock Option.

(v)" Officer" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

(w)" Option" means a stock option granted pursuant to the Plan.

(x)" Outside Director" means a Director who is not an Employee.

(y)" Parent" means a "parent corporation," whether now or hereafter existing, as defined in Section 424(e) of the Code.

(z)" Participant" means the holder of an outstanding Award.

(aa)" Performance Share" means an Award denominated in Shares which may be earned in whole or in part upon attainment of performance goals or other vesting criteria as the Administrator may determine pursuant to Section 10.

(bb)" Performance Unit" means an Award which may be earned in whole or in part upon attainment of performance goals or other vesting criteria as the Administrator may determine and which may be settled for cash, Shares or other securities or a combination of the foregoing pursuant to Section 10.

(cc)" Period of Restriction" means the period during which the transfer of Shares of Restricted Stock are subject to restrictions and therefore, the Shares are subject to a substantial risk of forfeiture. Such restrictions may be based on the passage of time, the achievement of target levels of performance, or the occurrence of other events as determined by the Administrator.

(dd)" Plan" means this 2016 Equity Incentive Plan.

(ee)" Restricted Stock" means Shares issued pursuant to a Restricted Stock award under Section 7 of the Plan, or issued pursuant to the early exercise of an Option.

(ff)" Restricted Stock Unit" means a bookkeeping entry representing an amount equal to the Fair Market Value of one Share, granted pursuant to Section 8. Each Restricted Stock Unit represents an unfunded and unsecured obligation of the Company.

(gg)" Rule 16b-3" means Rule 16b-3 of the Exchange Act or any successor to Rule 16b-3, as in effect when discretion is being exercised with respect to the Plan.

(hh)" Section 16(b)" means Section 16(b) of the Exchange Act.

(ii)" Service Provider" means an Employee, Director or Consultant.

(jj)" Share" means a share of the Common Stock, as adjusted in accordance with Section 14 of the Plan.

(kk)" Stock Appreciation Right" means an Award, granted alone or in connection with an Option, that pursuant to Section 9 is designated as a Stock Appreciation Right.

(ll)" Subsidiary" means a "subsidiary corporation," whether now or hereafter exist-ing, as defined in Section 424(f) of the Code.

3. Stock Subject to the Plan.

(a) Stock Subject to the Plan. Subject to the provisions of Section 14 of the Plan, the maximum aggregate number of Shares that may be issued under the Plan is 1,491,251 Shares, plus any Shares subject to stock options or similar awards granted under the the Company's 2002 Stock Option Plan (the "Prior Plan") that, on or after the Effective Date, expire or otherwise terminate without having been exercised in full and Shares issued pursuant to awards granted under the Prior Plan that are forfeited to or repurchased by the Company, with the maximum number of Shares to be added to the Plan from previously granted awards under the Prior Plan equal to 152,857. The Shares may be authorized, but unissued, or reacquired Common Stock.

(b) Automatic Share Reserve Increase. Subject to the provisions of Section 14 of the Plan, the number of Shares available for issuance under the Plan will be increased on the first day of each Fiscal Year beginning with the 2021 Fiscal Year, in an amount equal to the least of (i) 1,000,000 Shares, (ii) four percent (4.0%) of the outstanding Shares on the last day of the immediately preceding Fiscal Year or (iii) such number of Shares determined by the Board; provided, however, that such determination under clause (iii) will be made no later than the last day of the immediately preceding Fiscal Year.

(c) Lapsed Awards. If an Award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an Exchange Program, or, with respect to Restricted Stock, Restricted Stock Units, Performance Units or Performance Shares, is forfeited to, or repurchased by, the Company due to failure to vest, then the unpurchased Shares (or for Awards other than Options or Stock Appreciation Rights the forfeited or repurchased Shares), which were subject thereto will become available for future grant or sale under the Plan (unless the Plan has terminated). With respect to Stock Appreciation Rights, only Shares actually issued (i.e., the net Shares issued) pursuant to a Stock Appreciation Right will cease to be available under the Plan; all remaining Shares under Stock Appreciation Rights will remain available for future grant or sale under the Plan (unless the Plan has terminated). Shares that actually have been issued under the Plan under any Award will not be returned to the Plan and will not become available for future distribution under the Plan; provided, however, that if Shares issued pursuant to Awards of Restricted Stock, Restricted Stock Units, Performance Shares or Performance Units are repurchased by the Company or are forfeited to the Company, such Shares will become available for future grant under the Plan. Shares used to pay the exercise price of an Award or to satisfy the tax withholding obligations related to an Award will become available for future grant or sale under the Plan. To the extent an Award under the Plan is paid out in cash rather than Shares, such cash payment will not result in reducing the number of Shares available for issuance under the Plan. Notwithstanding the foregoing and, subject to adjustment as provided in Section 14, the maximum number of Shares that may be issued upon the exercise of Incentive Stock Options will equal the aggregate Share number stated in Section 3(a), plus, to the extent allowable under Section 422 of the Code, any Shares that become available for issuance under the Plan pursuant to Sections 3(b) and 3(c).

(d) Share Reserve. The Company, during the term of this Plan, will at all times reserve and keep available such number of Shares as will be sufficient to satisfy the requirements of the Plan.

4. Administration of the Plan.

(a) Procedure.

(i) Multiple Administrative Bodies. Different Committees with respect to different groups of Service Providers may administer the Plan.

(ii) Section 162(m). To the extent that the Administrator determines it to be desirable to qualify Awards granted hereunder as "performance-based compensation" within the meaning of Section 162(m) of the Code, the Plan will be administered by a Committee of two (2) or more "outside directors" within the meaning of Section 162(m) of the Code.

(iii) Rule 16b-3. To the extent desirable to qualify transactions hereunder as exempt under Rule 16b-3, the transactions contemplated hereunder will be structured to satisfy the requirements for exemption under Rule 16b-3.

(iv) Other Administration. Other than as provided above, the Plan will be administered by (A) the Board or (B) a Committee, which committee will be constituted to satisfy Applicable Laws.

(b) Powers of the Administrator. Subject to the provisions of the Plan, and in the case of a Committee, subject to the specific duties delegated by the Board to such Committee, the Administrator will have the authority, in its discretion:

(i) to determine the Fair Market Value;

(ii) to select the Service Providers to whom Awards may be granted hereunder;

(iii) to determine the number of Shares to be covered by each Award granted hereunder;

(iv) to approve forms of Award Agreements for use under the Plan;

(v) to determine the terms and conditions, not inconsistent with the terms of the Plan, of any Award granted hereunder. Such terms and conditions include, but are not limited to, the exercise price, the time or times when Awards may be exercised (which may be based on performance criteria), any vesting acceleration or waiver of forfeiture restrictions, and any restriction or limitation regarding any Award or the Shares relating thereto, based in each case on such factors as the Administrator will determine;

(vi) to institute and determine the terms and conditions of an Exchange Program;

(vii) to construe and interpret the terms of the Plan and Awards granted pursuant to the Plan;

(viii) to prescribe, amend and rescind rules and regulations relating to the Plan, including rules and regulations relating to sub-plans established for the purpose of satisfying applicable foreign laws or for qualifying for favorable tax treatment under applicable foreign laws;

(ix) to modify or amend each Award (subject to Section 19 of the Plan), including but not limited to the discretionary authority to extend the post-termination exercisability period of Awards and to extend the maximum term of an Option (subject to Section 6(b) of the Plan regarding Incentive Stock Options);

(x) to allow Participants to satisfy tax withholding obligations in such manner as prescribed in Section 15 of the Plan;

(xi) to authorize any person to execute on behalf of the Company any instrument required to effect the grant of an Award previously granted by the Administrator;

(xii) to allow a Participant to defer the receipt of the payment of cash or the delivery of Shares that otherwise would be due to such Participant under an Award; and

(xiii) to make all other determinations deemed necessary or advisable for administering the Plan.

(c) Effect of Administrator's Decision. The Administrator's decisions, determinations and interpretations will be final and binding on all Participants and any other holders of Awards.

5. Eligibility. Nonstatutory Stock Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, Performance Shares and Performance Units may be granted to Service Providers. Incentive Stock Options may be granted only to Employees.

6. Stock Options.

(a) Limitations. Each Option will be designated in the Award Agreement as either an Incentive Stock Option or a Nonstatutory Stock Option. However, notwithstanding such designation, to the extent that the aggregate Fair Market Value of the Shares with respect to which Incentive Stock Options are exercisable for the first time by the Participant during any calendar year (under all plans of the Company and any Parent or Subsidiary) exceeds one hundred thousand dollars ($100,000), such Options will be treated as Nonstatutory Stock Options. For purposes of this Section 6(a), Incentive Stock Options will be taken into account in the order in which they were granted. The Fair Market Value of the Shares will be determined as of the time the Option with respect to such Shares is granted.

(b) Term of Option. The term of each Option will be stated in the Award Agreement. In the case of an Incentive Stock Option, the term will be ten (10) years from the date of grant or such shorter term as may be provided in the Award Agreement. Moreover, in the case of an Incentive Stock Option granted to a Participant who, at the time the Incentive Stock Option is granted, owns stock representing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any Parent or Subsidiary, the term of the Incentive Stock Option will be five (5) years from the date of grant or such shorter term as may be provided in the Award Agreement.

(c) Option Exercise Price and Consideration.

(i) Exercise Price. The per share exercise price for the Shares to be issued pursuant to exercise of an Option will be determined by the Administrator, subject to the following:

(1) In the case of an Incentive Stock Option

(A) granted to an Employee who, at the time the Incentive Stock Option is granted, owns stock representing more than ten percent (10%) of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the per Share exercise price will be no less than one hundred ten percent (110%) of the Fair Market Value per Share on the date of grant.

(B) granted to any Employee other than an Employee described in paragraph (A) immediately above, the per Share exercise price will be no less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(2) In the case of a Nonstatutory Stock Option, the per Share exercise price will be no less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(3) Notwithstanding the foregoing, Options may be granted with a per Share exercise price of less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of the Code.

(ii) Waiting Period and Exercise Dates. At the time an Option is granted, the Administrator will fix the period within which the Option may be exercised and will determine any conditions that must be satisfied before the Option may be exercised.

(iii) Form of Consideration. The Administrator will determine the acceptable form of consideration for exercising an Option, including the method of payment. In the case of an Incentive Stock Option, the Administrator will determine the acceptable form of consideration at the time of grant. Such consideration may consist entirely of: (1) cash; (2) check; (3) promissory note, to the extent permitted by Applicable Laws, (4) other Shares, provided that such Shares have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which such Option will be exercised and provided that accepting such Shares will not result in any adverse accounting consequences to the Company, as the Administrator determines in its sole discretion; (5) consideration received by the Company under a broker-assisted (or other) cashless exercise program (whether through a broker or otherwise) implemented by the Company in connection with the Plan; (6) by net exercise; (7) such other consideration and method of payment for the issuance of Shares to the extent permitted by Applicable Laws; or (8) any combination of the foregoing methods of payment.

(d) Exercise of Option.

(i) Procedure for Exercise; Rights as a Stockholder. Any Option granted hereunder will be exercisable according to the terms of the Plan and at such times and under such conditions as determined by the Administrator and set forth in the Award Agreement. An Option may not be exercised for a fraction of a Share.

An Option will be deemed exercised when the Company receives: (i) a notice of exercise (in such form as the Administrator may specify from time to time) from the person entitled to exercise the Option, and (ii) full payment for the Shares with respect to which the Option is exercised (together with applicable withholding taxes). Full payment may consist of any consideration and method of payment authorized by the Administrator and permitted by the Award Agreement and the Plan. Shares issued upon exercise of an Option will be issued in the name of the Participant or, if requested by the Participant, in the name of the Participant and his or her spouse. Until the Shares are issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares subject to an Option, notwithstanding the exercise of the Option. The Company will issue (or cause to be issued) such Shares promptly after the Option is exercised. No adjustment will be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Section 14 of the Plan.

Exercising an Option in any manner will decrease the number of Shares thereafter available, both for purposes of the Plan and for sale under the Option, by the number of Shares as to which the Option is exercised.

(ii) Termination of Relationship as a Service Provider. If a Participant ceases to be a Service Provider, other than upon the Participant's termination as the result of the Participant's death or Disability, the Participant may exercise his or her Option within such period of time as is specified in the Award Agreement to the extent that the Option is vested on the date of termination (but in no event later than the expiration of the term of such Option as set forth in the Award Agreement). In the absence of a specified time in the Award Agreement, the Option will remain exercisable for three (3) months following the Participant's termination. Unless otherwise provided by the Administrator, if on the date of termination the Participant is not vested as to his or her entire Option, the Shares covered by the unvested portion of the Option will revert to the Plan. If after termination the Participant does not exercise his or her Option within the time specified by the Administrator, the Option will terminate, and the Shares covered by such Option will revert to the Plan.

(iii) Disability of Participant. If a Participant ceases to be a Service Provider as a result of the Participant's Disability, the Participant may exercise his or her Option within such period of time as is specified in the Award Agreement to the extent the Option is vested on the date of termination (but in no event later than the expiration of the term of such Option as set forth in the Award Agreement). In the absence of a specified time in the Award Agreement, the Option will remain exercisable for twelve (12) months following the Participant's termination. Unless otherwise provided by the Administrator, if on the date of termination the Participant is not vested as to his or her entire Option, the Shares covered by the unvested portion of the Option will revert to the Plan. If after termination the Participant does not exercise his or her Option within the time specified herein, the Option will terminate, and the Shares covered by such Option will revert to the Plan.

(iv) Death of Participant. If a Participant dies while a Service Provider, the Option may be exercised following the Participant's death within such period of time as is specified in the Award Agreement to the extent that the Option is vested on the date of death (but in no event may the option be exercised later than the expiration of the term of such Option as set forth in the Award Agreement), by the Participant's designated beneficiary, provided such beneficiary has been designated prior to Participant's death in a form acceptable to the Administrator. If no such beneficiary has been designated by the Participant, then such Option may be exercised by the personal representative of the Participant's estate or by the person(s) to whom the Option is transferred pursuant to the Participant's will or in accordance with the laws of descent and distribution. In the absence of a specified time in the Award Agreement, the Option will remain exercisable for twelve (12) months following Participant's death. Unless otherwise provided by the Administrator, if at the time of death Participant is not vested as to his or her entire Option, the Shares covered by the unvested portion of the Option will immediately revert to the Plan. If the Option is not so exercised within the time specified herein, the Option will terminate, and the Shares covered by such Option will revert to the Plan.

7. Restricted Stock.

(a) Grant of Restricted Stock. Subject to the terms and provisions of the Plan, the Administrator, at any time and from time to time, may grant Shares of Restricted Stock to Service Providers in such amounts as the Administrator, in its sole discretion, will determine.

(b) Restricted Stock Agreement. Each Award of Restricted Stock will be evidenced by an Award Agreement that will specify the Period of Restriction, the number of Shares granted, and such other terms and conditions as the Administrator, in its sole discretion, will determine. Unless the Administrator determines otherwise, the Company as escrow agent will hold Shares of Restricted Stock until the restrictions on such Shares have lapsed.

(c) Transferability. Except as provided in this Section 7 or the Award Agreement, Shares of Restricted Stock may not be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated until the end of the applicable Period of Restriction.

(d) Other Restrictions. The Administrator, in its sole discretion, may impose such other restrictions on Shares of Restricted Stock as it may deem advisable or appropriate.

(e) Removal of Restrictions. Except as otherwise provided in this Section 7, Shares of Restricted Stock covered by each Restricted Stock grant made under the Plan will be released from escrow as soon as practicable after the last day of the Period of Restriction or at such other time as the Administrator may determine. The Administrator, in its discretion, may accelerate the time at which any restrictions will lapse or be removed.

(f) Voting Rights. During the Period of Restriction, Service Providers holding Shares of Restricted Stock granted hereunder may exercise full voting rights with respect to those Shares, unless the Administrator determines otherwise.

(g) Dividends and Other Distributions. During the Period of Restriction, Service Providers holding Shares of Restricted Stock will be entitled to receive all dividends and other distributions paid with respect to such Shares, unless the Administrator provides otherwise. If any such dividends or distributions are paid in Shares, the Shares will be subject to the same restrictions on transferability and forfeitability as the Shares of Restricted Stock with respect to which they were paid.

(h) Return of Restricted Stock to Company. On the date set forth in the Award Agreement, the Restricted Stock for which restrictions have not lapsed will revert to the Company and again will become available for grant under the Plan.

8. Restricted Stock Units.

(a) Grant. Restricted Stock Units may be granted at any time and from time to time as determined by the Administrator. After the Administrator determines that it will grant Restricted Stock Units under the Plan, it will advise the Participant in an Award Agreement of the terms, conditions, and restrictions related to the grant, including the number of Restricted Stock Units.

(b) Vesting Criteria and Other Terms. The Administrator will set vesting criteria in its discretion, which, depending on the extent to which the criteria are met, will determine the number of Restricted Stock Units that will be paid out to the Participant. The Administrator may set vesting criteria based upon the achievement of Company-wide, divisional, business unit, or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the Administrator in its discretion.

(c) Earning Restricted Stock Units. Upon meeting the applicable vesting criteria, the Participant will be entitled to receive a payout as determined by the Administrator. Notwithstanding the foregoing, at any time after the grant of Restricted Stock Units, the Administrator, in its sole discretion, may reduce or waive any vesting criteria that must be met to receive a payout.

(d) Form and Timing of Payment. Payment of earned Restricted Stock Units will be made as soon as practicable after the date(s) determined by the Administrator and set forth in the Award Agreement. The Administrator, in its sole discretion, may only settle earned Restricted Stock Units in cash, Shares, or a combination of both.

(e) Cancellation. On the date set forth in the Award Agreement, all unearned Restricted Stock Units will be forfeited to the Company.

9. Stock Appreciation Rights.

(a) Grant of Stock Appreciation Rights. Subject to the terms and conditions of the Plan, a Stock Appreciation Right may be granted to Service Providers at any time and from time to time as will be determined by the Administrator, in its sole discretion.

(b) Number of Shares. The Administrator will have complete discretion to determine the number of Stock Appreciation Rights granted to any Service Provider.

(c) Exercise Price and Other Terms. The per share exercise price for the Shares to be issued pursuant to exercise of a Stock Appreciation Right will be determined by the Administrator and will be no less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant. Otherwise, the Administrator, subject to the provisions of the Plan, will have complete discretion to determine the terms and conditions of Stock Appreciation Rights granted under the Plan.

(d) Stock Appreciation Right Agreement. Each Stock Appreciation Right grant will be evidenced by an Award Agreement that will specify the exercise price, the term of the Stock Appreciation Right, the conditions of exercise, and such other terms and conditions as the Administrator, in its sole discretion, will determine.

(e) Expiration of Stock Appreciation Rights. A Stock Appreciation Right granted under the Plan will expire ten (10) years from the date of grant or such shorter term as may be provided in the Award Agreement, as determined by the Administrator, in its sole discretion. Notwithstanding the foregoing, the rules of Section 6(d) relating to exercise also will apply to Stock Appreciation Rights.

(f) Payment of Stock Appreciation Right Amount. Upon exercise of a Stock Appreciation Right, a Participant will be entitled to receive payment from the Company in an amount determined by multiplying:

(i) The difference between the Fair Market Value of a Share on the date of exercise over the exercise price; times

(ii) The number of Shares with respect to which the Stock Appreciation Right is exercised.

At the discretion of the Administrator, the payment upon Stock Appreciation Right exercise may be in cash, in Shares of equivalent value, or in some combination thereof.

10. Performance Units and Performance Shares.

(a) Grant of Performance Units/Shares. Performance Units and Performance Shares may be granted to Service Providers at any time and from time to time, as will be determined by the Administrator, in its sole discretion. The Administrator will have complete discretion in determining the number of Performance Units and Performance Shares granted to each Participant.

(b) Value of Performance Units/Shares. Each Performance Unit will have an initial value that is established by the Administrator on or before the date of grant. Each Performance Share will have an initial value equal to the Fair Market Value of a Share on the date of grant.

(c) Performance Objectives and Other Terms. The Administrator will set performance objectives or other vesting provisions (including, without limitation, continued status as a Service Provider) in its discretion which, depending on the extent to which they are met, will determine the number or value of Performance Units/Shares that will be paid out to the Service Providers. The time period during which the performance objectives or other vesting provisions must be met will be called the "Performance Period." Each Award of Performance Units/Shares will be evidenced by an Award Agreement that will specify the Performance Period, and such other terms and conditions as the Administrator, in its sole discretion, will determine. The Administrator may set performance objectives based upon the achievement of Company-wide, divisional, business unit or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws, or any other basis determined by the Administrator in its discretion.

(d) Earning of Performance Units/Shares. After the applicable Performance Period has ended, the holder of Performance Units/Shares will be entitled to receive a payout of the number of Performance Units/Shares earned by the Participant over the Performance Period, to be determined as a function of the extent to which the corresponding performance objectives or other vesting provisions have been achieved. After the grant of a Performance Unit/Share, the Administrator, in its sole discretion, may reduce or waive any performance objectives or other vesting provisions for such Performance Unit/Share.

(e) Form and Timing of Payment of Performance Units/Shares. Payment of earned Performance Units/Shares will be made as soon as practicable after the expiration of the applicable Performance Period. The Administrator, in its sole discretion, may pay earned Performance Units/Shares in the form of cash, in Shares (which have an aggregate Fair Market Value equal to the value of the earned Performance Units/Shares at the close of the applicable Performance Period) or in a combination thereof.

(f) Cancellation of Performance Units/Shares. On the date set forth in the Award Agreement, all unearned or unvested Performance Units/Shares will be forfeited to the Company, and again will be available for grant under the Plan.

11. Outside Director Limitations.

(a) Cash-settled Awards. No Outside Director may be granted, in any Fiscal Year, cash-settled Awards with a grant date fair value (determined in accordance with U.S. generally accepted accounting principles) of greater than $300,000, increased to $500,000 in the Fiscal Year of his or her initial service as an Outside Director.

(b) Stock-settled Awards. Subject to the provisions of Section 14 of the Plan, no Outside Director may be granted, in any Fiscal Year, Awards covering more than 500,000 Shares, increased to 750,000 Shares in the Fiscal Year of his or her initial service as an Outside Director.

Any Awards granted to an individual while he or she was an Employee, or while he or she was a Consultant but not an Outside Director, will not count for purposes of the limitations under this Section 11.

12. Leaves of Absence/Transfer Between Locations. Unless the Administrator provides otherwise, vesting of Awards granted hereunder will be suspended during any unpaid leave of absence. A Participant will not cease to be an Employee in the case of (i) any leave of absence approved by the Company or (ii) transfers between locations of the Company or between the Company, its Parent, or any Subsidiary. For purposes of Incentive Stock Options, no such leave may exceed three (3) months, unless reemployment upon expiration of such leave is guaranteed by statute or contract. If reemployment upon expiration of a leave of absence approved by the Company is not so guaranteed, then six (6) months following the first (1st) day of such leave any Incentive Stock Option held by the Participant will cease to be treated as an Incentive Stock Option and will be treated for tax purposes as a Nonstatutory Stock Option.

13. Transferability of Awards. Unless determined otherwise by the Administrator, an Award may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised, during the lifetime of the Participant, only by the Participant. If the Administrator makes an Award transferable, such Award will contain such additional terms and conditions as the Administrator deems appropriate.

14. Adjustments; Dissolution or Liquidation; Change in Control.

(a) Adjustments. In the event that any dividend or other distribution (whether in the form of cash, Shares, other securities, or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of Shares or other securities of the Company, or other change in the corporate structure of the Company affecting the Shares occurs, the Administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under the Plan, will adjust the number and class of Shares that may be delivered under the Plan and/or the number, class, and price of Shares covered by each outstanding Award, and the numerical Share limits in Sections 3 and 11(b) of the Plan.

(b) Dissolution or Liquidation. In the event of the proposed dissolution or liquidation of the Company, the Administrator will notify each Participant as soon as practicable prior to the effective date of such proposed transaction. To the extent it previously has not been exercised, an Award will terminate immediately prior to the consummation of such proposed action.

(c) Change in Control. In the event of a Change in Control, each outstanding Award will be treated as the Administrator determines, including, without limitation, that (i) Awards may be assumed, or substantially equivalent Awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof) with appropriate adjustments as to the number and kind of shares and prices; (ii) upon written notice to a Participant, that the Participant's Awards will terminate upon or immediately prior to the consummation of such Change in Control; (iii) outstanding Awards will vest and become exercisable, realizable, or payable, or restrictions applicable to an Award will lapse, in whole or in part prior to or upon consummation of such Change in Control, and, to the extent the Administrator determines, terminate upon or immediately prior to the effectiveness of such merger or Change in Control; (iv) (A) the termination of an Award in exchange for an amount of cash and/or property, if any, equal to the amount that would have been attained upon the exercise of such Award or realization of the Participant's rights as of the date of the occurrence of the transaction (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction the Administrator determines in good faith that no amount would have been attained upon the exercise of such Award or realization of the Participant's rights, then such Award may be terminated by the Company without payment), or (B) the replacement of such Award with other rights or property selected by the Administrator in its sole discretion; or (v) any combination of the foregoing. In taking any of the actions permitted under this Section 14(c), the Administrator will not be required to treat all Awards similarly in the transaction.

In the event that the successor corporation does not assume or substitute for the Award, the Participant will fully vest in and have the right to exercise all of his or her outstanding Options and Stock Appreciation Rights, including Shares as to which such Awards would not otherwise be vested or exercisable, all restrictions on Restricted Stock and Restricted Stock Units will lapse, and, with respect to Awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at one hundred percent (100%) of target levels and all other terms and conditions met. In addition, if an Option or Stock Appreciation Right is not assumed or substituted in the event of a Change in Control, the Administrator will notify the Participant in writing or electronically that the Option or Stock Appreciation Right will be exercisable for a period of time determined by the Administrator in its sole discretion, and the Option or Stock Appreciation Right will terminate upon the expiration of such period.

For the purposes of this subsection (c), an Award will be considered assumed if, following the Change in Control, the Award confers the right to purchase or receive, for each Share subject to the Award immediately prior to the Change in Control, the consideration (whether stock, cash, or other securities or property) received in the Change in Control by holders of Common Stock for each Share held on the effective date of the transaction (and if holders were offered a choice of consideration, thes type of consideration chosen by the holders of a majority of the outstanding Shares); provided, however, that if such consideration received in the Change in Control is not solely common stock of the successor corporation or its Parent, the Administrator may, with the consent of the successor corporation, provide for the consideration to be received upon the exercise of an Option or Stock Appreciation Right or upon the payout of a Restricted Stock Unit, Performance Unit or Performance Share, for each Share subject to such Award, to be solely common stock of the successor corporation or its Parent equal in fair market value to the per share consideration received by holders of Common Stock in the Change in Control.

Notwithstanding anything in this Section 14(c) to the contrary, an Award that vests, is earned or paid-out upon the satisfaction of one or more performance goals will not be considered assumed if the Company or its successor modifies any of such performance goals without the Participant's consent; provided, however, a modification to such performance goals only to reflect the successor corporation's post-Change in Control corporate structure will not be deemed to invalidate an otherwise valid Award assumption.

(d) Outside Director Awards. With respect to Awards granted to an Outside Director, in the event of a Change in Control, the Participant will fully vest in and have the right to exercise Options and/or Stock Appreciation Rights as to all of the Shares underlying such Award, including those Shares which otherwise would not be vested or exercisable, all restrictions on Restricted Stock and Restricted Stock Units will lapse, and, with respect to Awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at one hundred percent (100%) of target levels and all other terms and conditions met.

15. Tax.

(a) Withholding Requirements. Prior to the delivery of any Shares or cash pursuant to an Award (or exercise thereof) or such earlier time as any tax withholding obligations are due, the Company will have the power and the right to deduct or withhold, or require a Participant to remit to the Company, an amount sufficient to satisfy federal, state, local, foreign or other taxes (including the Participant's FICA obligation) required to be withheld with respect to such Award (or exercise thereof).

(b) Withholding Arrangements. The Administrator, in its sole discretion and pursuant to such procedures as it may specify from time to time, may permit a Participant to satisfy such tax withholding obligation, in whole or in part by (without limitation) (a) paying cash, (b) electing to have the Company withhold otherwise deliverable cash or Shares having a Fair Market Value equal to the minimum statutory amount required to be withheld, or (c) delivering to the Company already-owned Shares having a Fair Market Value equal to the minimum statutory amount required to be withheld. The Fair Market Value of the Shares to be withheld or delivered will be determined as of the date that the taxes are required to be withheld.

(c) Compliance With Code Section 409A. Awards will be designed and operated in such a manner that they are either exempt from the application of, or comply with, the requirements of Code Section 409A such that the grant, payment, settlement or deferral will not be subject to the additional tax or interest applicable under Code Section 409A, except as otherwise determined in the sole discretion of the Administrator. The Plan and each Award Agreement under the Plan is intended to meet the requirements of Code Section 409A and will be construed and interpreted in accordance with such intent, except as otherwise determined in the sole discretion of the Administrator. To the extent that an Award or payment, or the settlement or deferral thereof, is subject to Code Section 409A, the Award will be granted, paid, settled or deferred in a manner that will meet the requirements of Code Section 409A, such that the grant, payment, settlement or deferral will not be subject to the additional tax or interest applicable under Code Section 409A.

16. No Effect on Employment or Service. Neither the Plan nor any Award will confer upon a Participant any right with respect to continuing the Participant's relationship as a Service Provider with the Company, nor will they interfere in any way with the Participant's right or the Company's right to terminate such relationship at any time, with or without cause, to the extent permitted by Applicable Laws.

17. Date of Grant. The date of grant of an Award will be, for all purposes, the date on which the Administrator makes the determination granting such Award, or such other later date as is determined by the Administrator. Notice of the determination will be provided to each Participant within a reasonable time after the date of such grant.

18. Term of Plan. Subject to Section 22 of the Plan, the Plan will become effective upon the date of its adoption by the Board. It will continue in effect for a term of ten (10) years from the date adopted by the Board, unless terminated earlier under Section 19 of the Plan.

19. Amendment and Termination of the Plan.

(a) Amendment and Termination. The Administrator may at any time amend, alter, suspend or terminate the Plan.

(b) Stockholder Approval. The Company will obtain stockholder approval of any Plan amendment to the extent necessary and desirable to comply with Applicable Laws.

(c) Effect of Amendment or Termination. No amendment, alteration, suspension or termination of the Plan will materially impair the rights of any Participant, unless mutually agreed otherwise between the Participant and the Administrator, which agreement must be in writing and signed by the Participant and the Company. Termination of the Plan will not affect the Administrator's ability to exercise the powers granted to it hereunder with respect to Awards granted under the Plan prior to the date of such termination.

20. Conditions Upon Issuance of Shares.

(a) Legal Compliance. Shares will not be issued pursuant to the exercise of an Award unless the exercise of such Award and the issuance and delivery of such Shares will comply with Applicable Laws and will be further subject to the approval of counsel for the Company with respect to such compliance.

(b) Investment Representations. As a condition to the exercise of an Award, the Company may require the person exercising such Award to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required.

21. Inability to Obtain Authority. The inability of the Company to obtain authority from any regulatory body having jurisdiction or to complete or comply with the requirements of any registration or other qualification of the Shares under any state, federal or foreign law or under the rules and regulations of the Securities and Exchange Commission, the stock exchange on which Shares of the same class are then listed, or any other governmental or regulatory body, which authority, registration, qualification or rule compliance is deemed by the Company's counsel to be necessary or advisable for the issuance and sale of any Shares hereunder, will relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority, registration, qualification or rule compliance will not have been obtained.

22. Stockholder Approval. The Plan will be subject to approval by the stockholders of the Company within twelve (12) months after the date the Plan is adopted by the Board. Such stockholder approval will be obtained in the manner and to the degree required under Applicable Laws.

Exhibit 10.11

SUMMARY OF CONSULTING AGREEMENT

On Feb 15, 2021 (the "Effective Date"), BioCardia, Inc. (the "Company") entered into a consulting agreement (the "Consulting Agreement") with Dr. Eric Duckers, former Chief Medical Officer of the Company. Dr. Duckers resigned as Chief Medical Officer of the Company, effective as of February 15th, 2021.

Pursuant to the terms of the Consulting Agreement, Dr. Duckers will serve as an advisor to the executive steering committee of the CardiAMP Heart Failure clinical study on an as-needed and ongoing basis and will be paid $400 per hour.

Either Dr. Duckers or the Company may terminate the Consulting Agreement at any time and for any reason upon thirty days advance written notice. Upon such termination, Dr. Duckers will be paid for services actually rendered and will not be entitled to any additional compensation.

Dr. Ducker's outstanding equity awards ceased vesting as of the Effective Date, and he will be able to exercise any outstanding equity awards for a period of ninety (90) days following the Effective Date.

Exhibit 21.1

Subsidiaries of BioCardia, Inc.

Name of Subsidiary	Jurisdiction of Organization
BioCardia Lifesciences, Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
BioCardia, Inc.:

We consent to the incorporation by reference in the registration statements (No. 333-215968, 333-224368, 333-236405) on Form S-8, the registration statement (No. 333-249426) on Form S-3, and the registration statement (No. 333-230779) on Form S-1 of BioCardia, Inc. of our report dated April 8, 2020, with respect to the consolidated balance sheet of BioCardia, Inc. as of December 31, 2019 and the related consolidated statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2019, and the related notes, which report appears in the December 31, 2020 annual report on Form 10-K of BioCardia, Inc.

Our report dated April 8, 2020 contains an explanatory paragraph that states that the Company has incurred net losses and negative cash flows from operations since its inception and had an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

San Francisco, California
March 29, 2021

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

The Board of Directors
BioCardia, Inc.:

We consent to the incorporation by reference in the registration statements (No. 333-215968, 333-224368, 333-236405) on Form S-8, (No. 333-249426) on Form S-3, and (No. 333-230779) on Form S-1 of BioCardia, Inc. of our report dated March 29, 2021, with respect to the consolidated balance sheet of BioCardia, Inc. as of December 31, 2020, the related consolidated statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2020, and the related notes, which report appears in the December 31, 2020 annual report on Form 10-K of BioCardia, Inc.

/s/ PKF San Diego, LLP
PKF San Diego, LLP
(formerly PKF, LLP)

San Diego, California
March 29, 2021

Exhibit 31.1

Certification of Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Peter Altman, certify that:

1. I have reviewed this Annual Report on Form 10-K of BioCardia, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2021

/s/ Peter Altman
Name: Peter Altman
Title: President and Chief Executive Officer

Exhibit 31.2

Certification of Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, David McClung, certify that:

1. I have reviewed this Annual Report on Form 10-K of BioCardia, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2021

/s/ David McClung
Name: David McClung
Title: Chief Financial Officer

Exhibit 32.1

Certification of Principal Executive Officer

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

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, Peter Altman, the President and Chief Executive Officer of BioCardia, Inc. (the "**Company**"), hereby certify, that, to my knowledge:

1. The Annual Report on Form 10-K for the year ended December 31, 2020 (the "**Report**") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 29, 2021

/s/ Peter Altman
Name: Peter Altman
Title: President and Chief Executive Officer

Exhibit 32.2

Certification of Principal Financial Officer

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

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, David McClung, the Vice President of Finance of BioCardia, Inc. (the "**Company**"), hereby certify, that, to my knowledge:

1. The Annual Report on Form 10-K for the year ended December 31, 2020 (the "**Report**") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 29, 2021

/s/ David McClung
Name: David McClung
Title: Chief Financial Officer