BioCardia, Inc.
Form 8-K/A
November 14, 2016
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K/A
(Amendment No. 1)

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): **October 21, 2016**

BIOCARDIA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**0-21419**	**23-2753988**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

125 Shoreway Road, Suite B, San Carlos, CA 94070

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(650) 226-0120**

Tiger X Medical, Inc.

4400 Biscayne Blvd, Miami, FL 33137
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Explanatory Note

BioCardia, Inc. (the "Company") is filing this Amendment No. 1 on Form 8-K/A (this "Amendment") to amend its Current Report on Form 8-K filed with the Securities and Exchange Commission ("SEC") on October 27, 2016 (the "Original Form 8-K") in order to provide financial information of BioCardia Lifesciences, Inc., a wholly owned subsidiary of the Company ("BioCardia Lifesciences") upon the consummation of the merger on October 24, 2016 (the "Merger") and the accounting acquirer, for its fiscal quarter ended September 30, 2016, in accordance with the guidance set forth under Topic 12 of the Division of Corporation Finance Financial Reporting Manual so that there is no lapse in periodic reporting for the quarter ended September 30, 2016. All other disclosures in the Original Form 8-K remain the same. This Current Report on Form 8-K/A should be read in conjunction with the Original Form 8-K.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Amendment, contains forward-looking statements, including, without limitation, in the section "Management's Discussion and Analysis of Financial Condition and Results of Operations," and elsewhere. Any and all statements contained in this Amendment 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," "anticip "develop," "plan," "believe," "continue," "intend," "expect," "future" and terms of similar import (including the negative of an 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. Forward-looking statements in this Report 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) a projection of income (including income/loss), earnings (including earnings/loss) per share, capital expenditures, dividends, capital structure or other financial items, (iii) 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 SEC and (iv) the assumptions underlying or relating to any statement described in points (i), (ii) or (iii) above.

The forward-looking statements are not meant to predict or guarantee actual results, performance, events or circumstances and may not be realized because they are based upon our current projections, plans, objectives, beliefs, expectations, estimates and assumptions and are subject to a number of risks and uncertainties and other influences, many of which we have no control over. Actual results and the timing of certain events and circumstances may differ materially from those described by the forward-looking statements as a result of these risks and uncertainties. Factors that may influence or contribute to the inaccuracy of the forward-looking statements or cause actual results to differ materially from expected or desired results may include, without limitation:

- our ability to obtain regulatory approval for our cell therapy systems;

market acceptance of our cell therapy systems;

the benefits of our cell therapy systems versus other products;

our ability to successfully sell and market our cell therapy systems;

competition from existing technologies or products or new technologies and products that may emerge;

the implementation of our business model and strategic plans for our business and our cell therapy systems;

the scope of protection we are able to establish and maintain for intellectual property rights covering our cell therapy systems;

estimates of our future revenue, expenses, capital requirements and our need for additional financing;

our financial performance;

our expectation related to the use of proceeds from the Merger; and

developments relating to our competitors and the healthcare industry.

Readers are cautioned not to place undue reliance on forward-looking statements because of the risks and uncertainties related to them and to the risk factors. We disclaim any obligation to update the forward-looking statements contained in this Amendment to reflect any new information or future events or circumstances or otherwise, except as required by law.

Readers should read this Amendment in conjunction with the discussion under the caption "Risk Factors," our financial statements and the related notes thereto in this Amendment and the Original Form 8-K, and other documents which we may file from time to time with the Securities and Exchange Commission, or the SEC.

Item 2.01 Completion of Acquisition or Disposition of Assets.

The disclosures required by Item 2.01 of Form 8-K were provided in the Original Form 8-K and are incorporated herein by reference. Additionally, Item 2.01(f) of Form 8-K states that if the registrant was a shell company, then the registrant must disclose the information that would be required if the registrant were filing a general form for registration of securities on Form 10 under the Securities Exchange Act of 1934, as amended. The Original Form 8-K provided the information that would be included on Form 10, and is hereby supplemented with the Management's Discussion and Analysis of Financial Condition and Results of Operations of BioCardia Lifesciences for the fiscal quarter ended September 30, 2016, set forth herein.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following management's discussion and analysis should be read in conjunction with the historical financial statements and the related notes thereto contained in this Amendment and the Original Form 8-K. The management's discussion and analysis contains forward-looking statements, such as statements of our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect" and the like, and/or future tense or conditional constructions ("will," "may," "could," "should," etc.), or similar expressions, identify certain of these forward-looking statements. These forward-looking statements are subject to risks and uncertainties, including those under "Risk Factors" contained in our Current Report on Form 8-K filed with the Securities and Exchange Commission on October 27, 2016 that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. The Company's actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors. The Company does not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Report.

The following discussion highlights BioCardia Lifesciences Inc.'s ("BioCardia") results of operations and the principal factors that have affected our financial condition as well as our liquidity and capital resources for the periods described, and provides information that management believes is relevant for an assessment and understanding of the statements of financial position and results of operations presented herein. The following discussion and analysis are based on BioCardia's unaudited financial statements attached to this Report as Exhibit 99.1 and the audited financial statements as of and for the year ended December 31, 2015 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Current Report on Form 8-K filed by us with the Securities and Exchange Commission on October 27, 2016, which we have prepared in accordance with United States generally accepted accounting principles. You should read the discussion and analysis together with such financial statements and the related notes thereto.

Basis of Presentation

The unaudited interim condensed financial statements of BioCardia for the three and nine months ended September 30, 2016 and 2015, contained herein include a summary of our significant accounting policies and should be read in conjunction with the discussion below. In the opinion of management, all material adjustments necessary to present fairly the results of operations for such unaudited interim periods have been included in these unaudited financial statements. All such adjustments are of a normal recurring nature.

Overview

We are a clinical-stage regenerative medicine company developing novel therapeutics for cardiovascular diseases with large unmet medical needs. Our lead therapeutic candidate is the CardiAMP Cell Therapy System, or CardiAMP. We anticipate enrolling the first patient in our U.S. Food and Drug Administration, or FDA, accepted Phase III pivotal trial for CardiAMP in ischemic systolic heart failure in late 2016 or early 2017 and obtaining top-line data in 2019. If our Phase III pivotal trial is successful, we believe we will be the first company to reach the market with a cell-based therapy to treat heart failure. Our second therapeutic candidate is the CardiALLO Cell Therapy System, or CardiALLO. We anticipate preparation of an Investigational New Drug, or IND, application for submission to the FDA for a Phase II trial for CardiALLO for the treatment of ischemic systolic heart failure. This IND is expected to have improved Chemistry Manufacturing Controls, or CMC, in the IND relative to our previous co-sponsored investigations. 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. Autologous cell therapies use autologous cells, which mean the patient's own cells, while allogeneic cell therapies use allogeneic cells, which means cells from a third party donor.

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. From our inception through September 30, 2016, we have funded our operations primarily through the sales of equity and convertible debt securities totaling approximately $49.6 million and certain government and private grants totaling approximately $481,000. All convertible debt securities will convert into shares of our Common Stock in connection with the Merger.

We have incurred net losses in each year since our inception. Our net losses were approximately $3.3 million for the three month period ended September 30, 2016, and $6.7 million for the nine month period ended September 30, 2016. As of September 30, 2016, we had an accumulated deficit of approximately $56.6 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs, clinical trials, intellectual property matters, building our manufacturing and sales capabilities, and from general and administrative costs associated with our operations.

We anticipate that our expenses will increase substantially if and as we:

- commence enrollment in our Phase III pivotal trial for CardiAMP;
- advance CardiALLO, our second program in heart failure using allogeneic cells;
- further build our sales, marketing and distribution infrastructure in the United States to commercialize any therapies or products for which we obtain marketing approval;
- seek to identify, assess, acquire or develop other products, therapeutic candidates or technologies;
- seek regulatory and marketing approvals in multiple jurisdictions for our therapeutic candidates that successfully complete clinical studies;
- establish collaborations with third parties for the development and commercialization of our products and therapeutic candidates;
- seek coverage and reimbursement from third-party payors, including government and private payors for future therapeutics and products;

- make milestone or other payments under our agreements pursuant to which we have licensed or acquired rights to intellectual property and technology;

- seek to maintain, protect, and expand our intellectual property portfolio;

- seek to attract and retain skilled personnel;

- create additional infrastructure to support our operations as a commercial-stage public company and our ongoing and new product development and planned future commercialization efforts; and

- experience any delays or encounter issues with any of the above.

We expect to continue to incur significant expenses and increasing losses for at least the next several years. Accordingly, we anticipate that we will need to raise additional capital prior to the commercialization of CardiAMP and CardiALLO. Until such time that we can generate meaningful revenue from product sales, 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. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, our therapeutic candidates. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research and development programs or the commercialization of any approved therapies or products or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially adversely affect our business, financial condition and results of operations.

Financial Overview

Revenue

We currently have a portfolio of enabling and delivery products, from which we have generated modest revenue.

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 enabling and delivery products.

Research and Development Expenses

Our research and development expenses consist primarily of:

- salaries and related overhead expenses, which include stock-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 material 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 to 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 performed.

From our inception through September 30, 2016, we have incurred approximately $25.4 million in research and development expenses. We plan to increase our research and development expenses for the foreseeable future as we continue to develop CardiAMP, and subject to the availability of additional funding, further advance the development of CardiALLO and any other therapeutic candidates for additional indications. 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.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our therapeutic candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our therapeutic candidates.

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 stock-based compensation expenses and benefits. Other significant 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.

We expect that our selling, general and administrative expenses will increase as we operate as a public company, conduct our Phase III pivotal trial for CardiAMP, and subject to the availability of additional funding, conduct our Phase II trial for CardiALLO and prepare for commercialization. We believe that these increases will likely include increased costs for director and officer liability insurance, costs related to the hiring of additional personnel to support product commercialization efforts and operations as a public company and increased fees for outside consultants, attorneys and accountants. We also expect to incur increased costs to comply with corporate governance, internal controls, investor relations and disclosures, and similar requirements applicable to public companies.

Other Income (Expense)

Other income and expense consists primarily of interest charges we incur in periods when we have convertible debt outstanding, interest income we earn on our cash and cash equivalents and changes in the fair value of our warrant and convertible shareholder note derivative liabilities. We expect our interest income to increase following the completion of the Merger as we invest our cash on hand pending its use in our operations.

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, or GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported expenses during the periods presented. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on other factors 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 readily apparent 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.

Revenue Recognition

We recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred, the price to the buyer is fixed or determinable and collection from the customer is reasonably assured.

- ***Net Product Revenue.*** We recognize revenues from product sales when title and risk of loss have passed to the customer, which typically occurs upon delivery. Product sale transactions are evidenced by customer purchase orders, customer contracts, invoices, and/or the related shipping documents. Revenue is recognized net of provisions made for discounts, expected sales returns and allowances. Estimated returns and allowances are based on historical experience and other relevant factors. We accept returns for unused, unopened and resellable product in its original packaging, subject to a 20% restocking fee.

- ***Collaboration Agreement Revenue.*** Collaboration agreement revenue is income from agreements under which we provide biotherapeutic delivery systems and customer training and support on their use in clinical trials and studies. We evaluate activities under these agreements to determine if they represent a multiple element arrangement by identifying the deliverables included within the agreement. We account for these deliverables as separate units of accounting if the following two criteria are met:

  - the delivered items have value to the customer on a stand-alone basis; and

  - if there is a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and within our control.

Factors considered in this determination include, among other things, whether any other vendors sell the items separately and if the customer could use the delivered item for its intended purpose without receipt of the remaining deliverables. A change in these assumptions could impact our reported revenue which could have a material impact to our financial statements.

If multiple deliverables included in an arrangement are separable into different units of accounting, we allocate the arrangement consideration to those units of accounting based on their relative selling prices and recognize the associated revenue when the appropriate recognition criteria are met for those deliverables. The amount of allocable arrangement consideration is limited to the amounts that are fixed and determinable.

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 September 30, 2016, 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.

Stock-Based Compensation

BioCardia granted stock-based compensation under its 2002 Stock Plan. The exercise price of options granted in 2016 was equivalent to the fair market value of our stock at the date of grant. The number of shares, terms, and vesting periods are determined by BioCardia'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 10 years from the date of grant. Compensation cost for employee stock-based awards is based on the grant-date fair value and will be recognized over the vesting period of the applicable award on a straight-line basis. Stock compensation expense for the three month periods ended September 30, 2016 and 2015 was approximately $87,000 and $120,000 respectively. Stock compensation expense for the nine month periods ended September 30, 2016 and 2015 was approximately $145,000 and $248,000 respectively. Unrecognized stock-based compensation for employee options granted through September 30, 2016, excluding performance stock option awards, is approximately $609,000 to be recognized over a remaining weighted average service period of 3.0 years.

In August and September 2016, the Company granted performance stock option awards to key employee and non-employee consultants. The vesting of these employee and non-employee options will commence upon the closing of the Merger and will vest equally over 48 months. The total grant-date fair value of these stock options is approximately $2.3 million for employees and $803,000 for non-employees. As of September 30, 2016, it was not considered probable that the performance condition would be met, and as such, no compensation expense has been recorded in the third quarter of 2016.

We measure and recognize stock-based compensation expense for equity awards to employees, directors and consultants based on fair value at the grant date. Unvested nonemployee awards are remeasured at each reporting date. We use the Black-Scholes-Merton option-pricing model, or BSM, to calculate fair value. Stock-based compensation expense recognized in the statements of operations is based on options ultimately expected to vest, taking into consideration estimated forfeitures, and is recognized in the period the services are performed. Stock-based compensation expense is revised in subsequent periods, if necessary, if actual forfeitures differ from these estimates. When estimating forfeitures, we consider historic voluntary termination behaviors as well as trends of actual option forfeitures. For options granted to nonemployees, we revalue the stock-based compensation and the resulting change in fair value is recognized in the statements of operations over the period the related services are rendered.

The BSM option-pricing model requires the input of highly subjective assumptions, including the risk-free interest rate, the expected volatility in the value of our 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, our stock-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.

- ***Volatility.*** As we do not have a trading history for our Common Stock following the Merger, the expected stock price volatility is estimated based on volatilities of a peer group of similar companies by taking the average historic volatility for these peers for a period equivalent to the expected term of the stock option grants. The peer group was developed based on companies in the biotechnology industry whose shares are publicly-traded.

- ***Expected Term.*** The expected term represents the period of time that options are expected to be outstanding. As we do 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.

- ***Expected Dividend.*** BioCardia never paid dividends on its common stock and have no plans to pay dividends on its Common Stock. Therefore, we use an expected dividend yield of zero.

- ***Fair Value of Common Stock.*** In the absence of a public trading market for our Common Stock, the estimated fair value is determined using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants, or AICPA, Audit and Accounting Practice Aid Series: *Valuation of Privately Held Company Equity Securities Issued as Compensation,* or the AICPA Practice Aid.

In determining the exercise price of stock options and the fair value of BioCardia's common stock underlying the options, BioCardia's board of directors considered the fair values of BioCardia's common stock derived in the

third-party valuations as one of the factors it considered when setting the exercise prices for options granted. The valuations were performed in accordance with applicable elements of the AICPA Practice Aid. The AICPA Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of BioCardia's common stock at each valuation date. In accordance with the AICPA Practice Aid, we considered the following methods:

- ***Option Pricing Method.*** Under the option pricing method, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.

- ***Hybrid Method.*** The hybrid method blends the concepts of the probability-weighted expected return method with the concepts of the option pricing method.

BioCardia's board of directors also considered a range of objective and subjective factors and assumptions in estimating the fair value of its common stock on the date of grant, including:

- progress of our research and development efforts;

- our operating results and financial condition, including our levels of available capital resources;

- rights and preferences of its common stock compared to the rights and preferences of our other outstanding equity securities;

- our stage of development and material risks related to our business;

- our commercial success in regard to our catheter sales;

- the achievement of enterprise milestones, including a favorable ruling by the FDA which allows us to enroll our first patient in a Phase III pivotal trial;

- the valuation of publicly-traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;

- equity market conditions affecting comparable public companies;

- the likelihood of achieving a liquidity event for the shares of its common stock, such as an initial public offering given prevailing market and biotechnology sector conditions; and

- that the grants involved illiquid securities in a private company.

Convertible Shareholder Notes Derivative Liability

We issued convertible notes in 2015, or the 2015 Notes, that have redemption features that were determined to be a compound embedded derivative requiring bifurcation and separate accounting at estimated fair value. The estimated fair value of these derivative instruments was recognized as a debt discount and as an embedded derivative liability on the balance sheet upon issuance of the notes. The debt discount is amortized to interest expense using the effective interest method. At the end of each reporting period, we recorded changes in fair value during the period as a component of other income / (expense). We continue to adjust the liability for changes in the estimated fair value of the embedded derivatives until the redemption feature is forfeited or expires or the 2015 Notes are converted or settled. We used a Monte Carlo simulation to calculate the potential liability in each of the conversion scenarios from inception through June 30, 2016. In scenarios where the liability includes created equity shares and warrants, the Black-Scholes based option pricing method is used to calculate the amounts due to investors. On September 30, 2016, the valuation of the compound embedded derivative was determined based on the settlement value of the common stock exchanged for the notes upon the closing of the Merger.

The derivative liability will be remeasured to fair market value immediately prior to the Merger and then reclassified to stockholders' equity upon conversion of the 2015 Notes in the Merger.

Preferred Stock Warrant Liability

We classify freestanding warrants for shares that are either puttable or redeemable as liabilities on the balance sheet at fair value. Therefore, the freestanding warrants that gave the holders the right to purchase our convertible preferred stock were liabilities that we recorded at estimated fair value. At the end of each reporting period, we recorded changes in fair value during the period as a component of other income (expense).

We continue to adjust the liability for changes in the estimated fair value of the warrants until the earlier of the exercise or expiration of the warrants to purchase shares of convertible preferred stock or the completion of a liquidation event.

We use the BSM to estimate the fair value of preferred stock warrant liabilities utilizing assumptions that include the estimated fair value of the underlying convertible preferred stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends, and the expected volatility of the price of the underlying convertible preferred stock. The contractual term of the warrants represents the period of time remaining before the warrants expire. Because our shares are not publicly traded and our shares are rarely traded privately, expected volatility is estimated based on the average historical volatility of similar entities with publicly traded shares. The risk-free rate is based on the U.S. Treasury yield curve with a maturity equal to the remaining contractual term of the warrant.

Most of the warrants were voluntarily exchanged for shares of BioCardia common stock immediately prior to the Merger. The warrants will be revalued immediately prior to the Merger and then reclassified to stockholder’s equity upon consummation of the Merger.

Income Taxes

We use the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

As of December 31, 2015, our total deferred tax assets, less our total deferred tax liabilities, were $18.9 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards.

Utilization of the net operating loss carryforwards may be subject to a substantial annual limitation due to ownership changes that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions. These ownership change limitations may limit the amount of net operating loss carryforwards and other tax attributes that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points (by value) of the outstanding stock of a company by certain stockholders. Since our formation, we have raised capital through the issuance of capital stock on several occasions, which separately or combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in such ownership changes, or could result in ownership changes in the future.

We have not completed 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 of the Code, which is determined by first multiplying the value of our stock at the time of the ownership change by the applicable long-term, tax-exempt rate, and then applying any additional adjustments that are required. Any limitation may result in expiration of a portion of the net operating loss carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets, with a corresponding reduction of the valuation allowance.

Results of Operations

The following table summarizes our results of operations for the three months ended September 30, 2016 and 2015, and the nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Net product revenue	$100	$206	$406	$660
Collaboration agreement revenue	17	4	33	38
Total revenue	117	210	439	698
Costs and expenses:				
Cost of goods sold	196	319	578	739
Research and development	684	432	1,622	1,300
Selling, general and administrative	919	858	2,375	3,197
Total costs and expenses	1,799	1,609	4,575	5,236
Operating loss	(1,682)	(1,399)	(4,136)	(4,538)
Write-off of deferred financing costs	-	(1,623)	-	(1,623)
Interest expense	(520)	(536)	(1,627)	(843)
Other (expense) income	(1,052)	328	(965)	219
Net loss	$(3,254)	$(3,230)	$(6,728)	$(6,785)

Revenue. Revenue decreased by approximately $93,000 from $210,000 for the three months ended September 30, 2015 to $117,000 for the three months ended September 30, 2016 due primarily to a reduction in sales volumes for the Morph products. Revenue decreased by approximately $259,000 from $698,000 for the nine months ended September 30, 2015 to $439,000 for the nine months ended September 30, 2016 due primarily to a reduction in sales volumes for Morph products.

Cost of Goods Sold. Cost of goods sold decreased by approximately $123,000 from $319,000 for the three months ended September 30, 2015 to $196,000 for the three months ended September 30, 2016 due primarily to an overall reduction in sales volumes for Morph products. Cost of goods sold decreased by $161,000 from $739,000 for the nine months ended September 30, 2015 to $578,000 for the nine months ended September 30, 2016, due primarily to a reduction in sales volumes for Morph products.

Research and Development Expenses. Research and development expenses increased by approximately $252,000 from $432,000 for the three months ended September 30, 2015 to $684,000 for the three months ended September 30, 2016 due primarily to expenses incurred in the planning and preparation for the CardiAMP Phase III pivotal trial. Research and development expenses increased by approximately $322,000 from $1.3 million for the nine months ended September 30, 2015 to $1.6 million for the nine months ended September 30, 2016 due primarily to expenses incurred in the planning and preparation for the CardiAMP Phase III pivotal trial. We expect research and development expenses to increase as we begin enrollment of the CardiAMP Phase III pivotal trial.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by approximately $61,000 from $858,000 for the three months ended September 30, 2015 to $919,000 for the three months ended September 30, 2016 due primarily to legal, accounting and consulting expenses associated with the Merger, partially offset by decreases in payroll and related expenses from a reduction in workforce in August 2015. Selling, general and administrative expenses decreased by approximately $822,000 from $3.2 million for the nine months ended September 30, 2015 to $2.4 million for the nine months ended September 30, 2016 primarily due to the workforce reduction in August 2015. We expect selling, general and administrative expenses to increase due to expenses to be incurred as we build our infrastructure to support the CardiAMP Phase III pivotal trial and public company operations.

Write Off of Deferred Financing Costs. The Company deferred costs incurred for a planned initial public offering, or the IPO, which included legal, accounting and other professional fees. The IPO was delayed and subsequently withdrawn, and as a result, the Company recorded a write-off of deferred offering costs of $1.6 million during the three and nine months ended September 30, 2015.

Interest Expense. Interest expense for the three months ended September 30, 2016 and 2015 and for the nine months ended September 30, 2016 and 2015 consisted primarily of interest expense related to convertible notes.

Other Income (Expense). Other income for the three months ended September 30, 2016 and 2015 and for the nine months ended September 30, 2016 and 2015 consisted primarily of the changes in value of the convertible preferred stock warrant liabilities and the change in value of the convertible shareholder note derivative liability.

Liquidity and Capital Resources

We have incurred net losses each year since our inception and as of September 30, 2016, we had an accumulated deficit of approximately $56.6 million. We anticipate that we will continue to incur net losses for at least the next several years. These conditions raise substantial doubt about our ability to continue as a going concern without additional financing. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our 2015 financial statements with respect to this uncertainty. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitment in the normal course of business. Our interim condensed financial statements for the three and nine months ended September 30, 2016 and 2015 do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty. We expect that our research and development and selling, general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may obtain through one or more public or private equity offerings, debt financings, government or other third-party funding, strategic alliances and licensing or collaboration arrangements.

Since our inception through September 30, 2016, we have funded our operations principally through the sales of equity and convertible debt securities totaling approximately $49.6 million. As of September 30, 2016, we had cash and cash equivalents of approximately $552,000. Subsequent to September 30, 2016, BioCardia issued $4.4 million aggregate principal amount of convertible promissory notes, all of which converted into shares of BioCardia’s common stock immediately prior to the Merger.

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

	Nine Months Ended September 30,	
	2016	**2015**
Net cash provided by (used in):		
Operating activities	$(3,007)	$(5,659)
Investing activities	-	(125)
Financing activities	2	7,496
Net (decrease) increase in cash and cash equivalents	$(3,005)	$1,712

Cash Flows from Operating Activities. Net cash used in operating activities was $3.0 million and $5.7 million for the nine months ended September 30, 2016 and 2015, respectively. The decrease in overall spending for operating activities of approximately $2.7 million relates primarily to the spending for the IPO in 2015 coupled with reductions in operating costs attributable to the reduction in workforce that occurred in August 2015.

Cash Flows from Investing Activities. We had no significant investing activities during the nine months ended September 30, 2016 and 2015.

Cash Flows from Financing Activities. We had no significant financing activities during the nine month period ended September 30, 2016. Net cash provided by financing activities of $7.5 million during the nine months ended September 30, 2015 was primarily the result of proceeds from the issuance of convertible notes.

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 or CardiALLO 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. Upon the closing of the Merger, we expect to incur additional costs associated with operating as a public company. 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.

Based upon our current operating plan, we believe that the cash on hand resulting from the Merger, together with our existing cash and cash equivalents, will enable us to fund our operations through late 2018. We intend to use the net proceeds we receive in connection with the Merger for the FDA accepted Phase III pivotal trial of CardiAMP, working capital, research and development of additional future products or therapies and general corporate purposes. 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 clinical trials;
- FDA acceptance of our CardiAMP and CardiALLO 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;

- 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 Stock holders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our Common Stock holders. 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 additional 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.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the rules of the Securities and Exchange Commission.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-15, Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, which requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued and provide related disclosures. This ASU will be effective for the Company in fiscal year 2016. Early adoption is permitted. The Company is currently assessing the future impact of this ASU on its financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which provides comprehensive guidance for revenue recognition. ASU 2014-09 affects any entity which either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets. The core principle of the guidance provides that a company should recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. Companies can adopt the new standard either using the full retrospective approach, a modified retrospective approach with practical expedients, or a cumulative effect upon adoption approach.

In August 2015, the FASB issued ASU 2015-14 Revenue from Contracts with Customers, which deferred the effective date for implementation of the standard. Nonpublic companies must apply the standard for annual reporting periods beginning after December 15, 2018 and interim reporting periods within annual reporting periods beginning after December 15, 2019. Early adoption for nonpublic entities is permitted as of an annual reporting period beginning after December 15, 2016, including interim reporting periods within that reporting period. Public entities are to apply the new standard for annual and interim reporting periods beginning after December 15, 2017 and earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. The Company is currently assessing the future impact of this ASU on its financial statements.

In July 2015, the FASB issued Accounting Standard Update ("ASU") No. 2015-11, "Inventory: Simplifying the Measurement of Inventory", that requires inventory not measured using either the last in, first out (LIFO) or the retail inventory method to be measured at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable cost of completion, disposal and transportation. The new standard will be effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, and will be applied prospectively. Early adoption is permitted. The adoption of this guidance is not expected to have a material impact on our financial position, results of operations or cash flows.

In February 2016, the FASB issued ASU 2016-02 Leases (Topic 842), which supersedes existing guidance on accounting for leases in "Leases (Topic 840)" and generally requires all leases to be recognized in the consolidated balance sheet. ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018; early adoption is permitted. The provisions of ASU 2016-02 are to be applied using a modified retrospective approach. The Company is currently assessing the future impact of this ASU on its financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The standard is intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact, classification in the statement of cash flows and forfeitures. ASU 2016-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is permitted. The Company is currently assessing the future impact of this ASU on its financial statements.

Item 2.02 Results of Operations and Financial Condition.

Reference is made to the disclosure set forth under Items 2.01 and 9.01 of this Current Report on Form 8-K concerning the financial information of BioCardia Lifesciences, which is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

Attached as Exhibit 99.1 and incorporated herein by reference are the unaudited condensed financial statements of BioCardia Lifesciences as of, and for the three and nine month periods ended September 30, 2016 and 2015, including the footnotes thereto.

The audited financial statements of BioCardia Lifesciences as of December 31, 2015 and 2014, and for each of the years then ended, including the footnotes thereto, were filed as exhibit 99.1 to the Original Form 8-K. The unaudited condensed financial statements of BioCardia Lifesciences as of, and for the six months ended June 30, 2016 and 2015, including the footnotes thereto, were filed as exhibit 99.2 to the Original Form 8-K.

(b) Pro Forma Financial Information.

The unaudited pro forma condensed combined financial statements as of, and for the fiscal years ended, December 31, 2015, and for the six months ended, June 30, 2016, were filed as exhibit 99.3 to the Original Form 8-K..

(d) Exhibits

Exhibit Number	Description
99.1	Unaudited condensed financial statements of BioCardia Lifesciences as of, and for the three and nine month periods ended September 30, 2016 and 2015, including the footnotes thereto.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOCARDIA, INC.

By: /s/ Peter Altman
Name: Peter Altman
Title: President and Chief Executive Officer

Dated: November 14, 2016

EXHIBIT INDEX

Exhibit Number	**Description**
99.1	Unaudited condensed financial statements of BioCardia Lifesciences as of, and for the three and nine month periods ended September 30, 2016 and 2015, including the footnotes thereto.