BioCardia, Inc.
Form 10-Q
May 10, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2018

or

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

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)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
		Emerging growth company

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

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

Indicate the number of shares outstanding of each of the issuer’s classes of common stock, as of the latest practicable date.

There were 38,241,244 shares of the registrant’s Common Stock issued and outstanding as of May 7, 2018.

FORWARD-LOOKING INFORMATION

This Quarterly Report on Form 10-Q, or report, contains forward-looking statements within the meaning of the U.S. federal securities laws that involve risks and uncertainties. Certain statements contained in this report are not purely historical including, without limitation, statements regarding our expectations, beliefs, intentions, anticipations, commitments or strategies regarding the future that are forward-looking. These statements include those discussed in Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations, including "Critical Accounting Policies and Estimates," "Results of Operations," "Liquidity and Capital Resources," and "Future Funding Requirements," and elsewhere in this report.

In this report, the words "may," "could," "would," "might," "will," "should," "plan," " forecast," "anticipate," "believe," "expect," "intend," "estimate," "predict," "potential," "continue," "future," "moving toward" or the

negative of these terms or other similar expressions also identify forward-looking statements. Our actual results could differ materially from those forward-looking statements contained in this report as a result of a number of risk factors including, but not limited to, those listed in our Annual Report on Form 10-K and elsewhere in this report. You should carefully consider these risks, in addition to the other information in this report and in our other filings with the SEC. All forward-looking statements and reasons why results may differ included in this report are made as of the date of this report, and we undertake no obligation to update any such forward-looking statement or reason why such results might differ after the date of this Quarterly Report on Form 10-Q, except as required by law.

PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIOCARDIA, INC.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	March 31, 2018 *(unaudited)*	**December 31, 2017**
Assets		
Current assets:		
Cash and cash equivalents	$ 9,653	$ 12,689
Accounts receivable, net of allowance for doubtful accounts of $6 at March 31, 2018 and December 31, 2017, respectively	127	95
Inventory	148	191
Prepaid expenses	277	340
Total current assets	10,205	13,315
Property and equipment, net	152	169
Other assets	54	54
Total assets	$ 10,411	$ 13,538
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 738	$ 902
Accrued expenses and other current liabilities	1,323	1,263
Deferred revenue	60	167
Total current liabilities	2,121	2,332
Deferred rent	83	81
Total liabilities	2,204	2,413
Stockholders' equity:		
Preferred stock, $0.001 par value, 25,000,000 shares authorized; no shares issued and outstanding as of March 31, 2018 and December 31, 2017	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized as of March 31, 2018 and December 31, 2017 respectively; 38,241,244 and 38,218,660 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively	38	38
Additional paid-in capital	84,157	83,537

Accumulated deficit	(75,988)	(72,450)
Total stockholders' equity	8,207	11,125
Total liabilities and stockholders' equity	$ 10,411	$ 13,538

See accompanying notes to condensed consolidated financial statements.

BIOCARDIA, INC.

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

(unaudited)

	Three months ended March 31,	
	2018	2017
Revenue:		
Net product revenue	$82	$109
Collaboration agreement revenue	117	28
Total revenue	199	137
Costs and expenses:		
Cost of goods sold	157	175
Research and development	1,955	1,033
Selling, general and administrative	1,707	1,804
Total costs and expenses	3,819	3,012
Operating loss	(3,620)	(2,875)
Other income (expense):		
Interest income	36	—
Other expense, net	—	(1)
Total other income (expense), net	36	(1)
Net loss	$(3,584)	$(2,876)
Net loss per share, basic and diluted	$(0.09)	$(0.08)
Weighted-average shares used in computing net loss per share, basic and diluted	38,236,056	38,137,881

See accompanying notes to condensed consolidated financial statements.

BIOCARDIA, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(unaudited)

	Three months ended March 31,	
	2018	2017
Operating activities:		
Net loss	$(3,584)	$(2,876)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	22	13
Share-based compensation	615	622
Changes in operating assets and liabilities:		
Accounts receivable	(32)	(47)
Inventory	43	(9)
Prepaid expenses	63	104
Accounts payable	(164)	(249)
Accrued liabilities	34	157
Deferred revenue	(35)	1
Deferred rent	2	6
Net cash used in operating activities	(3,036)	(2,278)
Investing activities:		
Purchase of property and equipment	(5)	(64)
Net used in in investing activities	(5)	(64)
Financing activities:		
Proceeds from the exercise of common stock options	5	22
Net cash provided by financing activities	5	22
Net decrease in cash and cash equivalents	(3,036)	(2,320)
Cash and cash equivalents at beginning of period	12,689	21,352
Cash and cash equivalents at end of period	$9,653	$19,032
Supplemental disclosure of noncash investing activity:		
Accounts payable recognized for the purchase of equipment	$—	$15

See accompanying notes to condensed consolidated financial statements.

(1) Summary of Business and Basis of Presentation

(a) Description of Business

BioCardia, Inc., (We or the Company), is 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 and our second therapeutic candidate is the CardiALLO cell therapy system. To date, we have devoted substantially all 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 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. We manage our operations as a single segment for the purposes of assessing performance and making operating decisions.

(2) Significant Accounting Policies

(a) Basis of Preparation

The accompanying condensed consolidated balance sheets, statements of operations and cash flows as of March 31, 2018 and for the three months ended March 31, 2018 and 2017 are unaudited. The condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP) and applicable rules and regulations of the Securities and Exchange Commission (SEC) for interim financial information and on a basis consistent with the annual financial statements and, in the opinion of management, reflect all adjustments which include only normal recurring adjustments, necessary to present fairly our financial position as of March 31, 2018, results of operations for the three months ended March 31, 2018 and 2017, and cash flows for the three months ended March 31, 2018 and 2017. The results for the three months ended March 31, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other interim period or for any other future year.

These condensed consolidated financial statements should be read in conjunction with the audited financial statements and related notes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 16, 2018.

(b) Liquidity

We have incurred net losses and negative cash flows from operations since our inception and had an accumulated deficit of $76.0 million as of March 31, 2018. Management expects operating losses and negative cash flows to continue through the next several years. Based on management’s current plans, management believes cash and cash equivalents of $9.7 million as of March 31, 2018 are sufficient to fund the Company into the fourth quarter of 2018. These factors raise substantial doubt about our ability to continue as a going concern beyond one year

from the date these financial statements are issued. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Our ability to continue as a going concern and to continue further development of our lead therapeutic candidate, the CardiAMP cell therapy system, and our second therapeutic candidate, the CardiALLO cell therapy system, through and beyond the fourth quarter of 2018, will require us to raise additional capital. We plan to raise additional capital, potentially including debt and equity arrangements, to finance our future operations. If adequate funds are not available, we may be required to reduce operating expenses, delay or reduce the scope of our product development programs, obtain funds through arrangements with others that may require us to relinquish rights to certain of our technologies or products that we would otherwise seek to develop or commercialize ourselves, or cease operations. While we believe we have a viable strategy to raise additional funds, there can be no assurances that we will be able to obtain additional capital on acceptable terms and in the amounts necessary to fully fund our operating needs.

(c) Use of Estimates

The preparation of the financial statements in accordance with U.S. GAAP requires management to make certain estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates. Significant items subject to such estimates and assumptions include share-based compensation, the useful lives of property and equipment, allowances for doubtful accounts and sales returns and inventory valuation.

(d) Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany accounts and transactions have been eliminated during the consolidation process.

(e) Changes to Significant Accounting Policies

Our significant accounting policies are described in Note 2 of the notes to the financial statements included in our Annual Report on Form 10-K filed for the year ended 2017. Apart from the adoption of ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) on January 1, 2018 which led to an amended revenue policy, as described in the following paragraphs, there have been no changes to those policies.

Revenue Recognition

Net product revenue – We currently have 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.

Collaboration agreement revenue – Collaboration agreement revenue is income from agreements under partnering programs with corporate and academic institutions, wherein we provide 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.

Revenue is recognized when control of products and services is transferred to the customer in an amount that reflects the consideration that we expect to receive from the customer in exchange for those products and services. This process involves identifying the contract with the customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identifiable from other promises in the contract. We consider a performance obligation satisfied once control of a good or service has been transferred to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service.

Amounts received from customers in advance of revenue recognition are recorded as deferred revenue on the consolidated balance sheets.

Recently Adopted Accounting Pronouncement

(f) In May 2014, the FASB issued Topic 606, which provides comprehensive guidance for revenue recognition. Topic 606 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. The new standard can be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of the change recognized at the date of the initial application in retained earnings.

On January 1, 2018, we adopted Topic *606* using the cumulative effect adoption method. Results for reporting periods beginning after January 1, 2018 are presented under Topic *606*, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under Topic 605. The adoption of Topic 606 did not have a material impact on our financial statements.

In January 2016, the FASB issued ASU No. 2016-01 (ASU 2016-01), Recognition and Measurement of Financial Assets and Financial Liabilities. ASU 2016-01 changes accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. In addition, the update clarifies guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. We adopted ASU 2016-01 on January 1, 2018 and the adoption did not have a material impact on our financial statements.

In May 2017, the FASB issued ASU No. 2017-09 Compensation – Stock Compensation (Topic 718) Scope of Modification Accounting (ASU 2017-09). The amendments in ASU 2017-09 provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. We adopted ASU 2017-09 effective January 1, 2018, and the adoption did not have a material impact on our financial statements.

(g) Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02 Leases (Topic 842) (ASU 2016-02), 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 Company does not plan to elect early adoption. 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 consolidated 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 Measurement

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 our financial assets measured on a recurring basis as of March 31, 2018 and December 31, 2017 and indicates the fair value hierarchy utilized to determine such fair value (in thousands).

	As of March 31, 2018			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and cash equivalents	$9,653	$ —	$ —	$9,653

	As of December 31, 2017			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and cash equivalents	$12,689	$ —	$ —	$12,689

(4) Inventories

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

	March 31, 2018	**December 31, 2017**
Raw materials	$ 78	$ 70
Work in process	15	92
Finished goods	55	29
Total	$ 148	$ 191

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 $9,000 for the three months ended March 31, 2018 and 2017, respectively.

(5) Property and Equipment, Net

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

	March 31, 2018	**December 31, 2017**
Computer equipment and software	$ 110	106
Laboratory and manufacturing equipment	447	447
Furniture and fixtures	48	48
Leasehold improvements	326	326
Property and equipment, gross	931	927
Less accumulated depreciation	(779)	(758)
Property and equipment, net	$ 152	169

Depreciation expense totaled approximately $22,000 and $13,000 for the three months ended March 31, 2018 and 2017, respectively.

(6) Accrued Expenses and Other Current Liabilities

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

	March 31, 2018	December 31, 2017
Accrued expenses	$579	$ 539
Grant liability	654	663
Customer deposits	90	61
Total	$1,323	$ 1,263

(7) Share-Based Compensation

The share-based compensation expense is recorded in cost of goods sold, research and development, and selling, general and administrative expenses based on the employee's respective function. No share-based compensation was capitalized during the periods presented. Share-based compensation expense for the three months ended March 31, 2018 and 2017 was recorded as follows (in thousands):

	Three months ended March 31,	
	2018	2017
Cost of goods sold	$30	$41
Research and development	197	172
Selling, general and administrative	388	409
Share-based compensation expense	$615	$622

The following table summarizes the activity of stock options and related information:

	Number of shares	Weighted average exercise price

Balance, December 31, 2017	4,213,100	$ 2.96
Stock options granted	1,429,075	2.60
Stock options exercised	(2,488)	1.80
Stock options cancelled	(20,833)	7.56
Balance, March 31, 2018	5,618,854	$ 2.85

The weighted average grant-date fair value of options granted during the three months ended March 31, 2018 was $1.86 per share.

Employee Share-Based Compensation (Stock Options)

During the three months ended March 31, 2018, we granted stock options to certain non-employee directors and employees to purchase 1,429,075 shares of common stock. The fair value of each option grant was estimated on the date of the grant using the Black-Scholes option pricing model with the following assumptions:

Risk-free interest rate	2.66%
Volatility	81%
Dividend yield	None
Expected term (in years)	6.25%

Unrecognized share-based compensation for employee options granted through March 31, 2018 is approximately $6.7 million to be recognized over a remaining weighted average service period of 3.1 years.

Non-Employee Director Share-Based Compensation (RSUs)

The following summarizes the activity of non-vested RSUs:

	Number of shares	Weighted average grant date fair value per share
Balance, December 31, 2017	97,996	$ 8.71
RSUs granted	—	
RSUs vested	(20,444)	11.04
RSUs forfeited	—	
Balance, March 31, 2018	77,552	$ 8.09

Unrecognized share-based compensation for employee RSUs granted through March 31, 2018 is approximately $441,000 to be recognized over a remaining weighted average service period of 1.7 years.

Nonemployee Share-Based Compensation

During the three months ended March 31, 2018, we did not grant any options to purchase shares of common stock to consultants. Options granted to consultants have been granted in exchange for consulting services to be rendered and vest over the term specified in the grant, which correlates to the period the services are rendered. We recorded approximately $45,000 and $233,000 for the three months ended March 31, 2018 and 2017, respectively, as nonemployee share-based compensation expense.

The Company accounts for share-based compensation arrangements with nonemployees, using the Black-Scholes option pricing model, based on the fair value as these instruments vest. Accordingly, at each reporting date, the Company revalues the unearned portion of the share-based compensation and the resulting change in fair value is recognized in the consolidated statements of operations over the period the related services are rendered. The following assumptions were used to value the awards for the three months ended March 31, 2018:

Risk-free interest rate	2.83%

Volatility	80%	
Dividend yield	None	
Expected term (in years)	8.4 -	8.8

(8) Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding for the period. 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. 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 our net loss position.

The following 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:

	Three months ended March 31,	
	2018	**2017**
Stock options to purchase common stock	5,618,854	3,816,927
Unvested restricted stock units	77,552	61,333
Total	5,696,406	3,878,260

(9) Income Taxes

During the three months ended March 31, 2018 and 2017, there was no income tax expense or benefit for federal or state income taxes in the accompanying condensed consolidated statement of operations due to the Company's net loss and a full valuation allowance on the resulting deferred tax assets.

As of March 31, 2018, we retain a full valuation allowance on our deferred tax assets in all jurisdictions. The realization of our deferred tax assets depends primarily on our ability to generate future taxable income which is uncertain. We do not believe that our deferred tax assets are realizable on a more-likely-than-not basis; therefore, the net deferred tax assets have been fully offset by a valuation allowance.

On December 22, 2017, the Tax Cuts and Jobs Act (H.R. 1) (the Tax Act) was signed into law. The new law resulted in significant changes to the U.S. corporate income tax system. These changes included the reduction of the corporate income tax rate from a maximum rate of 35% to 21% and the elimination or reduction of certain domestic deductions and credits.

The 2017 provisional charge related to the Tax Act was an estimate and the measurement of net deferred tax assets is subject to further analysis and potential correlative adjustments as developing interpretations and guidance from the U.S. Treasury Department, the Internal Revenue Service, and other standard setting bodies provide additional clarifications of the provisions of the Tax Act. Updated guidance and regulations could result in changes to this provisional charge during 2018 when the analysis is complete, and, in accordance with the guidance in Staff Accounting Bulletin 118, we will continue to monitor guidance and make necessary adjustments. No measurement-period adjustments were made during the quarter ended March 31, 2018.

(10) Related Party Transactions

In August 2016, we granted an option to purchase 418,977 shares of common stock, with 4-year vesting period and an exercise price of $1.80 per share, to OPKO Health, Inc. ("OPKO") as consideration for consulting services to be provided by OPKO. We recorded $37,000 and $122,000 as share-based compensation expense related to the OPKO stock option during the three months ended March 31, 2018 and 2017, respectively. The estimated grant-date fair value of the option was $5.3 million. The term of the consulting agreement is 4 years and will be automatically renewed for successive one year periods. 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 and OPKO itself is also a beneficial owner of more than 5% of the outstanding shares of the Company's common stock.

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ITEM 2. 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 Quarterly Report on Form 10-Q. 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 listed in our Annual Report on Form 10-K and elsewhere in this report. Historical results are not necessarily indicative of future results.

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 investigational CardiAMP Cell Therapy System, which 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 and chronic myocardial ischemia.

We initiated our U.S. Food and Drug Administration, or FDA, accepted Phase III pivotal trial for CardiAMP Cell Therapy in ischemic systolic heart failure, in December 2016. 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 trial's primary endpoint is a clinical composite of six minute walk distance and major adverse cardiac and cerebrovascular events. In September 2017, the independent Data Safety Monitoring Board (DSMB) completed the pre-specified interim analysis of safety outcomes for the first 10 patients treated in the Phase III trial of its investigational CardiAMP cell therapy product. The DSMB indicated there were no significant safety concerns with the CardiAMP study results and recommended that the trial continue, as planned. Currently 13 world class medical centers are actively enrolling in the study. Efficacy results from the primary endpoint in the open label roll in cohort are anticipated in the second half of 2018. We anticipate that trial enrollment will be completed in the first half of 2019.

In January 2018, the FDA approved a second investigational device exemption (IDE) for the randomized controlled pivotal trial of autologous bone marrow mononuclear cells using the CardiAMP Cell Therapy System in patients with refractory chronic myocardial ischemia for up to 343 patients at up to 40 clinical sites in the United States. This therapeutic approach uses many of the same novel aspects as the CardiAMP Heart Failure Trial and leverages our experience and investment in the heart failure trial.

The Department of Health & Human Services Centers for Medicare & Medicaid Services, or CMS, has designated that both the CardiAMP Heart Failure Trial and the CardiAMP Chronic Myocardial Ischemia Trial qualify for Medicare national coverage. Covered costs are anticipated to 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.

Our second therapeutic candidate is the CardiALLO Cell Therapy System, which utilizes bone marrow derived mesenchymal cells from a donor to treat heart failure. We anticipate submitting an Investigational New Drug (IND) application for submission to the FDA for a Phase II trial for CardiALLO Cell Therapy System for the treatment of ischemic systolic heart failure in 2018. This IND is expected to have improved Chemistry Manufacturing Controls relative to our previous co-sponsored investigations utilizing culture expanded bone marrow derived mesenchymal stem cells.

To date, we have devoted substantially all 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.

We have incurred net losses in each year since our inception. Our net losses were approximately $3.6 million and $2.9 million for the three months ended March 31, 2018 and 2017, respectively. As of March 31, 2018, we had an accumulated deficit of approximately $76.0 million. Substantially all 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. As discussed in more detail under “Liquidity and Capital Resources”, there is substantial doubt about our ability to continue as a going concern within one year after the date these financial statements are issued, and we plan to raise additional capital, potentially including debt and equity arrangements, to finance our future 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 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 performed.

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 the CardiAMP and CardiALLO Cell Therapy Systems, and subject to the availability of additional funding, develop 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.

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 consists primarily of interest income we earn on our cash, cash equivalents and investments.

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.

Apart from the adoption of ASU No. 2014-09 Revenue from Contracts with Customers (Topic 606) on January 1, 2018, which led to an amended revenue policy described below, there were no material changes during the three months ended March 31, 2018 in our critical accounting estimates or accounting policies described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K.

Revenue Recognition

Net product revenue – We currently have 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.

Collaboration agreement revenue – Collaboration agreement revenue is income from agreements under partnering programs with corporate and academic institutions, wherein we provide 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.

Revenue is recognized when control of products and services is transferred to the customer in an amount that reflects the consideration that we expect to receive from the customer in exchange for those products and services. This process involves identifying the contract with the customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identifiable from other promises in the contract. We consider a performance obligation satisfied once control of a good or service has been transferred to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service.

Amounts received from customers in advance of revenue recognition are recorded as deferred revenue on the consolidated balance sheets.

Results of Operations

Comparison of Three Months Ended March 31, 2018 and 2017

The following table summarizes our results of operations for the three months ended March 31, 2018 and 2017 (in thousands):

	Three months ended March 31,	
	2018	**2017**
Revenue:		
Net product revenue	$82	$109
Collaboration agreement revenue	117	28
Total revenue	199	137
Costs and expenses:		
Cost of goods sold	157	175
Research and development	1,955	1,033
Selling, general and administrative	1,707	1,804
Total costs and expenses	3,819	3,012
Operating loss	(3,620)	(2,875)
Other income (expense):		
Interest income	36	—
Other income (expense)	—	(1)
Total other income (expense), net	36	(1)
Net loss	$(3,584)	$(2,876)

Revenue. Revenue increased by approximately $62,000 in the three months ended March 31, 2018 compared to the three months ended March 31, 2017 primarily due to increased revenue earned under programs with our collaborative partners due to the adoption of Topic 606. We expect overall sales volumes to increase modestly in 2018, resulting in moderate growth in net product revenue year over year.

Cost of Goods Sold. Cost of goods sold decreased by approximately $18,000 in the three months ended March 31, 2018 compared to the three months ended March 31, 2017 primarily due to a decrease in product sales volumes. We expect cost of goods sold to increase moderately in 2018 due to growth in net product revenues during the latter half of the year.

Research and Development Expenses. Research and development expenses increased by approximately $922,000 in the three months ended March 31, 2018 compared to the three months ended March 31, 2017 primarily due to increased expenses incurred in conducting the ongoing pivotal CardiAMP Heart Failure Trial and in the development of the CardiALLO Cell Therapy System. These expenses include fees paid to consultants and contract research organizations (CRO) and additional personnel costs. We expect research and development expenses to continue to increase as enrollment accelerates in the CardiAMP Heart Failure Trial and we further develop the CardiAMP and CardiALLO platforms.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the three months ended March 31, 2018 totaled $1,707,000, which was a 5.4% decrease as compared to $1,804,000 for three months ended March 31, 2017. We expect selling, general and administrative expenses for 2018 to increase moderately in the latter half of 2018 compared to 2017, as we continue to enhance and strengthen the supporting staff and infrastructure needed to support the CardiAMP Heart Failure Trial and development of our therapeutic programs.

Liquidity and Capital Resources

We have incurred net losses each year since our inception and as of March 31, 2018, we had an accumulated deficit of approximately $76.0 million. We anticipate that we will continue to incur net losses for 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 reverse merger transaction completed on October 24, 2016. As of March 31, 2018, we had cash and cash equivalents of approximately $9.7 million.

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

	Three months ended March 31,	
	2018	2017
Net cash provided by (used in):		
Operating activities	$(3,036)	(2,278)
Investing activities	(5)	(64)
Financing activities	5	22
Net decrease in cash and cash equivalents	$(3,036)	$(2,320)

Cash Flows from Operating Activities. The increase in overall spending for operating activities of $758,000 in the three months ended March 31, 2018 compared to the three months ended March 31, 2017 related primarily to increased cash outflows to conduct the pivotal CardiAMP Heart Failure Trial, further develop the CardiAMP and CardiALLO programs and to build the supporting infrastructure to sustain these efforts and support operations as a public company. We expect spending to increase as we continue enrolling and treating patients in the CardiAMP Heart Failure Trial, further develop the CardiAMP and CardiALLO cell therapy systems and continue to strengthen and enhance the supporting organization.

Cash Flows from Investing Activities. Net cash used in investing activities of $5,000 during the three months ended March 31, 2018 consisted of the purchases of property and equipment.

Cash Flows from Financing Activities. Net cash provided by financing activities of $5,000 during the three months ended March 31, 2018 consisted of the proceeds from the exercise of stock options.

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. 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 and cash equivalents of $9.7 million as of March 31, 2018 are sufficient to fund our operations into the fourth quarter of 2018. In order to continue to further the development of our lead therapeutic candidates, the CardiAMP Cell Therapy System, and our second therapeutic candidate, the CardiALLO Cell Therapy System, through and beyond the fourth quarter of 2018, we will be required to raise additional capital. We plan to raise additional capital, potentially including debt and equity arrangements, to finance our future operations. 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 and related development programs;
- 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;
- 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 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 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.

Our condensed consolidated financial statements as of and for the three months ended March 31, 2018 have been prepared on the basis that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. Due to the factors described above, there is substantial doubt about our ability to continue as a going concern within one year after the date these financial statements are issued. Our ability to continue as a going concern will depend in a large part, on our ability to raise additional capital.

If adequate funds are not available, we may be required to reduce operating expenses, delay or reduce the scope of our product development programs, obtain funds through arrangements with others that may require us to relinquish rights to certain of our technologies or products that we would otherwise seek to develop or commercialize ourselves, or cease operations. While we believe we have a viable strategy to raise additional funds, there can be no assurances that we will be able to obtain additional capital on acceptable terms and in the amounts necessary to fully fund our operating needs.

The financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we are unable to continue as a going concern, we may be forced to liquidate assets. In such a scenario, the values received for assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

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

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in our market risks during the quarter ended March 31, 2018.

Our exposure to market risk is currently limited to our cash and cash equivalents, all of which have maturities of less than three months. The goals of our investment policy are preservation of capital, maintenance of liquidity needs, and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk or departing from our investment policy. We currently do not hedge interest rate exposure. Because of the short-term nature of our cash equivalents, we do not believe that an increase in market rates would have a material negative impact on the value of our portfolio.

Interest Rate Risk

As of March 31, 2018, based on current interest rates and total borrowings outstanding, a hypothetical 100 basis point increase or decrease in interest rates would have an immaterial pre-tax impact on our results of operations.

Foreign Currency Exchange Risks

We are a U.S. entity and our functional currency is the U.S. dollar. The vast majority of our revenues were derived from sales in the United States. We have business transactions in foreign currencies, however, we believe we do not have significant exposure to risk from changes in foreign currency exchange rates at this time. We do not currently engage in hedging or similar transactions to reduce our foreign currency risks. We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

ITEM 4. 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 Quarterly Report on Form 10-Q, as of March 31, 2018, 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 our Chief Financial Officer have concluded that, as of March 31, 2018, our disclosure controls and procedures were, in design and operation, effective.

Changes 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 quarter ended March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We may be subject to various claims, complaints, and legal actions that arise from time to time in the normal course of business. Management does not believe that we are a party to any currently pending legal proceedings. There can be no assurance that existing or future legal proceedings arising in the ordinary course of business or otherwise will not have a material adverse effect on our business, financial position, results of operations, or cash flows.

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2017, which could materially affect our business, financial condition, or future results. The risks described in this report and in our Annual Report on 10-K are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBIT INDEX

The exhibits listed in the Exhibit Index to this Quarterly Report on Form 10-Q are incorporated herein by reference.

SIGNATURES

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 thereunto duly authorized.

BIOCARDIA, INC.

(Registrant)

Date: May 10, 2018 By: /s/ Peter Altman
Peter Altman
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 10, 2018 By: /s/ David McClung
David McClung
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Exhibit Description
31.1*	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to Rule 13a-14(b) and Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith.

+ The financial information contained in these XBRL documents is unaudited and is furnished, not filed with the Securities and Exchange Commission.

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