BioCardia, Inc.
Form 10-Q
August 14, 2017

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 June 30, 2017

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)

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

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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 457,818,571 shares of the registrant’s Common Stock issued and outstanding as of August 14, 2017.

FORWARD-LOOKING INFORMATION

This 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)

	June 30, 2017 *(unaudited)*	**December 31, 2016**
Assets		
Current assets:		
Cash and cash equivalents	$ 15,109	$ 21,352
Accounts receivable, net of allowance for doubtful accounts of $1 and $2 at June 30, 2017 and December 31, 2016, respectively	142	74
Inventory	193	135
Short-term investments	1,796	—
Prepaid expenses	282	356
Total current assets	17,522	21,917
Property and equipment, net	180	111
Other assets	54	54
Total assets	$ 17,756	$ 22,082
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 590	$ 525
Accrued expenses and other current liabilities	864	848
Deferred revenue	153	71
Total current liabilities	1,607	1,444
Deferred rent	68	56
Total liabilities	1,675	1,500
Stockholders' equity:		
Preferred stock, $0.001 par value, 50,000,000 shares authorized, no shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock, $0.001 par value, 750,000,000 shares authorized at June 30, 2017 and December 31, 2016, 457,682,784 shares and 457,575,631 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	458	458
Additional paid-in capital	81,586	80,266
Accumulated deficit	(65,963)	(60,142)
Total stockholders' equity	16,081	20,582

Total liabilities and stockholders' equity	$ 17,756	$ 22,082

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 June 30,		Six Months ended June 30,	
	2017	2016	2017	2016
Revenue:				
Net product revenue	$101	$138	$210	$306
Collaboration agreement revenue	11	6	39	16
Total revenue	112	144	249	322
Costs and expenses:				
Cost of goods sold	203	156	378	382
Research and development	1,295	497	2,328	938
Selling, general and administrative	1,582	869	3,386	1,456
Total costs and expenses	3,080	1,522	6,092	2,776
Operating loss	(2,968)	(1,378)	(5,843)	(2,454)
Other income (expense):				
Interest income	23	—	23	—
Interest expense	—	(557)	—	(1,107)
Change in fair value of convertible preferred stock warrant liability	—	167	—	220
Change in fair value of maturity date preferred stock warrant liability	—	8	—	7
Change in fair value of convertible shareholder notes derivative liability	—	(217)	—	(139)
Other income (expense), net	—	(1)	(1)	(1)
Total other income (expense), net	23	(600)	22	(1,020)
Net loss	$(2,945)	$(1,978)	$(5,821)	$(3,474)
Net loss per share, basic and diluted	$(0.01)	$(0.11)	$(0.01)	$(0.19)
Weighted-average shares used in computing net loss per share, basic and diluted	457,682,784	18,723,511	457,668,755	18,723,511

See accompanying notes to condensed consolidated financial statements.

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BIOCARDIA, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(unaudited)

	Six Months ended June 30,	
	2017	2016
Operating activities:		
Net loss	$(5,821)	$(3,474)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	36	21
Change in fair value of convertible preferred stock warrant liability	—	(220)
Change in fair value of maturity date preferred stock warrant liability	—	(7)
Change in fair value of convertible shareholder notes derivative liability	—	139
Stock based compensation	1,298	58
Non-cash interest expense on convertible shareholder notes	—	1,107
Changes in operating assets and liabilities:		
Accounts receivable	(68)	22
Inventory	(58)	18
Prepaid expenses	74	98
Accounts payable	60	185
Accrued expenses and other current liabilities, excluding accrued interest on convertible note	16	161
Deferred revenue	82	37
Deferred rent	12	(15)
Net cash used in operating activities	(4,369)	(1,870)
Investing activities:		
Purchase of property and equipment	(100)	—
Purchase of short-term investments	(1,796)	—
Net cash used in investing activities	(1,896)	—
Financing activities:		
Proceeds from the exercise of stock options	22	—
Net cash provided by financing activities	22	—
Net decrease in cash and cash equivalents	(6,243)	(1,870)
Cash and cash equivalents at beginning of period	21,352	3,557
Cash and cash equivalents at end of period	$15,109	$1,687
Supplemental disclosures for noncash investing activity:		
Accounts payable recognized for the purchase of equipment	$5	$—

See accompanying notes to condensed consolidated financial statements.

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(1) Summary of Business and Basis of Presentation

(a) Description of Business

BioCardia, Inc., or the Company, is a clinical-stage regenerative medicine company developing novel therapeutics for cardiovascular diseases with large unmet medical needs. Its lead therapeutic candidate is the CardiAMP cell therapy system and its second therapeutic candidate is the CardiALLO cell therapy system. To date the Company has devoted substantially all of its resources to research and development efforts relating to its therapeutic candidates and biotherapeutic delivery systems including conducting clinical trials, developing manufacturing and sales capabilities, in-licensing related intellectual property, providing general and administrative support for these operations and protecting its intellectual property.

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

(b) Reverse Merger

On August 22, 2016, the Company, its wholly-owned subsidiary, Icicle Acquisition Corp, and BioCardia Lifesciences, Inc., or BioCardia Lifesciences (at the time named BioCardia, Inc.), entered into an Agreement and Plan of Merger, or the Merger Agreement. The transactions contemplated by the Merger Agreement closed on October 24, 2016, pursuant to which Icicle Acquisition Corp. merged with and into BioCardia Lifesciences, with BioCardia Lifesciences continuing as the surviving company, or the Merger. BioCardia Lifesciences was determined to be the accounting acquirer in the Merger based upon the terms of the Merger and other factors, including: (i) former BioCardia Lifesciences security holders owned approximately 54% of the combined company (on a fully diluted basis) immediately following the closing of the Merger, (ii) former BioCardia Lifesciences directors hold the majority of the board seats in the combined company, and (iii) former BioCardia Lifesciences management holds all of the key positions in the management of the combined company. Following the completion of the Merger, the Company changed its name to BioCardia, Inc.

Exchange Ratio

Pursuant to the Merger Agreement, each share of BioCardia Lifesciences common stock issued and outstanding prior to the Merger, including shares of common stock underlying outstanding preferred stock, convertible notes (which converted into common stock immediately prior to the Merger), and stock options were converted into the right to receive 19.3678009 shares of Company common stock, or the Exchange Ratio. The accompanying condensed consolidated financial statements and notes to the condensed consolidated financial statements give retroactive effect

to the capital structure as a result of the Merger.

(2) Significant Accounting Policies

(a) Basis of Preparation

The accompanying condensed consolidated balance sheets, statements of operations, comprehensive loss and cash flows as of June 30, 2017 and for the three and six months ended June 30, 2017 and 2016 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 June 30, 2017, results of operations for the three and six months ended June 30, 2017 and 2016, and cash flows for the six months ended June 30, 2017 and 2016. The results for the three and six months ended June 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 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, 2016, filed with the SEC on March 30, 2017.

(b) Liquidity

The Company has incurred net losses and negative cash flows from operations since its inception and had an accumulated deficit of $66 million as of June 30, 2017. Management expects operating losses and negative cash flows to continue through at least the next several years.

Based on management's current plans, management believes cash and cash equivalents of $15.1 million and short-term investments of $1.8 million as of June 30, 2017 are sufficient to fund the Company into the third quarter of 2018. In order to continue to further the development of the Company's lead therapeutic candidate, the CardiAMP cell therapy system, and the Company's second therapeutic candidate, the CardiALLO cell therapy system, through and beyond Q3 2018, we will be required to raise additional capital. The Company plans to raise additional capital, potentially including debt and equity arrangements, to finance its future operations. If adequate funds are not available, the Company may be required to reduce operating expenses, delay or reduce the scope of its product development programs, obtain funds through arrangements with others that may require the Company to relinquish rights to certain of its technologies or products that the Company would otherwise seek to develop or commercialize itself, or cease operations. While the Company believes in the viability of its strategy to raise additional funds, there can be no assurances to that effect.

(c) Use of Estimates

The preparation of the financial statements in accordance with U.S. GAAP requires Company management to make certain estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates. Significant items subject to such estimates and assumptions include the useful lives of property and equipment; allowances for doubtful accounts and sales returns; inventory valuation; fair value of the convertible preferred stock warrant liability; fair value of the maturity date preferred stock warrant liability; fair value of the convertible shareholder notes derivative liability; and share-based compensation.

(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) Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 of the notes to the financial statements included in the Company's 2016 Form 10-K. There have been no changes to those policies except as described below.

(f) Investments

Short-term investments consist of debt securities classified as available-for-sale and have maturities greater than 90 days, but less than 365 days from the date of acquisition. All investments are carried at fair value based upon quoted market prices. Unrealized gains and losses on available-for-sale securities are excluded from earnings and are reported as a component of accumulated other comprehensive loss. Realized gains and losses on the sale of marketable securities are determined using the specific-identification method and recorded in other income (expense), net on the accompanying unaudited condensed consolidated statements of operations. The Company periodically evaluates these investments for other-than-temporary impairment.

Premiums and discounts on debt securities are amortized or accreted over the life of the security as an adjustment to yield using the effective-interest method. Such amortization and accretion is reported as interest income (expense) in the statement of operations. Dividend and interest income are recognized when earned.

(g) Recently Adopted Accounting Pronouncement

In March 2016, the FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (ASU 2016-09). 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. The Company adopted ASU 2016-09 effective January 1, 2017.

The impact of adopting ASU 2016-09 resulted in the following:

- We classified the excess income tax benefits from stock-based compensation arrangement as a discrete item within income tax expense, rather than recognizing such excess income tax benefits in additional paid-in capital. The adoption of this guidance had no material impact to our condensed consolidated financial statements due to a full valuation allowance recognized against our deferred tax assets.
- We elected to recognize forfeitures as they occur. The cumulative effect adjustment as a result of the adoption of this guidance on a modified retrospective basis was insignificant.
- We applied the change in classification of cash flows resulting from excess tax benefits and cash paid by us when directly withholding shares for tax-withholding purposes on a retrospective basis. The adoption of these provisions did not result in changes in our condensed consolidated statements of cash flow.

There were no other material impacts to our condensed consolidated financial statements as a result of adopting this updated standard.

(g) Recently Issued Accounting Pronouncements

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. 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.

In August 2015, the FASB issued ASU 2015-14 Revenue from Contracts with Customers, which deferred the effective date for implementation of the standard. 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 has not elected early adoption. The Company has formed a task force that is in process of assessing the Company’s customer contracts and the potential impacts the standard may have on previously reported revenues and future revenues. Given the relatively small volume of revenue arrangements, the Company believes that the analysis will be completed in sufficient time to adopt the new standard when required. The Company expects to elect the cumulative effect adoption method.

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 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.

In May 2017, the FASB issued ASU 2017-09 Compensation – Stock Compensation (Topic 718) Scope of Modification Accounting. 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. The adoption of ASU 2017-09, which will become effective for annual periods beginning after December 15, 2017, is not expected to have a material impact on the Company’s 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 Company's money market instruments are classified as Level 2 because they are valued using observable inputs other than quoted market prices. The Company's marketable securities consist of available-for-sale securities and are classified as Level 2 because their value is based on valuation using significant inputs derived from or corroborated by observable market data.

The following table sets forth the fair value of our financial assets measured on a recurring basis as of June 30, 2017 and indicates the fair value hierarchy utilized to determine such fair value (in thousands).

	Level 1	**Level 2**	**Level 3**	**Total**
Cash and cash equivalents:				
Cash	$3,901	$—	$ —	$3,901
Money market instruments	—	8,711	—	8,711
US government securities	—	649	—	649
US government agency securities	—	1,848	—	1,848
Total cash and cash equivalents	$3,901	$11,208	$ —	$15,109
Marketable securities:				
US government securities	—	1,796	—	1,796
Total marketable securities	$—	$1,796	$ —	$1,796

The following table sets forth the fair value of our financial assets measured on a recurring basis as of December 31, 2016 and indicates the fair value hierarchy utilized to determine such fair value (in thousands).

	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash	$21,352	$ —	$ —	$21,352

As discussed in Note 8, in 2015, the Company issued warrants to purchase preferred stock in connection with the note agreements to various shareholders as described below. The warrant liabilities were recorded at the fair value on the date of issuance and were remeasured each subsequent balance sheet date and as of the warrant exercise date, with fair value changes recognized as income (decrease in fair value) or expense (increase in fair value) in other income (expense) in the consolidated statements of operations. No warrants are outstanding as of June 30, 2017.

In May 2015, the Company entered into note agreements with various stockholders of the Company and other lenders for a total of $7.2 million, or the 2015 Notes. As discussed more fully in Note 8, the 2015 Notes include embedded derivative features that were determined to be a compound embedded derivative requiring bifurcation and separate accounting at estimated fair value. The Company estimated the fair value of the compound embedded derivative utilizing a Monte Carlo simulation model from inception through June 30, 2016. The inputs used to determine the estimated fair value of the compound embedded derivative instrument include the probability of an underlying event triggering the redemption event and its timing prior to the maturity date of the 2015 Notes. The fair value measurement is based upon significant inputs not observable in the market. These assumptions are inherently subjective and involve significant management judgment. Upon the completion of the Merger, the valuation of the compound embedded derivative was determined based on the settlement value of the common stock exchanged for the notes on October 24, 2016. No notes are outstanding as of June 30, 2017.

(4) Investments

The following table summarizes the estimated value of the Company's cash equivalents and marketable securities and the gross unrealized gains and losses as of June 30, 2017 (in thousands):

	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
US government securities	$ 1,796	$ —	$ —	$ 1,796
Total marketable securities	$ 1,796	$ —	$ —	$ 1,796

As of June 30, 2017, the contractual maturity of the available-for-sale marketable securities is less than one year. There was no other-than-temporary impairment recognized during the 6 months ended June 30, 2017.

(5) Inventories

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

	June 30, 2017	December 31, 2016
Raw materials	$ 62	59
Work in process	16	—
Finished goods	115	76
Total	$ 193	135

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, scrap, shrinkage and expired inventories totaled approximately $1,000 and $19,000 for the three months ended June 30, 2017 and 2016, respectively, and approximately $10,000 and $37,000 for the six months ended June 30, 2017 and 2016, respectively.

(6) Property and Equipment, Net

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

	June 30, 2017	December 31, 2016
Computer equipment and software	$183	143
Laboratory and manufacturing equipment	431	366
Furniture and fixtures	48	48
Leasehold improvements	325	325
Property and equipment, gross	987	882
Less accumulated depreciation	(807)	(771)
Property and equipment, net	$180	111

Depreciation expense totaled approximately $23,000 and $11,000 for the three months ended June 30, 2017 and 2016, respectively, and approximately $36,000 and $21,000 for the six months ended June 30, 2017 and 2016, respectively.

(7) Accrued Expenses and Other Current Liabilities

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

	June 30, 2017	December 31, 2016
Accrued expenses	$406	478
Accrued clinical trial costs	126	—
Grant liability	269	304
Customer deposits	63	66
Total	$864	848

(8) Convertible Notes

In May 2015, BioCardia Lifesciences entered into note agreements with various stockholders of BioCardia Lifesciences and other lenders for a total of $7.2 million, or the 2015 Notes. The 2015 Notes accrued 8% annual simple interest, matured 18 months from the issue date and were callable after the maturity date by written demand of a majority of the holders of the outstanding note principle. If BioCardia Lifesciences closed an effective registration statement filed under the Securities Act of 1933, as amended, covering the sale of BioCardia Lifesciences common stock (an IPO) prior to maturity, the outstanding principle and accrued interest would have automatically converted into shares of common stock at 80% of the price of the shares of common stock purchased in the IPO. If at any time prior to the maturity date, the Company closed a private placement of the Company's preferred stock for aggregate sales proceeds of at least $5.0 million excluding note conversions, at the note holder's option, or the Optional Conversion Right, the outstanding principle and interest may have been converted into shares of the preferred stock at a conversion price equal to 80% of the price of the preferred shares sold in such financing, plus preferred stock warrant coverage equal to 8% with an exercise price equal to the purchase price of the preferred stock sold in such financing. If the notes were held to maturity, subject to BioCardia Lifesciences authorizing sufficient shares of a new class of preferred stock, or the Maturity Date Preferred Stock, the holder would have had the option to convert the outstanding principle and interest to this new class of Maturity Date Preferred Stock at an exercise price of $0.07 per share, plus 8% warrant coverage.

In August 2016, the Company and the holders of the 2015 Notes amended the 2015 Notes, pursuant to which the outstanding principal amount and all accrued interest through August 31, 2016 automatically converted into shares of BioCardia Lifesciences common stock at 80% of the conversion price of the convertible notes issued in October 2016. In addition, the amendment eliminated the payment of interest for the period subsequent to August 31, 2016, and through the date of the closing of the Merger. Upon the completion of the Merger, the 2015 Notes and accrued interest converted into shares of BioCardia Lifesciences common stock, which were then exchanged at the Exchange Ratio into 67,443,988 shares of the Company's common stock.

The 2015 Notes had redemption features that were determined to be a compound embedded derivative requiring bifurcation and separate accounting at estimated fair value. The changes in the estimated value are reflected in the change in fair value of convertible shareholder notes derivative liability in the consolidated statements of operations. We estimated the fair value of the compound embedded derivative utilizing a Monte Carlo simulation model. The inputs used to determine the estimated fair value of the compound embedded derivative instrument include the probability of an underlying event triggering the redemption event and its timing prior to the maturity date of the 2015 Notes. The fair value measurement is based upon significant inputs not observable in the market. These assumptions are inherently subjective and involve significant management judgment. Immediately prior to the closing of the Merger, the compound embedded derivative was remeasured based on the settlement value of the common stock exchanged for the notes, and we reclassified the balance of the convertible shareholder notes derivative liability to additional paid-in capital.

The Company recognized interest expense, including amortization of the debt discount of approximately $0 and $557,000 for the three months ended June 30, 2017 and 2016, respectively, and approximately $0 and $1.1 million for

the six months ended June 30, 2017 and 2016, respectively.

(9) Share-Based Compensation

BioCardia Lifesciences adopted, and the BioCardia Lifesciences shareholders approved, the 2002 Stock Plan in 2002, or the 2002 Plan, and the Company assumed the 2002 Plan in the Merger. We will not grant any additional awards under the 2002 Plan following the Merger. In 2016, BioCardia Lifesciences adopted, and the BioCardia Lifesciences shareholders approved, the 2016 Equity Incentive Plan, or the 2016 Plan, and the Company assumed the 2016 Plan in the Merger. We will grant awards, including incentive stock options and nonstatutory stock options, under the 2016 Plan following the Merger.

Stock compensation attributable to manufacturing operations was not significant and was expensed directly to cost of goods sold in the condensed consolidated statements of operations. Share-based compensation expense for the three and six months ended June 30, 2017 and 2016 was recorded as follows (in thousands):

	Three Months ended June 30,		**Six Months ended June 30,**	
	2017	**2016**	**2017**	**2016**
Cost of goods sold	$33	$ —	$74	$ 1
Research and development	154	—	326	1
Selling, general and administrative	489	28	898	56
Share-based compensation expense	$676	$ 28	$1,298	$ 58

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

	Options outstanding	
	Number of shares	**Weighted average exercise price**
Balance, December 31, 2016	41,903,728	$ 0.15
Stock options granted	6,714,410	0.73
Stock options exercised	(107,153)	0.20
Stock options cancelled	(407,382)	0.04
Balance, June 30, 2017	48,103,603	$ 0.23

The weighted average grant-date fair value of options granted during the six months ended June 30, 2017 was $0.57 per share.

Employee Share-Based Compensation (Stock Options)

During the six months ended June 30, 2017, the Company granted stock options to certain non-employee directors and employees to purchase 4,766,627 shares of common stock. The fair value of each option grant is estimated on the date of the grant using the BSM option pricing model with the weighted average assumptions in the table below.

Risk-free interest rate	1.88 – 2.12%
Volatility	85 – 89%
Dividend yield	None
Expected terms (in years)	5.50 – 6.25

Unrecognized share-based compensation for employee options granted through June 30, 2017 is approximately $4.4 million to be recognized over a remaining weighted average service period of 3.0 years.

Employee Share-Based Compensation (RSUs)

During the six months ended June 30, 2017, the Company granted to certain non-employee directors 1,176,000 restricted stock units, or RSUs. The fair value of each RSU is estimated on the closing market price on the grant date.

The following summarizes the activity of non-vested RSUs:

	Number of shares	Weighted average grant date fair value per share
Balance, December 31, 2016	—	
RSUs granted	1,176,000	$ 0.73
RSUs vested	—	
RSUs forfeited	—	
Balance, June 30, 2017	1,176,000	$ 0.73

Unrecognized share-based compensation for employee RSUs granted through June 30, 2017 is approximately $742,000 to be recognized over a remaining weighted average service period of 2.1 years.

Nonemployee Share-Based Compensation

During the six months ended June 30, 2017, the Company granted options to purchase 1,947,783 shares of common stock to consultants. These options were 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. The Company recorded approximately $277,000 and $1,000 for the three months ended June 30, 2017 and 2016, respectively, and approximately $510,000 and $2,000 for the six months ended June 30, 2017 and 2016, respectively, as nonemployee share-based compensation expense.

The Company accounts for share-based compensation arrangements with nonemployees, using the BSM 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 as of June 30, 2017:

Risk-free interest rate	2.25 – 2.28%
Volatility	87%
Dividend yield	None
Expected terms (in years)	9.1 – 9.5

(10) 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. Since we were in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive.

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:

June 30,

	2017	2016
Stock options to purchase common stock	48,103,603	12,464,656
Restricted stock units	1,176,000	-
Total	49,279,603	12,464,656

(11) Income Taxes

During the six months ended June 30, 2017 and 2016, 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 June 30, 2017, the Company retains a full valuation allowance on its deferred tax assets in all jurisdictions. The realization of the Company's deferred tax assets depends primarily on its ability to generate future taxable income which is uncertain. The Company does not believe that its 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.

(12) Related Party Transactions

In August 2016, the Company granted an option to purchase 5,027,726 shares of common stock, with 4-year vesting period, to OPKO Health, Inc., or OPKO, as consideration for consulting services to be provided by OPKO in accordance with the consulting agreement entered into between the Company and OPKO. The unearned portion of the share-based compensation related to the OPKO option was revalued at June 30, 2017, and the Company recorded $184,000 and $306,000 as expense during the three and six months ended June 30, 2017, respectively. 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.

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.

Special Note Regarding Smaller Reporting Company Status

We are filing this Quarterly Report on Form 10-Q as a "smaller reporting company" (as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended) based on our public float (the aggregate market value of our common equity held by non-affiliates of the Company) as of the last business day of our second fiscal quarter of 2016. As a result of being a smaller reporting company, we are allowed and have elected to omit certain information, including tabular disclosure of contractual obligations, from this Management's Discussion and Analysis of Financial Condition and Results of Operations; however, we have provided all information for the periods presented that we believe to be appropriate and necessary.

Overview

We are a clinical-stage regenerative medicine company developing novel therapeutics for cardiovascular diseases with large unmet medical needs. Our lead therapeutic candidate is the CardiAMP Cell Therapy System, or CardiAMP. We initiated our U.S. Food and Drug Administration, or FDA, accepted Phase III pivotal trial for CardiAMP in ischemic systolic heart failure, in December 2016 and we expect to obtain top-line data in 2019. If our trial is successful, we believe we will be the first company to reach the market with a cell-based therapy to treat heart failure. An Investigational Device Exemption submission to FDA for CardiAMP in the indication of post myocardial indication, or the treatment of patients in the immediate aftermath of a heart attack, is anticipated in 2017. Our second therapeutic candidate is the CardiALLO Cell Therapy System, or CardiALLO, which utilizes bone marrow derived mesenchymal cells from a donor to treat heart failure. We anticipate submitting 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 in 2018. 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 means the patient's own cells, while allogeneic cell therapies use allogeneic cells, which means cells from a third party donor. As we engage in clinical trials of our therapeutic candidates, we have compensated and intend to compensate all parties performing the trials or studies (including all the parties identified in

our Annual Report on Form 10-K) only on terms that are standard and customary in clinical study arrangements.

To date, we have devoted substantially all of our resources to research and development efforts relating to our therapeutic candidates and biotherapeutic delivery systems, including conducting clinical trials, developing manufacturing and sales capabilities, in-licensing related intellectual property, providing general and administrative support for these operations and protecting our intellectual property. We have also generated modest revenues from sales of our approved products. We have funded our operations primarily through the sales of equity and convertible debt securities, and certain government and private grants. All convertible debt securities were converted 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 $2.9 million and 2.0 million for the three months ended June 30, 2017 and 2016, respectively, and approximately $5.8 million and $3.5 million for the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017, we had an accumulated deficit of approximately $66 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.

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 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.

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 share-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 advance our Phase III pivotal heart failure 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 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 income we earn on our cash, cash equivalents and investments, interest charges we incurred in periods when we have convertible debt outstanding, and changes in the fair value of our warrant and convertible shareholder note derivative liabilities in periods when we have warrants or convertible debt outstanding. Subsequent to the Merger we have no interest charges related to the convertible debt and changes in the fair value of our warrant and convertible shareholder note derivative liabilities as such instruments were converted, cancelled or exchanged as part of the Merger. 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 U.S. 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.

Other than below, there were no material changes in our critical accounting estimates or accounting policies described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2016 Form 10-K during the six months ended June 30, 2017.

Share-Based Compensation

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

For options granted to nonemployees, we revalue the unearned portion of the share-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 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 share-based compensation expense could be materially different in the future.

Results of Operations

Comparison of Three Months Ended June 30, 2017 and 2016

The following table summarizes our results of operations for the three months ended June 30, 2017 and 2016 (in thousands):

	Three Months Ended June 30,	
	2017	**2016**
Revenue:		
Net product revenue	$101	$138
Collaboration agreement revenue	11	6
Total revenue	112	144
Cost and expenses:		
Cost of goods sold	203	156
Research and development	1,295	497
Selling, general and administrative	1,582	869
Total cost and expenses	3,080	1,522
Operating loss	(2,968)	(1,378)
Interest income	23	-
Interest expense	-	(557)
Other (expense) income	-	(43)
Net loss	$(2,945)	$(1,978)

Revenue. Revenue decreased by approximately $32,000 in the three months ended June 30, 2017 compared to the three months ended June 30, 2016 primarily due to a reduction in Morph sales volumes. We expect current sales volumes to remain consistent, with modestly lower net product revenue for 2017 relative to 2016.

Cost of Goods Sold. Cost of goods sold increased by approximately $47,000 in the three months ended June 30, 2017 compared to the three months ended June 30, 2016 primarily due to increased stock compensation cost for manufacturing personnel. We expect cost of goods sold for 2017 to be relatively consistent with 2016.

Research and Development Expenses. Research and development expenses increased by approximately $798,000 in the three months ended June 30, 2017 compared to the three months ended June 30, 2016 primarily due to expenses incurred in the planning, preparation and inception of the CardiAMP Phase III pivotal heart failure trial. We expect research and development expenses to increase as we continue to enroll and treat patients in the trial and incur additional development expenses related to CardiALLO therapeutic program.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by approximately $713,000 in the three months ended June 30, 2017 compared to the three months ended June 30, 2016 primarily due to additional costs for the organizational structure needed to support the CardiAMP Phase III pivotal trial and operations as a public company. These expenses include additional salary expenses, stock compensation and legal, accounting, tax and other corporate expenses. We expect selling, general and administrative expenses for the remaining quarters of 2017 to increase moderately from the three month period ended June 30, 2017 as we continue to build the supporting staff and infrastructure to support the CardiAMP Phase III pivotal trial and public company operations.

Interest Income. Interest income for the three months ended June 30, 2017 consisted primarily of interest income earned on cash equivalents and short-term investments.

Interest Expense. Interest expense for the three months ended June 30, 2016 consisted primarily of interest expense related to convertible notes which are no longer outstanding.

Other Income (Expense). Other income (expense) for the three months ended June 30, 2016 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.

Comparison of Six Months Ended June 30, 2017 and 2016

The following table summarizes our results of operations for the six months ended June 30, 2017 and 2016 (in thousands):

	Six Months Ended June 30,	
	2017	**2016**
Revenue:		
Net product revenue	$210	$306
Collaboration agreement revenue	39	16
Total revenue	249	322
Cost and expenses:		
Cost of goods sold	378	382
Research and development	2,328	938
Selling, general and administrative	3,386	1,456
Total cost and expenses	6,092	2,776
Operating loss	(5,843)	(2,454)
Interest income	23	-
Interest expense	-	(1,107)
Other (expense) income	(1)	87
Net loss	$(5,821)	$(3,474)

Revenue. Revenue decreased by approximately $73,000 in the six months ended June 30, 2017 compared to the six months ended June 30, 2016 primarily due to a reduction in Morph sales volumes. We expect current sales volumes to remain consistent, with modestly lower net product revenue for 2017 relative to 2016.

Cost of Goods Sold. Cost of goods sold decreased by approximately $4,000 in the six months ended June 30, 2017 compared to the six months ended June 30, 2016 primarily due to the decrease in revenues, partially offset by increased stock compensation cost for manufacturing personnel. We expect cost of goods sold for 2017 to be relatively consistent with 2016.

Research and Development Expenses. Research and development expenses increased by approximately $1.4 million in the six months ended June 30, 2017 compared to the six months ended June 30, 2016 primarily due to

expenses incurred in the planning, preparation and inception of the CardiAMP Phase III pivotal heart failure trial, including fees paid to consultants and contract research organization (CRO), higher personnel costs and increased stock compensation expense. We expect research and development expenses to increase as we continue to enroll and treat patients in the trial and incur additional development expenses related to CardiALLO therapeutic program.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by approximately $1.9 million in the six months ended June 30, 2017 compared to the six months ended June 30, 2016 primarily due to additional costs for the organizational structure needed to support the CardiAMP Phase III pivotal trial and operations as a public company. These costs include additional salary expenses, stock compensation and legal, accounting, tax, and other corporate expenses. We expect selling, general and administrative expenses for the remaining quarters to increase moderately from the six month period ended June 30, 2017 as we continue to build the supporting staff and infrastructure to support the CardiAMP Phase III pivotal trial and public company operations.

Interest Income. Interest income for the six months ended June 30, 2017 consisted primarily of interest income earned on cash equivalents and short-term investments.

Interest Expense. Interest expense for the six months ended June 30, 2016 consisted primarily of interest expense related to convertible notes which are no longer outstanding.

Other Income (Expense). Other income (expense) for the six months ended June 30, 2016 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 June 30, 2017, we had an accumulated deficit of approximately $66 million. We anticipate that we will continue to incur net losses for at least the next several years.

We have funded our operations principally through the sales of equity and convertible debt securities as well as the cash acquired through the Merger. As of June 30, 2017, we had cash and cash equivalents of approximately $15.1 million.

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

	Six Months Ended June 30,	
	2017	2016
Net cash provided by (used in):		
Operating activities	$(4,369)	$(1,870)
Investing activities	(1,896)	-
Financing activities	22	-
Net decrease in cash and cash equivalents	$(6,243)	$(1,870)

Cash Flows from Operating Activities. The increase in overall spending for operating activities of approximately $2.5 million in the six months ended June 30, 2017 compared to the six months ended June 30, 2016 relates primarily to increased cash outflows to conduct the CardiAMP Phase III pivotal 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.

Cash Flows from Investing Activities. Net cash used in investing activities of $1.9 million during the six months ended June 30, 2017 consists of the purchases of property and equipment and short-term investments.

Cash Flows from Financing Activities. Net cash provided by financing activities of $22,000 during the six months ended June 30, 2017 consists 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 $15.1 million coupled with $1.8 million in short-term investments as of June 30, 2017 are sufficient to fund our operations into the third quarter of 2018. In order to continue to further the development of the Company's lead therapeutic candidate, the CardiAMP cell therapy system, and the Company's second therapeutic candidate, the CardiALLO cell therapy system, through and beyond Q3 2018, we will be required to raise additional capital. The Company plans to raise additional capital, potentially including debt and equity arrangements, to finance its future operations. If adequate funds are not available, the Company may be required to reduce operating expenses, delay or reduce the scope of its product development programs, obtain funding, obtain funds through arrangements with others that may require the Company to relinquish rights to certain of its technologies or products that the Company would otherwise seek to develop or commercialize itself, or cease operations. While the Company believes in the viability of its strategy to raise additional funds, there can be no assurances to that effect. 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 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. 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.

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

Not applicable.

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 the Company's reports under the Securities Exchange Act of 1934, as amended, or 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 Vice President of Finance, 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 the Company's 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 June 30, 2017, an evaluation was performed under the supervision and with the participation of our management, including the Chief Executive Officer and Vice President of Finance, 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). Due to the material weakness in internal control over financial reporting described in our Annual Report on 10-K for the fiscal year end dated December 31, 2016, our Chief Executive Officer and Vice President of Finance concluded that our disclosure controls and procedures were not effective as of June 30, 2017. These conclusions were communicated to the Audit Committee. Notwithstanding the existence of this material weakness, management has concluded that the condensed consolidated financial statements in this Form 10-Q fairly present, in all material respects, the Company's financial position, results of operations and cash flows for all periods and dates presented.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three month period covered by this Quarterly Report on Form 10-Q that have materially affected or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The Company may be subject to various claims, complaints, and legal actions that arise from time to time in the normal course of business. Management does not believe that the Company is 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 the Company's 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, 2016, 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: August 14, 2017 By: /s/ Peter Altman
Peter Altman
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 14, 2017 By: /s/ David McClung
David McClung
Vice President of Finance
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Exhibit Description
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Amended and Restated Bylaws.
31.1*	Certification of Periodic Report by Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Periodic Report by Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to Rule 13a-14(b) and Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Title 18, United States Code).
32.2**	Certification of Principal Financial Officer Pursuant to Rule 13a-14(b) and Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Title 18, United States Code).
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema 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.

(1) Previously filed as an exhibit to the Current Report on Form 8-K filed by us on April 11, 2017.

(2) Previously filed as an exhibit to the Current Report on Form 8-K filed by us on April 11, 2017.