BioCardia, Inc.
Form 10-Q
May 11, 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 March 31, 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)

(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

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 457,682,784 shares of the registrant’s Common Stock issued and outstanding as of May 9, 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 assume no obligation to update any such forward-looking statement or reason why such results might differ, 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)

Assets	**March 31, 2017**	**December 31, 2016**
	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 19,032	$ 21,352
Accounts receivable, net of allowance for doubtful accounts of $1 and $2 at March 31, 2017 and December 31, 2016, respectively	121	74
Inventory	144	135
Prepaid expenses	252	356
Total current assets	19,549	21,917
Property and equipment, net	177	111
Other assets	54	54
Total assets	$ 19,780	$ 22,082
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 291	$ 525
Accrued liabilities	720	544
Deferred revenue	72	71
Grant liability	285	304
Total current liabilities	1,368	1,444
Deferred rent	62	56
Total liabilities	1,430	1,500
Stockholders' equity:		
Preferred stock, $0.001 par value, 50,000,000 shares authorized, no shares issued and outstanding at March 31, 2017 and December 31, 2016	—	—
Common stock, $0.001 par value, 750,000,000 shares authorized at March 31, 2017 and December 31, 2016, 457,682,784 shares and 457,575,631 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	458	458
Additional paid-in capital	80,910	80,266
Accumulated deficit	(63,018)	(60,142)
Total stockholders' equity	18,350	20,582
Total liabilities and stockholders' equity	$ 19,780	$ 22,082

See accompanying notes to condensed consolidated financial statements.

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BIOCARDIA, INC.

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

(unaudited)

	Three Months ended March 31,	
	2017	**2016**
Revenue:		
Net product revenue	$ 109	$ 168
Collaboration agreement revenue	28	10
Total revenue	137	178
Costs and expenses:		
Cost of goods sold	175	226
Research and development	1,033	441
Selling, general and administrative	1,804	587
Total costs and expenses	3,012	1,254
Operating loss	(2,875)	(1,076)
Other income (expense):		
Interest expense, net	—	(550)
Change in fair value of convertible preferred stock warrant liability	—	53
Change in fair value of maturity date preferred stock warrant liability	—	(1)
Change in fair value of convertible shareholder notes derivative liability	—	78
Other expense	(1)	—
Total other expense, net	(1)	(420)
Net loss	$ (2,876)	$ (1,496)
Net loss per share, basic and diluted	$ (0.01)	$ (0.08)
Weighted-average shares used in computing net loss per share, basic and diluted	457,654,570	18,947,536

See accompanying notes to condensed consolidated financial statements.

BIOCARDIA, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(unaudited)

	Three Months ended March 31, 2017	2016
Operating activities:		
Net loss	$(2,876)	$ (1,496)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	13	10
Change in fair value of convertible preferred stock warrant liability	—	(53)
Change in fair value of maturity date preferred stock warrant liability	—	1
Change in fair value of convertible shareholder notes derivative liability	—	(78)
Share-based compensation	622	30
Non-cash interest expense on convertible shareholder notes	—	550
Changes in operating assets and liabilities:		
Accounts receivable	(47)	(4)
Inventory	(9)	42
Prepaid expenses	104	28
Accounts payable	(249)	103
Accrued liabilities excluding accrued interest on convertible note	176	86
Deferred revenue	1	40
Deferred rent	6	(7)
Grant liability	(19)	—
Net cash used in operating activities	(2,278)	(748)
Investing activities:		
Purchase of property and equipment	(64)	—
Net cash used in investing activities	(64)	—
Financing activities:		
Proceeds from the exercise of stock options	22	—
Net cash provided by financing activities	22	—
Net decrease in cash and cash equivalents	(2,320)	(748)
Cash and cash equivalents at beginning of period	21,352	3,557
Cash and cash equivalents at end of period	$19,032	$ 2,809
Supplemental disclosures for 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., 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, which offers advanced catheter products for interventional medicine. 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 consolidated financial statements and notes to the 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 and cash flows as of March 31, 2017 and for the three months ended March 31, 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 March 31, 2017, results of operations and cash flows for the three months ended March 31, 2017 and 2016. The results for the three months ended March 31, 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 $63.0 million as of March 31, 2017. Management expects operating losses and negative cash flows to continue through at least the next several years.

Upon closing of the Merger Agreement, the combined company had approximately $24.0 million in cash, including $19.0 million of cash acquired as part of the Merger and $4.4 million in net proceeds from the issuance of convertible notes in October 2016. Management believes cash of $19.0 million as of March 31, 2017 is sufficient to fund the Company for at least the next twelve-month period following the date of issuance of these financial statements. The Company also plans to raise other 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 2016 Form 10-K. There have been no changes to those policies except as described below.

(f) ***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 will classify 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 and has not concluded on an adoption method. The Company has formed a task force that is beginning to assess 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.

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.

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, 2017 and indicates the fair value hierarchy utilized to determine such fair value (in thousands).

	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and cash equivalents	$19,032	$ —	$ —	$19,032

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:				