BioCardia, Inc.
Form 10-Q
November 08, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**(Mark One)**

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

**For the quarterly period ended September 30, 2018**

**or**

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

**Commission file number: 0-21419**

**BioCardia, Inc.**

**(Exact name of registrant as specified in its charter)**

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| **Delaware** | **23-2753988** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification Number)** |

**125 Shoreway Road, Suite B**

**San Carlos, California 94070**

**(Address of principal executive offices including zip code)**

**(650) 226-0120**

**(Registrant's telephone number, including area code)**

**N/A**

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

| | |
|---|---|
| Large accelerated filer | Accelerated filer |
| Non-accelerated filer | Smaller reporting company |
| | Emerging growth company |

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

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

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

There were 38,277,908 shares of the registrant’s Common Stock issued and outstanding as of November 2, 2018.

## FORWARD-LOOKING INFORMATION

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

*In this report, the words "may," "could," "would," "might," "will," "should," "plan," " forecast," "anticipate," "believe," "expect," "intend," "estimate," "predict," "potential," "continue," "future," "moving toward" or the negative of these terms or other similar expressions also identify forward-looking statements. Our actual results could differ materially from those forward-looking statements contained in this report as a result of a number of risk factors*

*including, but not limited to, those listed in our Annual Report on Form 10-K for the year ended December 31, 2017 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)

| | **September 30, 2018** *(unaudited)* | **December 31, 2017** |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 4,820 | $ 12,689 |
| Accounts receivable, net of allowance for doubtful accounts of $6 and $6 at September 30, 2018 and December 31, 2017, respectively | 170 | 95 |
| Inventory | 134 | 191 |
| Prepaid expenses | 224 | 340 |
| Total current assets | 5,348 | 13,315 |
| Property and equipment, net | 154 | 169 |
| Other assets | 54 | 54 |
| Total assets | $ 5,556 | $ 13,538 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,102 | $ 902 |
| Accrued expenses and other current liabilities | 1,430 | 1,263 |
| Deferred revenue | — | 167 |
| Total current liabilities | 2,532 | 2,332 |
| Deferred rent | 80 | 81 |
| Total liabilities | 2,612 | 2,413 |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value, 25,000,000 shares authorized; no shares issued and outstanding as of September 30, 2018 and December 31, 2017 | — | — |

| | | |
|---|---|---|
| Common stock, $0.001 par value, 100,000,000 shares authorized as of September 30, 2018 and December 31, 2017 respectively; 38,277,908 and 38,218,660 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively | 38 | 38 |
| Additional paid-in capital | 85,625 | 83,537 |
| Accumulated deficit | (82,719) | (72,450) |
| Total stockholders' equity | 2,944 | 11,125 |
| Total liabilities and stockholders' equity | $ 5,556 | $ 13,538 |

See accompanying notes to condensed consolidated financial statements.

BIOCARDIA, INC.

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

(unaudited)

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Revenue: | | | | |
| Net product revenue | $52 | $88 | $223 | $298 |
| Collaboration agreement revenue | 32 | 42 | 299 | 81 |
| Total revenue | 84 | 130 | 522 | 379 |
| Costs and expenses: | | | | |
| Cost of goods sold | 109 | 147 | 401 | 525 |
| Research and development | 2,262 | 1,700 | 6,248 | 4,028 |
| Selling, general and administrative | 1,283 | 1,322 | 4,315 | 4,708 |
| Total costs and expenses | 3,654 | 3,169 | 10,964 | 9,261 |
| Operating loss | (3,570) | (3,039) | (10,442) | (8,882) |
| Other income (expense): | | | | |
| Interest income | 29 | 35 | 100 | 58 |
| Other expense, net | (3) | 3 | (3) | 2 |
| Total other income, net | 26 | 38 | 97 | 60 |
| Net loss | $(3,544) | $(3,001) | $(10,345) | $(8,822) |
| Net loss per share, basic and diluted | $(0.09) | $(0.08) | $(0.27) | $(0.23) |
| Weighted-average shares used in computing net loss per share, basic and diluted | 38,277,908 | 38,146,751 | 38,254,583 | 38,141,654 |

See accompanying notes to condensed consolidated financial statements.

BIOCARDIA, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(unaudited)

| | Nine months ended September 30, | |
|---|---|---|
| | **2018** | **2017** |
| Operating activities: | | |
| Net loss | $(10,345) | $(8,822) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 66 | 57 |
| Share-based compensation | 2,083 | 1,999 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (75) | (16) |
| Inventory | 57 | (105) |
| Prepaid expenses | 116 | 168 |
| Accounts payable | 200 | (80) |
| Accrued liabilities | 141 | 545 |
| Deferred revenue | (65) | 89 |
| Deferred rent | (1) | 19 |
| Net cash used in operating activities | (7,823) | (6,146) |
| Investing activities: | | |
| Purchase of property and equipment | (51) | (107) |
| Purchase of short-term investments | — | (1,799) |
| Net used in in investing activities | (51) | (1,906) |
| Financing activities: | | |
| Proceeds from the exercise of common stock options | 5 | 26 |
| Net cash provided by financing activities | 5 | 26 |
| Net decrease in cash and cash equivalents | (7,869) | (8,026) |
| Cash and cash equivalents at beginning of period | 12,689 | 21,352 |
| Cash and cash equivalents at end of period | $4,820 | $13,326 |

See accompanying notes to condensed consolidated financial statements.

**(1) Summary of Business and Basis of Presentation**

***Description of Business***

BioCardia, Inc., ("we" or "the Company"), is a clinical-stage regenerative medicine company developing novel therapeutics for cardiovascular diseases with large unmet medical needs. Our lead therapeutic candidate is the CardiAMP Cell Therapy System, an investigational autologous bone marrow derived cell therapy being advanced for two large cardiac indications under FDA approved pivotal trials. Our second therapeutic candidate is the CardiALLO Cell Therapy System, an investigational allogenic culture expanded "off the shelf" mesenchymal cell therapy being advanced initially to treat patients who are not eligible for CardiAMP cell therapy due to the quality of their cells. To date, we have devoted substantially all our resources to research and development efforts relating to our therapeutic candidates and biotherapeutic delivery systems including conducting clinical trials, developing manufacturing and sales capabilities, in-licensing related intellectual property, providing general and administrative support for these operations and protecting our intellectual property.

We have three enabling device product lines which have one or more approvals in the USA and/or EU: (1) the CardiAMP cell processing system; (2) the Helix biotherapeutic delivery system, or Helix; and (3) the Morph vascular access product line, or Morph. We manage our operations as a single segment for the purposes of assessing performance and making operating decisions.

**(2) Significant Accounting Policies**

***(a) Basis of Preparation***

The accompanying condensed consolidated balance sheets, statements of operations and cash flows as of and for the three and nine months ended September 30, 2018 and 2017 are unaudited. The condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP, and applicable rules and regulations of the Securities and Exchange Commission, or SEC, for interim financial information and on a basis consistent with the annual financial statements. In the opinion of management, they also reflect all adjustments which include only normal recurring adjustments, necessary to present fairly our financial position for the interim periods presented. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other interim period or for any other future year.

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

***(b) Liquidity***

We have incurred net losses and negative cash flows from operations since our inception and had an accumulated deficit of $82.7 million as of September 30, 2018. Management expects operating losses and negative cash flows to continue through the next several years. Based on management's current plans, management believes cash and cash equivalents of $4.8 million as of September 30, 2018 are sufficient to fund us into Q1 2019. These factors raise substantial doubt about our ability to continue as a going concern beyond one year from the date these financial statements are issued. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Our ability to continue as a going concern and to continue further development of our lead therapeutic candidate, the CardiAMP Cell Therapy System, and our second therapeutic candidate, the CardiALLO Cell Therapy System, through and beyond Q1 2019, will require us to raise additional capital. We plan to raise additional capital, potentially including debt and equity arrangements, to finance our future operations. If adequate funds are not available, we may be required to reduce operating expenses, delay or reduce the scope of our product development programs, obtain funds through arrangements with others that may require us to relinquish rights to certain of our technologies or products that we would otherwise seek to develop or commercialize ourselves, or cease operations. While we believe we have a viable strategy to raise additional funds, there can be no assurances that we will be able to obtain additional capital on acceptable terms and in the amounts necessary to fully fund our operating needs.

***(c) Use of Estimates***

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

***(d) Principles of Consolidation***

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

***(e) Changes to Significant Accounting Policies***

Our significant accounting policies are described in Note 2 of the notes to the financial statements included in our Annual Report on Form 10-K filed for the year ended December 31, 2017. Apart from the adoption of ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) on January 1, 2018, which led to an amended revenue policy as described in the following paragraphs, there have been no changes to those policies.

***Revenue Recognition***

**Net product revenue** – We currently have a portfolio of enabling and delivery products. Revenue from product sales is recognized generally upon shipment to the end customer, which is when control of the product is deemed to be transferred.

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

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

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

***(f) Recently Adopted Accounting Pronouncement***

In May 2014, the FASB issued Topic 606, which provides comprehensive guidance for revenue recognition. Topic 606 affects any entity which either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets. The core principle of the guidance provides that a company should recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. The new standard can be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of the change recognized at the date of the initial application in retained earnings.

On January 1, 2018, we adopted Topic 606 using the cumulative effect adoption method. Results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under Topic 605. We recorded a net reduction to opening accumulated deficit of $76,000 as of January 1, 2018 due to the cumulative impact of adopting Topic 606, with the impact related to our collaboration revenues.

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

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

***(g) Recently Issued Accounting Pronouncements***

In February 2016, the FASB issued ASU No. 2016-02 Leases (Topic 842) (ASU 2016-02), which supersedes existing guidance on accounting for leases in Leases (Topic 840) and generally requires all leases to be recognized in the consolidated balance sheet. ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018; early adoption is permitted. The provisions of ASU 2016-02 are to be applied using a modified retrospective approach, or if we elect we may use a cumulative-effect adjustment to accumulated deficit as of January 1, 2019. We expect to adopt the new standard on January 1, 2019 and use the effective date as our date of initial application. Consequently, financial information will not be updated, and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. The new standard provides a number of optional practical expedients in transition. We expect to elect the ‘package of practical expedients’, which permits us not to reassess under the new standard our prior conclusions about the lease identification, lease classification and initial direct costs. We do not expect to elect the use-of-hindsight or the practical expedient pertaining to land easements, the latter not being applicable to us. We expect that this new standard will have a material effect on our financial statements. While we continue to assess all the effects of adoption, we currently believe the most significant effects relate to (1) the recognition of new right-to-use (ROU) assets and lease liabilities on our balance sheet for our real estate operating lease and (2) providing significant new disclosures about our leasing activities. We do not expect a significant change in our leasing activities between now and adoption.

In June 2018, the FASB issued ASU 2018-07 Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, (ASU 2018-07). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance is intended to align the accounting for such payments to nonemployees with the existing requirements for share-based payments granted to employees. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018 and is to be adopted through a cumulative-effect adjustment to retained earnings as of January 1, 2019 for then outstanding share-based payments to nonemployees. We are currently assessing the future impact of this ASU on our 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 September 30, 2018 and December 31, 2017 and indicates the fair value hierarchy utilized to determine such fair value (in thousands).

| | As of September 30, 2018 | | | |
|---|---|---|---|---|
| | **Level 1** | **Level 2** | **Level 3** | **Total** |
| Assets: | | | | |
| Cash equivalents | $4,854 | $ — | $ — | $4,854 |

| | As of December 31, 2017 | | | |
|---|---|---|---|---|
| | **Level 1** | **Level 2** | **Level 3** | **Total** |
| Assets: | | | | |
| Cash equivalents | $12,063 | $ — | $ — | $12,063 |

**(4) Inventories**

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

| **September 30, 2018** | **December 31,** |
|---|---|

| | | 2017 |
|---|---|---|
| Raw materials | $ 62 | $ 70 |
| Work in process | 3 | 92 |
| Finished goods | 69 | 29 |
| Total | $ 134 | $ 191 |

Write downs for excess or expired inventory are based on management's estimates of forecasted usage of inventories and are included in cost of goods sold. A significant change in the timing or level of demand for certain products as compared to forecasted amounts may result in recording additional write downs for excess or expired inventory in the future. Charges to cost of goods sold for inventory write-downs, reserve adjustments, scrap, and expired inventories totaled approximately $13,000 and $15,000 for the three months ended September 30, 2018 and 2017 respectively, and $15,000 and $25,000 for the nine months ended September 30, 2018 and 2017, respectively.

**(5) Property and Equipment, Net**

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

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Computer equipment and software | $ 116 | $ 106 |
| Laboratory and manufacturing equipment | 474 | 447 |
| Furniture and fixtures | 55 | 48 |
| Leasehold improvements | 331 | 326 |
| Construction in progress | 1 | — |
| Property and equipment, gross | 977 | 927 |
| Less accumulated depreciation | (823) | (758) |
| Property and equipment, net | $ 154 | $ 169 |

**(6) Accrued Expenses and Other Current Liabilities**

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

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Accrued expenses | $ 226 | $ 129 |
| Accrued employee costs | 455 | 410 |
| Grant liability | 666 | 663 |
| Customer deposits | 83 | 61 |
| Total | $ 1,430 | $ 1,263 |

**(7) Share-Based Compensation**

The share-based compensation expense is recorded in cost of goods sold, research and development, and selling, general and administrative expenses based on the employee's respective function. No share-based compensation was capitalized during the periods presented. Share-based compensation expense for the three and nine months ended September 30, 2018 and 2017 was recorded as follows (in thousands):

| | Three months ended | | Nine months ended | |
|---|---|---|---|---|
| | September 30, | | September 30, | |
| | 2018 | 2017 | 2018 | 2017 |
| Cost of goods sold | $39 | $33 | $105 | $107 |
| Research and development | 250 | 172 | 711 | 498 |
| Selling, general and administrative | 441 | 496 | 1,267 | 1,394 |
| Share-based compensation expense | $730 | $701 | $2,083 | $1,999 |

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

| | Number of options outstanding | Weighted average exercise price |
|---|---|---|
| Balance, December 31, 2017 | 4,213,100 | $ 2.96 |
| Stock options granted | 1,698,452 | 2.41 |
| Stock options exercised | (2,488) | 1.80 |
| Stock options cancelled | (359,958) | 2.93 |
| Balance, September 30, 2018 | 5,549,106 | $ 2.80 |

The weighted average grant-date fair value of options granted during the nine months ended September 30, 2018 was $1.72 per share.

*Employee Share-Based Compensation (Stock Options)*

During the nine months ended September 30, 2018, we granted stock options to certain non-employee directors and employees to purchase 1,698,452 shares of common stock. The fair value of each option grant was estimated on the date of the grant using the Black-Scholes option pricing model with the following assumptions:

| | |
|---|---|
| Risk-free interest rate | 2.66% - 2.87% |
| Volatility | 81% - 82% |
| Dividend yield | None |
| Expected term (in years) | 6.25 |

Unrecognized share-based compensation for employee options as of September 30, 2018 was approximately $5.6 million to be recognized over a remaining weighted average service period of 2.7 years.

*Restricted Stock Units (RSUs)*

The following summarizes the activity of non-vested RSUs:

| | Number of shares | Weighted average grant date fair value per share |
|---|---|---|
| Balance, December 31, 2017 | 97,996 | $ 8.71 |
| RSUs granted | 226,471 | 1.36 |
| RSUs vested | (57,108 ) | 7.03 |
| Balance, September 30, 2018 | 267,359 | $ 2.84 |

Unrecognized share-based compensation for employee RSUs granted as of September 30, 2018 was approximately $292,000 to be recognized over a remaining weighted average service period of 1.3 years.

*Nonemployee Share-Based Compensation*

During the nine months ended September 30, 2018, we did not grant any options to purchase shares of common stock to consultants. Options granted to consultants have been granted in exchange for consulting services to be rendered and vest over the term specified in the grant, which correlates to the period the services are rendered. We recorded $74,000 and $188,000 for the three months ended September 30, 2018 and 2017, respectively, and $150,000 and $698,000 for the nine months ended September 30, 2018 and 2017, respectively as nonemployee share-based compensation expense.

We account for share-based compensation arrangements with nonemployees, using the Black-Scholes option pricing model, based on the fair value as these instruments vest. Accordingly, at each reporting date, we revalue the unearned portion of the share-based compensation and the resulting change in fair value is recognized in the consolidated statements of operations over the period the related services are rendered. The following assumptions were used to value the awards for the nine months ended September 30, 2018:

| | | | |
|---|---|---|---|
| Risk-free interest rate | 2.80% | - | 2.84% |
| Volatility | 78% | - | 85% |
| Dividend yield | | None | |
| Expected term (in years) | 7.9 | - | 8.8 |

**(8) Net Loss per Share**

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

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

| | **September 30,** | |
|---|---|---|
| | **2018** | **2017** |
| Stock options to purchase common stock | 5,549,106 | 4,142,692 |
| Unvested restricted stock units | 267,359 | 97,996 |
| Total | 5,816,465 | 4,240,688 |

**(9) Income Taxes**

During the nine months ended September 30, 2018 and 2017, there was no income tax expense or benefit for federal or state income taxes in the accompanying condensed consolidated statements of operations due to the Company's net loss and a full valuation allowance on the resulting deferred tax assets.

As of September 30, 2018, we retain a full valuation allowance on our deferred tax assets in all jurisdictions. The realization of our deferred tax assets depends primarily on our ability to generate future taxable income which is uncertain. We do not believe that our deferred tax assets are realizable on a more-likely-than-not basis; therefore, the net deferred tax assets have been fully offset by a valuation allowance.

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

The 2017 provisional charge related to the Tax Act was an estimate and the measurement of net deferred tax assets is subject to further analysis and potential correlative adjustments as developing interpretations and guidance from the U.S. Treasury Department, the Internal Revenue Service, and other standard setting bodies provide additional clarifications of the provisions of the Tax Act. Updated guidance and regulations could result in changes to this provisional charge during 2018 when the analysis is complete, and, in accordance with the guidance in Staff Accounting Bulletin 118, we will continue to monitor guidance and make necessary adjustments. No measurement-period adjustments were made during the nine months ended September 30, 2018.

**(10) Related Party Transactions**

In August 2016, we granted an option to purchase 418,977 shares of common stock, with a four year vesting period and an exercise price of $1.80 per share, to OPKO Health, Inc. ("OPKO") as consideration for consulting services to be provided by OPKO. We recorded $121,000 and $432,000 as share-based compensation expense related to the OPKO stock option during the nine months ended September 30, 2018 and 2017, respectively. The estimated grant-date fair value of the option was $5.3 million. The term of the consulting agreement is four 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 our common stock and OPKO itself is also a beneficial owner of more than 5% of the outstanding shares of our 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 for the year ended December 31, 2017and elsewhere in this report. Historical results are not necessarily indicative of future results.*

**Overview**

We are a clinical-stage regenerative medicine company developing novel therapeutics for cardiovascular diseases with large unmet medical needs. Our lead therapeutic candidate is the investigational CardiAMP Cell Therapy System, which provides an autologous bone marrow derived cell therapy (using a patient's own cells) for the treatment of two clinical indications: heart failure that develops after a heart attack and chronic myocardial ischemia.

We initiated our United States Food and Drug Administration, or FDA, Phase III pivotal trial for CardiAMP Cell Therapy in ischemic systolic heart failure, in December 2016. The CardiAMP Heart Failure Trial is a Phase III, multi-center, randomized, double-blinded, sham-controlled study of up to 260 patients at 40 centers nationwide, which includes a 10-patient roll-in cohort. The trial's primary endpoint is a clinical composite of six minute walk distance and major adverse cardiac and cerebrovascular events.

In September 2017, the independent Data Safety Monitoring Board, or DSMB, completed the pre-specified interim analysis of safety outcomes for the first 10 patients treated in the open-label phase of the Phase III trial of its investigational CardiAMP cell therapy product. The DSMB indicated there were no significant safety concerns with the CardiAMP study results and recommended that the trial continue, as planned.

Preliminary results at six month follow-up for these first 10 patients were published in a viewpoint article in Circulation Research in September 2018. The paper reported that treated patients showed improvements in Six Minute Walk Distance (+47.8m ± 19.6, 20.5% relative improvement; p=0.01), improvements in New York Heart Association Heart Failure Class (40% of patients improving one class, p=0.037), and a positive trend in MLHFQ Score (-10.2 ± 7.9, 31% relative improvement, p=0.21) at six months when compared to their baseline values. The magnitude of

these improvements is greater than those seen in the trial's predecessor, the double blind, Phase II Transendocardial Autologous Cell Therapy in Heart Failure Trial, which demonstrated statistical significance in functional capacity as measured by six-minute walk and quality of life as measured by the Minnesota Living with Heart Failure Questionnaire.

Nine month follow-up data for these 10 patients was presented at the Transcatheter Therapeutics conference on September 28, 2018, showing clinically meaningful improvements in symptoms, quality of life and exercise capacity, as measured by New York Heart Association class, Minnesota Living with Heart Failure Questionnaire and Six Minute Walk Distance, respectively. At nine months, the improvements seen in Six Minute Walk Distance, New York Heart Association Heart Failure Class and Minnesota Living with Heart Failure Questionnaire, which were statistically significant at six months relative to baseline, were clinically meaningful but not statistically significant. This difference was due in part to the lack of nine month follow-up data on one patient due to a major adverse cardiac event which was assigned a score intended to capture the event for comparison to the control arm. The improvements in exercise capacity and quality of life at nine months were greater in magnitude than those observed in the previous Phase II randomized placebo-controlled trial of CardiAMP therapy, which reached statistical significance in both endpoints when compared to control.

CardiAMP Heart Failure efficacy results from the primary endpoint in the open label roll-in cohort at twelve months is expected to be presented at the American Heart Association Scientific Sessions 2018 Conference on November 12, 2018. Currently 18 world class medical centers are actively enrolling in the study. We anticipate that trial enrollment will be completed in Q3 2019.

In January 2018, the FDA approved the randomized controlled pivotal trial of the CardiAMP Cell Therapy System for a second indication, for patients with refractory chronic myocardial ischemia. Under the approved investigational device exemption ("IDE"), up to 343 patients at up to 40 clinical sites in the United States may be enrolled in the CardiAMP Chronic Myocardial Ischemia Trial. This therapeutic approach uses many of the same novel aspects as the CardiAMP Heart Failure Trial and leverages our experience and investment in the heart failure trial. We anticipate dosing the first patient in Q1 2019.

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

Our second therapeutic candidate is the CardiALLO Cell Therapy System, an investigational culture expanded bone marrow derived “off the shelf” mesenchymal stem cell therapy. CardiALLO cell therapy cells are bone marrow derived from Neurokinin-1 receptor positive bone marrow cells. These cells are being advanced to treat heart failure, but have potential for numerous therapeutic applications as these are anticipated to be the cells that respond to the release of Substance P. Substance P (“SP”) is a neuropeptide released from sensory nerves and is associated with the inflammatory processes and pain. The endogenous receptor for SP is the neurokinin-1 receptor (“NK1-receptor” or “NK1R”), which is distributed over cytoplasmic membranes of many cell types (for example neurons, glia, endothelia of capillaries and lymphatics, fibroblasts, stem cells, and white blood cells) in many tissues and organs. SP amplifies or excites most cellular processes. Elevation of serum, plasma, or tissue SP and/or its receptor NK1R has been associated with many diseases: sickle cell crisis, inflammatory bowel disease, major depression and related disorders, fibromyalgia rheumatological, and infections such as HIV/AIDS and respiratory syncytial virus, as well as in cancer. Our CardiALLO NK1R positive derived cells are believed to be an important subset of the cells that we have delivered in our previous preclinical and clinical mesenchymal stem cell studies. We are actively performing manufacturing validation runs of these cells at BioCardia to support future clinical studies. We anticipate submitting an Investigational New Drug (“IND”) application to the FDA for a Phase II trial for CardiALLO Cell Therapy System for the treatment of ischemic systolic heart failure in Q4 2018.

Improvements to our enabling delivery system products are also in active development. We anticipate submitting in Q4 2018 for FDA approval of our new AVANCE™ steerable introducer, indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. Our data indicates the AVANCE™ steerable introducer has improved performance characteristics relative to other products currently available for this indication, which address an established and highly competitive market estimated in excess of $500 million annually. We also anticipate submitting an application for FDA approval in Q1 2019 of our new Morph® “DNA” steerable guide, indicated for introducing various cardiovascular catheters into the heart. This product is also expected to further enhance delivery of our CardiAMP and CardiALLO cell therapies Both products have the potential to be cleared for market release by the FDA before the end of Q2 2019.

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

We have incurred net losses in each year since our inception. Our net losses were approximately $10.3 million and $8.8 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of approximately $82.7 million. Substantially all our net losses have resulted from costs incurred in connection with our research and development programs, clinical trials, intellectual property matters, building our manufacturing and sales capabilities, and from general and administrative costs associated with our operations. As discussed in more detail under “Liquidity and Capital Resources”, we believe our cash and cash equivalents as of September 30, 2018 are sufficient to fund our operations into Q1 2019. As a result there is substantial doubt about our ability to continue as a going concern within one year after the date these financial

statements are issued. We plan to raise additional capital, potentially including debt and equity arrangements, to finance our future operations. Please see “Future Funding Requirements” below for additional information regarding our need for additional funding.

**Financial Overview**

***Revenue***

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

***Cost of Goods Sold***

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

***Research and Development Expenses***

Our research and development expenses consist primarily of:

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

- payments related to licensed products and technologies.

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

We plan to increase our research and development expenses for the foreseeable future as we continue the pivotal CardiAMP Heart Failure Trial, advance the pivotal CardiAMP Chronic Myocardial Ischemia Trial, further develop the CardiAMP and CardiALLO Cell Therapy Systems, and subject to the availability of additional funding, develop other therapeutic candidates for additional indications. We typically use our employee and infrastructure resources across multiple research and development programs, and accordingly, we have not historically allocated resources specifically to our individual programs.

***Selling, General and Administrative Expenses***

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

***Other Income (Expense)***

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

**Critical Accounting Policies and Estimates**

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

Apart from the adoption of ASU No. 2014-09 Revenue from Contracts with Customers (Topic 606) on January 1, 2018, which led to an amended revenue policy described below, there were no material changes during the nine months ended September 30, 2018 in our critical accounting estimates or accounting policies described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2017.

***Revenue Recognition***

**Net product revenue** – We currently have a portfolio of enabling and delivery products. Revenue from product sales is recognized generally upon shipment to the end customer, which is when control of the product is deemed to be transferred.

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

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

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

**Results of Operations**

*Comparison of Three Months Ended September 30, 2018 and 2017*

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2017 (in thousands):

| | Three months ended September 30, | |
|---|---|---|
| | **2018** | **2017** |
| Revenue: | | |
| Net product revenue | $52 | $88 |
| Collaboration agreement revenue | 32 | 42 |
| Total revenue | 84 | 130 |
| Costs and expenses: | | |
| Cost of goods sold | 109 | 147 |
| Research and development | 2,262 | 1,700 |
| Selling, general and administrative | 1,283 | 1,322 |
| Total costs and expenses | 3,654 | 3,169 |
| Operating loss | (3,570) | (3,039) |
| Other income (expense): | | |
| Interest income | 29 | 35 |
| Other expense | (3) | 3 |
| Total other income, net | 26 | 38 |
| Net loss | $(3,544) | $(3,001) |

*Revenue.* Revenue decreased by $46,000 in the three months ended September 30, 2018 compared to the three months ended September 30, 2017, primarily due to reduced product sales volumes in the third quarter coupled with less revenue earned under programs with our collaborative partners after the adoption of Topic 606. We expect total revenues to increase in 2018 as compared to 2017, primarily due to increased revenue earned under collaboration programs during the first half of the year.

*Cost of Goods Sold.* Cost of goods sold decreased by $38,000 in the three months ended September 30, 2018 compared to the three months ended September 30, 2017 primarily due to a decrease in product sales volumes. We expect cost of goods sold to remain in line with lower 2018 net product sales volumes relative to 2017, resulting in proportionally lower cost of goods sold.

*Research and Development Expenses.* Research and development expenses increased by $562,000 in the three months ended September 30, 2018 compared to the three months ended September 30, 2017 primarily due to increased expenses incurred in conducting the ongoing pivotal CardiAMP Heart Failure Trial and in the development of the CardiALLO Cell Therapy System. These expenses include fees paid to consultants and CROs and additional personnel costs. We expect research and development expenses to continue to increase as enrollment accelerates in the CardiAMP Heart Failure Trial and we further develop the CardiAMP and CardiALLO cell therapy platforms.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses for the three months ended September 30, 2018 totaled $1,283,000 which was a 3% decrease as compared to $1,322,000 for three months ended September 30, 2017, due primarily to lower consulting expense, sales commissions, and personnel costs. We expect selling, general and administrative expenses for 2018 to decrease moderately in the last quarter of 2018 compared to 2017, as we continue to manage our spending and infrastructure without compromising the needed support for the CardiAMP Heart Failure Trial and development of our therapeutic programs.

*Comparison of Nine Months Ended September 30, 2018 and 2017*

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2017 (in thousands):

| | **Nine months ended September 30,** | |
|---|---|---|
| | **2018** | **2017** |
| Revenue: | | |
| Net product revenue | $223 | $298 |
| Collaboration agreement revenue | 299 | 81 |
| Total revenue | 522 | 379 |
| Costs and expenses: | | |
| Cost of goods sold | 401 | 525 |
| Research and development | 6,248 | 4,028 |
| Selling, general and administrative | 4,315 | 4,708 |
| Total costs and expenses | 10,964 | 9,261 |
| Operating loss | (10,442) | (8,882) |
| Other income (expense): | | |
| Interest income | 100 | 58 |
| Other expense | (3) | 2 |
| Total other income, net | 97 | 60 |
| Net loss | $(10,345) | $(8,822) |

*Revenue.* Revenue increased by $143,000 in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 primarily due to increased revenue earned under programs with our collaborative partners after the adoption of Topic 606 and sales activities in the first half of 2018. Total revenue is expected to increase moderately in 2018 as compared to 2017 levels, primarily due to increased revenues earned under collaborative programs during the first half of the year.

*Cost of Goods Sold.* Cost of goods sold decreased by $124,000 in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017, primarily due to a decrease in product sales volumes. We expect cost of goods sold to remain in line with lower 2018 net product sales volumes relative to 2017, resulting in proportionally lower cost of goods sold.

*Research and Development Expenses.* Research and development expenses increased by $2,220,000 in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 primarily due to increased expenses incurred in conducting the ongoing pivotal CardiAMP Heart Failure Trial and in the development of the

CardiALLO Cell Therapy System. These expenses include fees paid to consultants and CROs and additional personnel costs. We expect research and development expenses to continue to increase as enrollment accelerates in the CardiAMP Heart Failure Trial, and we further develop the CardiAMP and CardiALLO platforms.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses for the nine months ended September 30, 2018 totaled $4,315,000, which was an 8% decrease as compared to $4,708,000 for nine months ended September 30, 2017, due primarily to lower consulting expense, sales commissions, and personnel costs. We expect selling, general and administrative expenses for 2018 to decrease moderately in the last quarter of 2018 compared to 2017, as we continue to tightly manage our spending and infrastructure without compromising the needed support for the CardiAMP Heart Failure Trial and development of our therapeutic programs.

**Liquidity and Capital Resources**

We have incurred net losses each year since our inception and as of September 30, 2018, we had an accumulated deficit of approximately $82.7 million. We anticipate that we will continue to incur net losses for the next several years.

We have funded our operations principally through the sales of equity and convertible debt securities as well as the cash acquired through the reverse merger transaction completed on October 24, 2016. As of September 30, 2018, we had cash and cash equivalents of approximately $4.8 million.

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

| | Nine months ended September 30, | |
|---|---|---|
| | **2018** | **2017** |
| Net cash provided by (used in): | | |
| Operating activities | $(7,823) | $(6,146) |
| Investing activities | (51) | (1,906) |
| Financing activities | 5 | 26 |
| Net decrease in cash and cash equivalents | $(7,869) | $(8,026) |

*Cash Flows from Operating Activities*. The increase in cash used in operating activities of $1,677,000 in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 related primarily to increased cash outflows to conduct the pivotal CardiAMP Heart Failure Trial, further develop the CardiAMP and CardiALLO cell therapy programs while tightly controlling the supporting infrastructure to sustain these efforts and support operations as a public company. We expect spending to increase in 2018 as compared to 2017 as we continue enrolling and treating patients in the CardiAMP Heart Failure Trial and further develop the CardiAMP and CardiALLO Cell Therapy Systems, while balancing the needs to strengthen and enhance the supporting organization.

*Cash Flows from Investing Activities*. Net cash used in investing activities of $51,000 during the nine months ended September 30, 2018 consisted of the purchases of property and equipment.

*Cash Flows from Financing Activities*. Net cash provided by financing activities of $5,000 during the nine months ended September 30, 2018 consisted of the proceeds from the exercise of stock options.

***Future Funding Requirements***

To date, we have generated modest revenue from sales of our approved products. We do not know when, or if, we will generate any revenue from our development stage biotherapeutic programs. We do not expect to generate any revenue from sales of our CardiAMP or CardiALLO therapeutic candidates unless and until we obtain regulatory approval. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our therapeutic candidates. In addition, subject to obtaining regulatory approval for any of our therapeutic and companion diagnostic candidates, 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 $4.8 million as of September 30, 2018 are sufficient to fund our operations into Q1 2019. In order to continue to further the development of our lead therapeutic candidates, the CardiAMP Cell Therapy System, and our second therapeutic candidate, the CardiALLO Cell Therapy System through and beyond Q1 2019, we will be required to raise additional capital. We plan to raise additional capital, potentially including debt and equity arrangements, to finance our future operations. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our therapeutic candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our therapeutic candidates.

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

- the progress, costs, results and timing of our CardiAMP and CardiALLO clinical trials and related development programs;
- FDA acceptance of our CardiAMP cell therapy for heart failure and chronic myocardial ischemia indications;
- FDA acceptance of our CardiALLO cell therapy for heart failure and other potential indications;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the costs associated with securing, establishing and maintaining commercialization and manufacturing capabilities;
- the number and characteristics of product candidates that we pursue, including our product candidates in preclinical development;

- the ability of our product candidates to progress through clinical development successfully;
- our need to expand our research and development activities;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the general and administrative expenses related to being a public company;
- our need and ability to hire additional management and scientific, medical and sales personnel;
- the effect of competing technological and market developments; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

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

Our condensed consolidated financial statements as of and for the three months ended September 30, 2018 have been prepared on the basis that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. Due to the factors described above, there is substantial doubt about our ability to continue as a going concern within one year after the date these financial statements are issued. Our ability to continue as a going concern will depend in a large part, on our ability to raise additional capital.

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

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

**Off-Balance Sheet Arrangements**

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

**Recent Accounting Pronouncements**

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

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in our market risks during the quarter ended September 30, 2018.

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

### Interest Rate Risk

As of September 30, 2018, based on current interest rates and total borrowings outstanding, a hypothetical 100 basis point increase or decrease in interest rates would have an immaterial pre-tax impact on our results of operations.

### Foreign Currency Exchange Risks

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

## ITEM 4. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

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

In connection with the preparation of this Quarterly Report on Form 10-Q, as of September 30, 2018, an evaluation was performed under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of September 30, 2018, our disclosure controls and procedures were, in design and operation, effective.

**Changes in Internal Control over Financial Reporting**

There were no changes to our internal control over financial reporting identified in connection with the evaluation required by rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

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

### ITEM 1A. RISK FACTORS

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

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

None.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

The exhibits listed in the Exhibit Index below are incorporated herein by reference.

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

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

**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: November 8, 2018 By: /s/ Peter Altman
Peter Altman
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 8, 2018 By: /s/ David McClung
David McClung
Chief Financial Officer
(Principal Financial and Accounting Officer)