# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, DC 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended SEPTEMBER 30, 2017**

**OR**

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

**For the transition period from _____ to _____**

**Commission File Number: 001-37685**

# PAVMED INC.
**(Exact Name of Registrant as Specified in Its Charter)**

| **Delaware**<br>**(State or Other Jurisdiction of Incorporation or Organization)** | **47-1214177**<br>**(IRS Employer Identification No.)** |
|---|---|
| **One Grand Central Place**<br>**Suite 4600**<br>**New York, NY**<br>**(Address of Principal Executive Offices)** | **10165**<br>**(Zip Code)** |

**(212) 949-4319**
**(Registrant's Telephone Number, Including Area Code)**

Securities registered under Section 12(b) of the Exchange Act:

| Title of each class | Name of each exchange on which registered |
|---|---|
| Common Stock, $0.001 par value per share | The NASDAQ Stock Market LLC |
| Warrants, each to purchase one share of Common Stock | The NASDAQ Stock Market LLC |

Securities registered under Section 12(g) of the Exchange Act: None

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 [X] 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 [X] 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 | [ ] (Do not check if a smaller reporting company) | Smaller reporting company | [X] |
| | | Emerging growth company | [X] |

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 [X]

As of November 10, 2017 there were 13,875,061 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

## TABLE OF CONTENTS


| | | Page |
|---|---|---|
| **PART I** | **FINANCIAL INFORMATION** | |
| Item 1 | Unaudited Condensed Consolidated Financial Statements | 1 |
| | Unaudited Condensed Consolidated Balance Sheets as of September 30, 2017 and December 31, 2016 | 1 |
| | Unaudited Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2017 and 2016 | 2 |
| | Unaudited Condensed Consolidated Statements of Changes in Series A Convertible Preferred Stock and Stockholders' Deficit for the nine months ended September 30, 2017 | 3 |
| | Unaudited Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2017 and 2016 | 4 |
| | Notes to Unaudited Condensed Consolidated Financial Statements | 5 |
| Item 2 | Management's Discussion and Analysis of Financial Condition and Results of Operations | 36 |
| Item 3 | Quantitative and Qualitative Disclosures About Market Risk | 72 |
| Item 4 | Controls and Procedures | 72 |
| **PART II** | **OTHER INFORMATION** | |
| Item 2 | Unregistered Sale of Equity Securities | 73 |
| Item 6 | Exhibits | 73 |
| **SIGNATURES** | | 74 |

**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**PAVMED INC.**
**and SUBSIDIARY**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
(unaudited)

| | September 30, 2017 | | December 31, 2016 | |
|---|---|---|---|---|
| **Assets** | | | | |
| **Current assets** | | | | |
| Cash | $ | 3,111,456 | $ | 585,680 |
| Prepaid expenses and other current assets | | 103,272 | | 155,490 |
| Total current assets | | 3,214,728 | | 741,170 |
| Equipment, net | | 17,994 | | 18,000 |
| Deferred offering costs | | — | | 111,249 |
| Total assets | $ | 3,232,722 | $ | 870,419 |
| | | | | |
| **Liabilities, Preferred Stock, and Stockholders' Deficit** | | | | |
| **Current liabilities** | | | | |
| Accounts payable | $ | 991,693 | $ | 949,413 |
| Accrued expenses and other current liabilities | | 354,289 | | 240,073 |
| Accrued interest expense | | 187,500 | | — |
| Series A Warrants | | 4,731,557 | | — |
| Derivative liability | | 1,298,113 | | — |
| Total current liabilities | | 7,563,152 | | 1,189,486 |
| | | | | |
| Senior Secured Note, net of $3,417,233 unamortized debt discount | | 1,582,767 | | — |
| | | | | |
| Total liabilities | $ | 9,145,919 | $ | 1,189,486 |
| | | | | |
| COMMITMENTS AND CONTINGENCIES (NOTE 10) | | | | |
| | | | | |
| **Preferred Stock** | | | | |
| par value $0.001, 20,000,000 shares authorized; | | | | |
| Series A Convertible Preferred Stock, par value $0.001, 422,838 and 0 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively | | — | | — |
| | | | | |
| **Stockholders' Deficit** | | | | |
| Series A-1 Convertible Preferred Stock, par value $0.001, 125,000 and 0 shares issued and outstanding at September 30, 2017 and December 31, 2016 respectively | | 189,550 | | — |
| Common stock, par value $0.001; 50,000,000 shares authorized, 13,343,061 and 13,330,811 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively | | 13,343 | | 13,331 |
| Additional paid-in capital | | 12,157,358 | | 7,369,437 |
| Accumulated deficit | | (18,273,448) | | (7,701,835) |
| Total Stockholders' Deficit | | (5,913,197) | | (319,067) |
| Total Liabilities, Series A Convertible Preferred Stock, and Stockholders' Deficit | $ | 3,232,722 | $ | 870,419 |

See accompanying notes to the unaudited condensed consolidated financial statements.

**PAVMED INC.**
**and SUBSIDIARY**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
(unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Revenue | $ — | $ — | $ — | $ — |
| General and administrative expenses | 1,263,122 | 1,350,248 | 4,082,366 | 2,827,721 |
| Research and development expenses | 704,866 | 578,474 | 2,063,319 | 1,112,616 |
| Total operating expenses | 1,967,988 | 1,928,722 | 6,145,685 | 3,940,337 |
| Loss from operations | (1,967,988) | (1,928,722) | (6,145,685) | (3,940,337) |
| Other income (expense) | | | | |
| Interest expense | (362,142) | — | (362,142) | — |
| Loss on the issuance of Series A Preferred Stock Units | — | — | (3,124,285) | — |
| Change in fair value of Series A Warrants liability | (2,215,671) | — | (680,851) | — |
| Change in fair value of derivative liability | (583,517) | — | (76,150) | — |
| Other income (expense), net | (3,161,330) | — | (4,243,428) | — |
| Loss before income tax | (5,129,318) | (1,928,722) | (10,389,113) | (3,940,337) |
| Income tax | — | — | — | — |
| Net loss | (5,129,318) | (1,928,722) | (10,389,113) | (3,940,337) |
| Series A Convertible Preferred Stock dividends | (52,299) | — | (130,010) | — |
| Series A-1 Convertible Preferred Stock dividends | (6,196) | — | (6,196) | — |
| Deemed dividend Series A-1 Convertible Preferred Stock | (182,500) | — | (182,500) | — |
| Net loss attributable to common stockholders | $ (5,370,313) | $ (1,928,722) | $ (10,707,819) | $ (3,940,337) |
| Net loss attributable to common stockholders per share, basic and diluted | $ (0.40) | $ (0.14) | $ (0.80) | $ (0.31) |
| Weighted average common shares outstanding - basic and diluted | 13,332,629 | 13,310,000 | 13,331,585 | 12,855,714 |

See accompanying notes to the unaudited condensed consolidated financial statements.

**PAVMED INC.**
**and SUBSIDIARY**
**CONDENSED CONSOLIDATED STATEMENTS OF**
**SERIES A CONVERTIBLE PREFERRED STOCK**
**and STOCKHOLDERS' DEFICIT**
(unaudited)

| | Series A Convertible Preferred Stock | | Stockholders' Deficit | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Series A-1 Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders (Deficit) |
| | Shares | Amount | Shares | Amount | Shares | Amount | | | |
| **Balance at December 31, 2016** | — | $ — | — | — | 13,330,811 | $ 13,331 | $ 7,369,437 | $ (7,701,835) | $ (319,067) |
| Issuance of Series A Convertible Preferred Stock | 422,838 | — | | | | | | | |
| Issuance of Series A-1 Convertible Preferred Stock and Series A-1 Warrants | | | 125,000 | 7,050 | | | 492,950 | | 500,000 |
| Series A-1 Convertible Preferred Stock deemed dividend | | | | 182,500 | | | | (182,500) | — |
| Issuance of Series S Warrants in connection with Senior Secured Note | | | | | | | 3.434,452 | | 3,434,452 |
| Common stock issued upon exercise of warrants | | | | | 12,250 | 12 | 61,238 | | 61,250 |
| Stock-based compensation | | | | | | | 799,281 | | 799,281 |
| Net loss | | | | | | | | (10,389,113) | (10,389,113) |
| **Balance at September 30, 2017** | 422,838 | $ — | 125,000 | $ 189,550 | 13,343,061 | $ 13,343 | $ 12,157,358 | $ (18,273,448) | $ (5,913,197) |

See accompanying notes to the unaudited condensed consolidated financial statements.

**PAVMED INC.**
**and SUBSIDIARY**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
(unaudited)

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2017 | 2016 |
| **Cash flows from operating activities** | | |
| Net loss | $ (10,389,113) | $ (3,940,337) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation expense | 5,307 | 2,315 |
| Stock-based compensation | 799,281 | 499,628 |
| Loss on the issuance of Preferred Stock Units | 3,124,285 | — |
| Change in fair value of Series A Warrants | 680,851 | — |
| Change in fair value of derivative liability | 76,150 | — |
| Amortization of discount on Senior Secured Note | 174,642 | — |
| Accrued interest expense - Senior Secured Note | 187,500 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 52,218 | (169,057) |
| Accounts payable | 42,280 | 538,063 |
| Accrued expenses and other current liabilities | 225,465 | (182,499) |
| Net cash flows used in operating activities | (5,021,134) | (3,251,887) |
| **Cash flows from investing activities** | | |
| Purchase of equipment | (5,301) | (21,793) |
| Net cash flows used in investing activities | (5,301) | (21,793) |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of Series A Preferred Stock Units | 2,537,012 | — |
| Payment of offering costs in connection with Series A Preferred Stock Units | (388,628) | — |
| Proceeds from issuance of Series A-1 Preferred Stock Units | 500,000 | — |
| Proceeds from issuance of senior secured note payable | 4,842,577 | — |
| Proceeds from issuance of units in connection with initial public offering | — | 5,300,000 |
| Payment of offering costs in connection with initial public offering | — | (1,004,938) |
| Proceeds from common stock issued upon exercise of warrants | 61,250 | — |
| Net cash flows provided by financing activities | 7,552,211 | 4,295,062 |
| Net increase in cash | 2,525,776 | 1,021,382 |
| Cash, beginning of period | 585,680 | 767,268 |
| Cash, end of period | $ 3,111,456 | $ 1,788,650 |
| **Supplemental non-cash financing activities** | | |
| Fair value of Series A Warrants - issue dates (aggregate) | $ 4,050,706 | $ — |
| Fair value of derivative liability - issue dates (aggregate) | $ 1,221,963 | $ — |
| Fair value of Series A-1 Warrant - issue date | $ 310,450 | $ — |
| Fair value of Series A-1 Convertible Preferred Stock - issue date | $ 7,050 | $ — |
| Fair value of senior secured note - issue date | $ 1,408,125 | $ — |
| Fair value of Series-S Warrants - issue date | $ 3,434,452 | $ — |
| Deferred offering costs in connection with initial public offering | $ — | $ 272,356 |

See accompanying notes to the unaudited condensed consolidated financial statements.

**Note 1 — The Company, Description of the Business, and Going Concern**

PAVmed Inc. ("PAVmed" or the "Company") is a highly-differentiated multi-product medical device company organized to advance a broad pipeline of innovative medical technologies from concept to commercialization, employing a business model focused on capital efficiency and speed to market. The Company is focused on advancing its lead products towards regulatory approval and commercialization, protecting its intellectual property, and building its corporate infrastructure and management team. The Company was organized under the laws of the State of Delaware on June 26, 2014 (inception), originally under the name of PAXmed Inc., and on April 19, 2015, changed its name to PAVmed Inc. The Company operates in one segment as a medical device company.

The Company has financed its operations principally through the issuances of its common stock, preferred stock, warrants, and debt. Prior to the Company's 2016 initial public offering (IPO), the Company raised approximately $2.1 million of net cash proceeds from private offerings of its common stock and warrants. See Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a discussion of the Company's common stock and warrants issued before the Company's IPO. The Company realized approximately $4.2 million of net cash proceeds resulting from the Company's IPO on April 28, 2016. In the nine months ended September 30, 2017, the Company has raised approximately $7.5 million of net cash proceeds resulting from three transactions, including: the Note and Security Purchase Agreement with Scopia Holdings LLC, including the issuance of a Senior Secured Note and Series S Warrants; the Series A-1 Preferred Stock Units private placement; and the Series A Preferred Stock Units private placement.

*Initial Public Offering*

Under a registration statement on Form S-1 (File No. 333-203569) declared effective January 29, 2016, the Company's IPO was consummated on April 28, 2016, resulting in $4.2 million of net cash proceeds, after deducting cash selling agent discounts and commissions and offering expenses, from the issuance of 1,060,000 units at an offering price of $5.00 per unit, with each such unit comprised of one share of common stock of the Company and one warrant to purchase a share of common stock of the Company, with such warrant referred to as a "Series W Warrant". The units issued in the IPO were initially listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "PAVMU", until July 27, 2016, when the PAVMU units ceased to be quoted and traded on Nasdaq, and the underlying shares of common stock and the Series W Warrants began separate trading on Nasdaq, under their respective individual symbols of "PAVM" for the shares of common stock and "PAVMW" for the Series W Warrants.

See Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a further discussion of the Company's common stock and Series W Warrants.

*Note and Security Purchase Agreement with Scopia Holdings LLC*

The Company and Scopia Holdings LLC ("Scopia or the Lender") entered into a Note and Security Purchase Agreement, under which, upon Scopia delivering to the Company $4.8 million in net cash proceeds by wire transfer on July 3, 2017, the Company issued to Scopia and its designees, a Senior Secured Note with an initial principal amount of $5.0 million ("Scopia Note"), and 2,660,000 Series S Warrants to purchase shares of common stock of the Company.

The Scopia Note bears interest at a fixed annual rate of 15.0%, with interest payable semi-annually in arrears on June 30 and December 30 of each calendar year, commencing on December 30, 2017. The Company may elect, at its sole discretion, to defer payment of up to 50% of the semi-annual interest, with the remaining unpaid interest added to and increasing the outstanding interest-bearing principal balance of the Scopia Note by such amount. The aggregate remaining unpaid principal balance of the Scopia Note is due on June 30, 2019.

The Series S Warrants were immediately exercisable upon issuance, have an exercise price of $0.01 per share, with such exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock, may be exercised for cash or on a cashless basis, and expire June 30, 2032, with any Series S Warrants outstanding on the expiration date automatically exercised on a cashless basis.

See Note 12, *Note and Securities Purchase Agreement, Senior Secured Note, and Series S Warrants*, for a further discussion of the Note and Security Purchase Agreement with Scopia Holdings LLC; and, Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for further information with respect to the Series S Warrants.

*Series A-1 Preferred Stock Units Private Placement*

On August 3, 2017, the Company's Board of Directors authorized the issuance of up to 150,000 Series A-1 Preferred Stock Units, and on August 4, 2017, the Company entered into a Securities Purchase Agreement, which was subsequently amended on October 18, 2017, pursuant to which the Company may issue up to an aggregate of $600,000 (subject to increase) of Series A-1 Preferred Stock Units at a price of $4.00 per unit, in a private placement transaction (Series A-1 Preferred Stock Units private placement).

At the August 4, 2017 closing of the Series A-1 Preferred Stock Units private placement, a total of 125,000 Series A-1 Preferred Stock Units were issued for aggregate proceeds of $500,000. The Company did not incur placement agent fees in connection with the Series A-1 Preferred Stock Units private placement.

A Series A-1 Preferred Stock Unit was comprised of one share of Series A-1 Convertible Preferred Stock convertible into a share of common stock of the Company, and one Series A-1 Warrant exercisable for a share of common stock of the Company, or the Series A-1 Warrant may be exchanged for five Series W Warrants or four Series X-1 Warrants each of which is exercisable for a share of common stock of the Company.

See Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a further discussion of the Series A-1 Preferred Stock Units private placement, the Series A-1 Convertible Preferred Stock, the Series A-1 Warrants, and the Series W Warrants or Series X-1 Warrants which may be issued upon the exchange of Series A-1 Warrants.

*Series A Preferred Stock Units Private Placement*

The Company's Board of Directors authorized the issuance of up to a total of 1.25 million Series A Preferred Stock Units, including authorizing 500,000 units on January 21, 2017 and 750,000 units on May 10, 2017. On January 26, 2017, the Company entered into a Securities Purchase Agreement pursuant to which the Company may issue up to an aggregate of $3,000,000 (subject to increase) of Series A Preferred Stock Units at a price of $6.00 per unit, in a private placement transaction (Series A Preferred Stock Units private placement).

At the Series A Preferred Stock Units private placement initial closing on January 26, 2017, and at subsequent closings on January 31, 2017 and March 8, 2017, a total of 422,838 Series A Preferred Stock Units were issued for aggregate gross proceeds of approximately $2.5 million and net proceeds of approximately $2.2 million, after payment of placement agent fees and closing costs.

A Series A Preferred Stock Unit was comprised of one share of Series A Convertible Preferred Stock convertible into a share of common stock of the Company, and one Series A Warrant exercisable for a share of common stock of the Company, or one Series A Warrant may be exchanged for four Series X Warrants, each of which is exercisable for a share of common stock of the Company.

See Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a further discussion of the Series A Preferred Stock Units private placement, Series A Convertible Preferred Stock, Series A Warrant, and the Series X Warrants which may be issued upon the exchange of Series A Warrants.

**Note 1 — The Company, Description of the Business, and Going Concern** (continued)

*Going Concern*

The provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements - Going Concern* (ASC 205-40) requires management to assess an entity's ability to continue as a going concern within one year of the date of the financial statements are issued. In each reporting period, including interim periods, an entity is required to assess conditions known and reasonably knowable as of the financial statement issuance date to determine whether it is probable an entity will not meet its financial obligations within one year from the financial statement issuance date. Substantial doubt about an entity's ability to continue as a going concern exists when conditions and events, considered in the aggregate, indicate it is probable the entity will be unable to meet its financial obligations as they become due within one year after the date the financial statements are issued.

The Company is an early stage and emerging growth company and has not generated any revenues to date. As such, the Company is subject to all of the risks associated with early stage and emerging growth companies. Since inception, the Company has incurred losses and negative cash flows from operating activities. The Company does not expect to generate positive cash flows from operating activities in the near future until such time, if at all, the Company completes the development process of its products, including regulatory approvals, and thereafter, begins to commercialize and achieve substantial acceptance in the marketplace for the first of a series of products in its medical device portfolio.

The Company incurred a net loss attributable to common stockholders of $10,707,819 and had net cash flows used in operating activities of $5,021,134 for the nine months ended September 30, 2017. At September 30, 2017, the Company had an accumulated deficit of $18,273,448 and working capital of $1,681,246, adjusted to exclude the Series A Warrants liability of $4,731,557 and the Series A Convertible Preferred Stock embedded conversion option derivative liability of $1,298,113. In the near future, the Company anticipates incurring operating losses and does not expect to experience positive cash flows from operating activities and may continue to incur operating losses for the next several years as it completes the development of its products, seeks regulatory approvals, and begin to market such products. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the unaudited condensed consolidated financial statements are issued.

The Company estimates its current cash resources absent any additional sources of cash, is sufficient to fund its operations into the quarter ended June 30, 2018. Accordingly, the Company does not have sufficient cash resources to fund its anticipated operating losses beyond the twelve months after the date these unaudited condensed consolidated financial statements are issued. Therefore, the Company must raise additional cash to support its operating and capital needs beyond the quarter ended June 30, 2018.

The Company's ability to fund its operations is dependent upon management's plans, which include raising additional capital, obtaining regulatory approvals for its products currently under development, commercializing and generating revenues from products currently under development, and continuing to control expenses. However, there is no assurance the Company will be successful in these efforts.

A failure to raise sufficient capital, obtain regulatory approvals for the Company's products, generate sufficient product revenues, or control expenditures, among other factors, will adversely impact the Company's ability to meet its financial obligations as they become due and payable and to achieve its intended business objectives, and therefore, raises substantial doubt of the Company's ability to continue as a going concern within one year after the date the unaudited condensed consolidated financial statements are issued.

The Company's unaudited condensed consolidated financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities should the Company be unable to continue as a going concern.

## Note 2 — Summary of Significant Accounting Policies

### Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany transactions and balances have been eliminated in consolidation. The condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), and applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding interim financial reporting. As permitted under SEC rules, certain footnotes or other financial information normally required by U.S. GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2016 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. These condensed consolidated financial statements have been prepared on the same basis as the Company's annual financial statements and in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the Company's financial information. The accompanying unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited financial statements and related notes thereto as of and for the year ended December 31, 2016 included in the Company's Annual Report on Form 10-K filed with the SEC.

The results of operations for the nine months ended September 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 or for any other interim period or for any other future periods.

### Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates in these unaudited condensed consolidated financial statements include those related to the fair value of warrants, the fair value of derivative liability, stock-based compensation, research and development expenses, the provision or benefit for income taxes and the valuation allowance on deferred tax assets. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. On an ongoing basis, the Company evaluates its estimates, judgements, and methodologies. The Company bases its estimates on historical experience and on various other assumptions believed to be reasonable. Due to the inherent uncertainty involved in making estimates, actual results could differ materially from those estimates.

### Cash

The Company maintains its cash at a major financial institution with high credit quality. At times, the balance of its cash deposits may exceed federally insured limits. The Company has not experienced and does not anticipate any losses on deposits with commercial banks and financial institutions which exceed federally insured limits.

### Research and Development Expenses

Research and development expenses are recognized as incurred and include the salary and stock-based compensation of the Company's Chief Medical Officer ("CMO") and the costs related to the Company's various contract research service providers, suppliers, engineering studies, supplies, and outsourced testing and consulting, as well as rental costs for equipment and access to certain facilities at one of the Company's contract research service providers.

### Offering Costs

Offering costs consist of certain legal, accounting, and other advisory fees incurred related to the Company's efforts to raise debt and equity capital. Offering costs in connection with equity financing are recognized as either an offset against the financing proceeds to extent the underlying security is equity classified or a current period expense to extent the underlying security is liability classified. Offering costs, lender fees, and warrants issued in connection with debt financing are recognized as debt discount, which reduces the reported carrying value of the debt, and which is amortized as interest expense, generally over the contractual term of the debt agreement, to result in a constant rate of interest. Offering costs associated with in-process capital financing are accounted for as deferred offering costs. The deferred offering costs at December 31, 2016 relate to legal fees incurred with respect to an in-process financing transaction involving the Series A Preferred Stock Units private placement transaction, with such transaction discussed in Note 13, *Series A Convertible Preferred Stock, Shareholders' Deficit, and Warrants*.

### Patent Costs and Purchased Patent License Rights

Patent related costs in connection with filing and prosecuting patent applications and patents filed by the Company are expensed as incurred, and are classified as general and administrative expenses. The purchase of patent license rights for use in research and development activities are expensed as incurred and are classified as research and development expense.

**Equipment**

Equipment is stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and resulting gain or loss, if any, is included in the consolidated statement of operations. The useful lives of equipment are as follows:

| | |
|---|---|
| Research and development equipment | 5 years |
| Computer equipment | 3 years |

**Long-Lived Assets**

The Company evaluates its long-lived assets, including equipment, for impairment whenever events or changes in circumstances indicate the carrying value of these assets may not be recoverable. Recoverability of these assets is measured by comparison of the carrying amount of each asset to the future undiscounted cash flows expected to result from the use of the asset and its eventual disposition. If the asset is considered impaired, the amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired assets. The Company has not recorded impairment of any long-lived assets in the periods presented.

**Fair Value Measurements**

FASB ASC Topic 820, *Fair Value* Measurement, (ASC 820) defines fair value as the price which would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at a transaction measurement date. The ASC 820 three-tier fair value hierarchy prioritizes the inputs used in the valuation methodologies, as follows:

Level 1 Valuations based on quoted prices for identical assets and liabilities in active markets.

Level 2 Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets which are not active, or other inputs observable or can be corroborated by observable market data.

Level 3 Valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

The carrying values of cash, accounts payable, and accrued expenses, approximate their respective fair value due to the short-term nature of these financial instruments at September 30, 2017 and December 31, 2016.

At September 30, 2017, the Series A Convertible Preferred Stock conversion option embedded derivative liability and the Series A Warrants liability were initially and are subsequently measured at fair value in accordance with FASB ASC 820, using a Monte Carlo simulation valuation model, using the Company's common stock price and certain Level 3 inputs to take into account the probabilities of certain events occurring over the life of the respective financial instrument. At December 31, 2016 the Company did not have any assets or liabilities required to be measured at fair value on a recurring basis in accordance with ASC 820. See Note 3, *Financial Instruments Fair Value Measurements*, for further information regarding the estimated fair value of these financial instruments.

The non-recurring issue-date fair values of the Senior Secured Note and Series S Warrants issued in connection with the Note and Security Purchase Agreement between the Company and Scopia Holdings LLC and the Series A-1 Convertible Preferred Stock and Series A-1 Warrants issued in the Series A-1 Preferred Stock Units private placement, utilized the Company's common stock price and certain Level 3 inputs in the development of discounted cash flow analyses and Black-Scholes valuation models. Further information regarding such non-recurring issue-date fair values is discussed in Note 12, *Note and Securities Purchase Agreement, Senior Secured Note, and Series S Warrants*; and, Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*.

**Financial Instruments**

The Company evaluates its financial instruments to determine if those instruments or any potential embedded components of those instruments qualify as derivatives that need to be separately accounted for in accordance with FASB ASC Topic 815, *Derivatives and Hedging* (ASC 815). Warrants are classified as either equity or a derivative liability depending on the specific terms of the respective warrant agreement. Generally, warrants with cash settlement or certain exercise price adjustment provisions, are accounted for as a derivative liability. A warrant classified as a liability, or a bifurcated embedded derivative classified as a liability, is initially measured at its issue-date fair value, with such fair value subsequently adjusted at each reporting period, with the resulting adjustment recognized as other income or expense. If upon the occurrence of an event resulting in the warrant liability or the embedded derivative liability being subsequently classified as equity, the fair value will be adjusted on such date-of-occurrence, with such date-of-occurrence fair value adjustment recognized as other income or expense, and then it will be classified as equity at such date-of-occurrence adjusted fair value.

**Note 2 — Summary of Significant Accounting Policies** (continued)

**Stock-Based Compensation**

The Company issues stock-based awards to employees, members of its board of directors, and non-employees. Stock-based awards to employees and members of its board of directors are accounted for in accordance with FASB ASC Topic 718, *Stock Compensation*, and stock-based awards to non-employees are accounted for in accordance with FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees.*

The Company measures the compensation expense of stock-based awards granted to employees and members of its board of directors using the grant-date fair value of the award and recognizes compensation expense for stock-based awards on a straight-line basis over the requisite service period, which is generally the vesting period of the respective stock option award.

The Company measures the expense of stock-based awards granted to non-employees on a vesting date basis, fixing the fair value of vested non-employee stock options as of the their respective vesting date. The fair value of vested non-employee stock options is not subject-to-change at subsequent reporting dates. The estimated fair value of the unvested non-employee stock options is remeasured to then current fair value at each subsequent reporting date. The expense of non-employee stock options is recognized on a straight-line basis over the service period, which is generally the vesting period of the respective non-employee stock option award.

In March 2016, the FASB issued Accounting Standards Update ("ASU") 2016-09, *Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting,* ("ASU 2016-09") which simplified several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for the Company beginning January 1, 2017, although early adoption is permitted. The Company elected to early adopt ASU 2016-09 effective as of April 1, 2016. As the Company did not have any stock options issued or outstanding prior to the closing of its IPO, the early adoption did not have an impact on the Company's consolidated financial position, results of operations and cash flows.

**Income Taxes**

The Company accounts for income taxes using the asset and liability method, as required by FASB ASC Topic 740, Income Taxes, (ASC 740). Current tax liabilities or receivables are recognized for the amount of taxes estimated to be payable or refundable for the current year. Deferred tax assets and liabilities are recognized for estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, along with net operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company assesses the likelihood its deferred tax assets will be recovered from future taxable income, and to the extent it deems reasonable, based on available evidence, it is more-likely-than-not all or a portion of the deferred tax assets will not be realized, a valuation allowance reserve is established through a charge to income tax expense.

The Company recognizes the benefit of an uncertain tax position it has taken or expects to take on its income tax return if such a position is more-likely-than-not to be sustained upon examination by the taxing authorities, with the tax benefit recognized being the largest amount having a greater than 50% likelihood of being realized upon ultimate settlement.

The Company's policy for recording interest and penalties associated with audits is to record such expense as a component of income tax expense. There were no amounts accrued for penalties or interest as of September 30, 2017 and December 31, 2016, or recognized during the three and nine months ended September 30, 2017 and 2016. As of September 30, 2017, the Company does not have any unrecognized tax benefits resulting from uncertain tax positions. The Company is not aware of any issues under review to potentially result in significant payments, accruals, or material deviations from its position.

**Net Loss Per Share**

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the sum of the weighted-average number of common shares outstanding during the reporting period, and, if dilutive, the incremental shares resulting from common stock equivalents, computed using the treasury stock method. The Company's common stock equivalents include: stock options, unit purchase options, convertible preferred stock, and warrants. Notwithstanding, as the Company's consolidated financial results resulted in a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share, due to the exclusion of incremental shares resulting from common stock equivalents as their inclusion would have been anti-dilutive.

**Segment Data**

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. No revenue has been generated since inception, and all tangible assets are held in the United States.

**JOBS Act Accounting Election**

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected to avail itself of this exemption from new or revised accounting standards, and, therefore, will not be subject to the same new or revised accounting standards as public companies that are not emerging growth companies.

**Recent Accounting Pronouncements**

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) - Part I - Accounting for Certain Financial Instruments with Down-Round Features, and Part II - Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* Principally, ASU 2017-11 amendments simplify the accounting for certain financial instruments with down-round features. The amendments require companies to disregard the down-round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. Companies that provide earnings per share (EPS) data will adjust their basic EPS calculation for the effect of the down-round feature when triggered (i.e., when the exercise price of the related equity-linked financial instrument is adjusted downward because of the down-round feature) and will also recognize the effect of the trigger within equity. Additionally, ASU 2017-11 also addresses "navigational concerns" within the FASB ASC related to an indefinite deferral available to private companies with mandatorily redeemable financial instruments and certain noncontrolling interests, which has resulted in the existence of significant "pending content" in the ASC. The FASB decided to reclassify the indefinite deferral as a scope exception, which does not have an accounting effect. The guidance of ASU 2017-11 is effective for public business entities, as defined in the ASC Master Glossary, for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and for all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Earlier adoption is permitted for all entities as of the beginning of an interim period for which financial statements (interim or annual) have not been issued or have not been made available for issuance. The Company is evaluating the impact of this guidance on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718) - Scope of Modification Accounting*. In ASU 2017-09, the FASB provides guidance on determining which changes to the terms and conditions of stock-based compensation arrangements require the application of "modification accounting" under ASC 718. Generally, ASC 718 modification accounting is not applicable if the stock-based arrangement immediately before and after the modification has the same fair value, vesting conditions, and balance sheet classification. The guidance of ASU 2017-09 is effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for public business entities, as defined in the ASC Master Glossary, for periods for which financial statements have not yet been issued, and for all other entities for reporting periods for which financial statements have not yet been made available for issuance. The Company adopted this guidance as of April 1, 2017, and it did not have an effect on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, which amends the guidance of FASB ASC Topic 805, Business Combinations (ASC 805) adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (disposals) of assets or businesses. The objective of ASU 2017-01 is to narrow the definition of what qualifies as a business under Topic 805 and to provide guidance for streamlining the analysis required to assess whether a transaction involves the acquisition (disposal) of a business. ASU 2017-01 provides a screen to assess when a set of assets and processes do not qualify as a business under Topic 805, reducing the number of transactions that need to be considered as possible business acquisitions. ASU 2017-01 also narrows the definition of output under Topic 805 to make it consistent with the description of outputs under Topic 606. The guidance of ASU 2017-01 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years and early adoption is permitted under certain circumstances. The Company is evaluating the impact of this guidance on its consolidated financial statements.

**Note 2 — Summary of Significant Accounting Policies** (continued)

**Recent Accounting Pronouncements** (continued)

In August 2016, the FASB issued ASU 2016-15, which amended the guidance of FASB ASC Topic 230, Statement of Cash Flows (ASC 230) on the classification of certain cash receipts and payments. The primary purpose of ASU 2016-15 is to reduce the diversity in practice which has resulted from a lack of consistent principles on this topic. The amendments of ASU 2016-15 add or clarify guidance on eight specific cash flow issues, including debt prepayment or debt extinguishment costs, settlement of zero-coupon debt instruments, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees, beneficial interests in securitization transactions, and separately identifiable cash flows and application of the predominance principle. The guidance of ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company is evaluating the impact of this guidance on its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* and subsequently issued additional updates amending the guidance contained in Topic 606 (ASC 606), thereby affecting the guidance contained in ASU 2014-09. ASU 2014-09 and the subsequent ASC 606 updates will supersede and replace nearly all existing U.S. GAAP revenue recognition guidance. The core principle of ASU 2014-09 is to recognize revenue when promised goods or services are transferred to customers in an amount equal to the consideration to which the entity expects to be entitled for those goods and services. ASU 2014-09 defines a five step process to achieve this core principle, and in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The standard is effective for annual periods beginning after December 15, 2017, including interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting the standard recognized at the date of adoption (which includes additional footnote disclosures). To date, since its inception, the Company has not generated any revenue, as such, the provisions of ASC 606 have not impacted the Company’s consolidated results of operations or financial condition.

In March 2016, the FASB issued ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations* (“ASU 2016-08”). The amendments are intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations by amending certain existing illustrative examples and adding additional illustrative examples to assist in the application of the guidance. The effective date and transition requirements for the amendments are the same as the effective date and transition requirements in Topic 606. The guidance is effective for the Company beginning January 1, 2018, although early adoption is permitted beginning January 1, 2017. To date, since its inception, the Company has not generated any revenue, as such, the provisions of ASC 606 have not impacted the Company’s consolidated results of operations or financial condition.

In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing* (“ASU 2016-10”). The amendments in ASU 2016-10 clarify the following two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. The amendments do not change the core principle of the guidance in Topic 606. The effective date and transition requirements for the amendments are the same as the effective date and transition requirements in Topic 606. The guidance is effective for the Company beginning January 1, 2018, although early adoption is permitted beginning January 1, 2017. To date, since its inception, the Company has not generated any revenue, as such, the provisions of ASC 606 have not impacted the Company’s consolidated results of operations or financial condition.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (“ASU 2016-02”), which establishes a right-of-use (“ROU”) model requiring a lessee to recognize a ROU asset and a lease liability for all leases with terms greater-than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods with those fiscal years. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of this guidance on its consolidated financial position, results of operations, and cash flows.

**Note 3 — Financial Instruments Fair Value Measurements**

*Recurring Fair Value Measurements*

The following fair value hierarchy table presents information about each major category of the Company's financial instruments measured at fair value on a recurring basis as of September 30, 2017. There were no such financial instruments as of December 31, 2016.

| | Fair Value Measurement on a Recurring Basis at Reporting Date Using: | | | |
|---|---|---|---|---|
| | Quoted Prices in Active Markets for Identical Items Level-1 | Significant Other Observable Inputs Level-2 | Significant Unobservable Inputs Level-3 | Total |
| **September 30, 2017** | | | | |
| Liabilities | | | | |
| Series A Warrants | $ — | $ — | $ 4,731,557 | $ 4,731,557 |
| Series A Convertible Preferred Stock conversion option embedded derivative liability | — | — | 1,298,113 | 1,298,113 |
| Total liabilities | $ — | $ — | $ 6,029,670 | $ 6,029,670 |

The Series A Preferred Stock Units were issued in three closings in the three months ended March 31, 2017, with each such unit comprised of one share of Series A Convertible Preferred Stock and one Series A Warrant - with each, at the option of the holder, convertible into and exercisable for, respectively, a share of the Company's common stock. See Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants* for further discussion of the Series A Preferred Stock Units private placement, the Series A Convertible Preferred Stock, and the Series A Warrant.

The Series A Warrant and the Series A Convertible Preferred Stock conversion option, which is accounted for as an embedded derivative and bifurcated from its host financial instrument, were determined to be derivatives under FASB ASC 815, as, along with other provisions, their conversion price and exercise price, respectively, are subject to potential adjustment resulting from future financing transactions, under certain conditions.

The Series A Warrants and the Series A Convertible Preferred Stock conversion option embedded derivative are each classified as a current liability on the unaudited condensed consolidated balance sheet, and were initially measured at fair value at the time of issuance and are subsequently remeasured at fair value at each reporting period, with changes in fair value recognized as other income or expense in the unaudited condensed consolidated statement of operations.

A reconciliation of the Series A Warrants liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability for the nine months ended September 30, 2017 is a follows:

| | Series A Warrants Liability | Series A Convertible Preferred Stock Conversion Option Embedded Derivative Liability |
|---|---|---|
| Balance at December 31, 2016 | $ — | $ — |
| Initial fair value on dates of issuance | 4,050,706 | 1,221,963 |
| Change in fair value | 680,851 | 76,150 |
| Balance at September 30, 2017 | $ 4,731,557 | $ 1,298,113 |

In the nine months ended September 30, 2017, the change in fair values resulted in the recognition of: an expense of $680,851 with respect to the Series A Warrants liability; and, an expense of $76,150 with respect to the Series A Convertible Preferred Stock conversion option embedded derivative liability. As the Series A Preferred Stock Units were issued in the three months ended March 31, 2017, there was no comparable amount in the prior year period.

**Note 3 — Financial Instruments Fair Value Measurements** (continued)

The fair value of the Series A Warrants liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability was determined using a Monte Carlo simulation valuation model - using the Company's common stock price and certain other Level-3 inputs to take into account the probabilities of certain events occurring over the life of the respective financial instrument. The resulting estimated fair value is subjective and is affected by changes in inputs to the valuation model including the Company's common stock price, and the assumptions regarding the estimated volatility in the value of the Company's common stock price; the Company's dividend yield; the likelihood and timing of dilutive transactions; and, the risk-free rates based on U.S. Treasury security yields. Changes in these assumptions can materially affect the estimated fair value of each financial instrument. The Series A Warrants liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability estimated fair value and the underlying assumptions as of the dates indicated, are as follows:

| Series A Warrants Liability | September 30, 2017 | Issue Dates' Aggregated Weighted Average |
|---|---|---|
| Fair value per Series A Warrant | $ 11.19 | $ 9.58 |
| Series A Warrants outstanding | 422,838 | 422,838 |
| Calculated aggregate fair value | $ 4,731,557 | $ 4,050,706 |
| Value of common stock | $ 5.43 | $ 5.73 |
| Exercise price per share | $ 6.65 | $ 8.00 |
| Expected term (years) | 6.59 | 7.21 |
| Volatility | 53% | 47% |
| Risk free rate | 2.1% | 2.3% |
| Dividend yield | 0% | 0% |

| Series A Convertible Preferred Stock Conversion Option Embedded Derivative Liability | September 30, 2017 | Issue Dates' Aggregated Weighted Average |
|---|---|---|
| Fair value per conversion option | $ 3.07 | $ 2.89 |
| Series A Convertible Preferred Stock shares outstanding | 422,838 | 422,838 |
| Calculated aggregate fair value | $ 1,298,113 | $ 1,221,963 |
| Value of common stock | $ 5.43 | $ 5.73 |
| Conversion price per share | $ 4.99 | $ 6.00 |
| Expected term (years) | 6.59 | 7.21 |
| Volatility | 53% | 47% |
| Risk-free interest rate | 2.1% | 2.3% |
| Dividend yield | 0% | 0% |

*Non-recurring Fair Value Measurements*

The non-recurring issue-date fair values of the Senior Secured Note and Series S Warrants issued in connection with the Note and Security Purchase Agreement between the Company and Scopia Holdings LLC, are presented in Note 12, *Note and Securities Purchase Agreement, Senior Secured Note, and Series S Warrants*.

The non-recurring issue-date fair values of the Series A-1 Convertible Preferred Stock and Series A-1 Warrants issued in the Series A-1 Preferred Stock Units private placement are presented in Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*.

**Note 4 — Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consisted of the following as of:

| | September 30, 2017 | December 31, 2016 |
|---|---|---|
| Security deposits | $ 14,250 | $ 48,350 |
| Prepaid insurance | 30,230 | 35,947 |
| Advanced payments to suppliers | 58,792 | 71,193 |
| Total prepaid expenses and other current assets | $ 103,272 | $ 155,490 |

**Note 5 — Equipment, Net**

Equipment, net consisted of the following as of:

| | September 30, 2017 | December 31, 2016 |
|---|---|---|
| Research and development equipment | $ 13,656 | $ 10,156 |
| Computer equipment | 13,438 | 11,637 |
| | 27,094 | 21,793 |
| Less: accumulated depreciation | (9,100) | (3,793) |
| Equipment, net | $ 17,994 | $ 18,000 |

Depreciation expense was $1,802 and $5,307 for the three and nine months ended September 30, 2017, respectively, and $1,478 and $2,315 for the three and nine months ended September 30, 2016, respectively.

**Note 6 — Agreement Related to Intellectual Property Right**

*Tufts Patent License Agreement - Antibiotic-Eluting Resorbable Ear Tubes*

On November 2, 2016, the Company executed a Patent License Agreement (the "Tufts Patent License Agreement") with Tufts University and its co-owners, the Massachusetts Eye and Ear Infirmary and Massachusetts General Hospital (the "Licensors"). Pursuant to the Tufts Patent License Agreement, the Licensors granted the Company the exclusive right and license to certain patents in connection with the development and commercialization of antibiotic-eluting resorbable ear tubes based on a proprietary aqueous silk technology conceived and developed by the Licensors. Upon execution of the Tufts Patent License Agreement, the Company paid the Licensors an upfront non-refundable fee of $50,000. The Tufts Patent License Agreement also provides for payments from the Company to the Licensors upon the achievement of certain product development and regulatory clearance milestones as well as royalty payments on net sales upon the commercialization of products developed utilizing the licensed patents. The Company incurred expenses related to patent fee reimbursement under the Tufts Patent License Agreement of $21,945 and $42,496 in the three and nine months ended September 30, 2017, respectively.

The Company accounted for the Tufts Patent License Agreement as an asset acquisition as the license agreement did not meet the definition of a business pursuant to the guidance prescribed in FASB ASC Topic 805, *Business Combinations*, as the transaction principally resulted in the acquisition of intellectual property rights only. In this regard, the Company did not acquire any employees or tangible assets, or any processes, protocols, or operating systems. Additionally, at the time of the transaction, there were no activities being conducted related to the licensed patents. As of the transaction date, the Company recognized as expense the cost of the acquired intellectual property rights, as required, since this intangible asset purchased from others for use in a research and development activity, and for which there are no alternative future uses. Accordingly, the Company recognized the $50,000 payment as research and development expense in the year ended December 31, 2016. The Company will record as expense any contingent milestone payments or royalties in the period in which such liabilities are incurred.

**Note 7 — Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following for the periods indicated:

| | September 30, 2017 | December 31, 2016 |
|---|---|---|
| Accrued bonus | $ 116,650 | $ — |
| Accrued payroll | 62,544 | — |
| Accrued vacation | 44,178 | 28,324 |
| Accrued board of director fees | 79,167 | 72,500 |
| Accrued professional fees | — | 111,249 |
| Accrued operating expenses | 51,750 | 28,000 |
| Total accrued expenses and other current liabilities | $ 354,289 | $ 240,073 |

At September 30, 2017, the accrued bonus represents the estimated amount recognized on a pro rata basis during 2017 of the guaranteed bonus payment to the Company's Chief Executive Officer ("CEO") under the CEO Employment Agreement. At December 31, 2016, the CEO waived his right to receive a guaranteed bonus payment for 2016. See Note 9, *Commitments and Contingencies*, for further details regarding the CEO compensation. In addition to the CEO guaranteed bonus payment, in December 2016, the Company also reversed the accrued discretionary bonus payments previously recognized throughout 2016, as the Company's board of directors determined no discretionary bonuses would be paid for 2016.

At September 30, 2017, the accrued payroll represents earned but unpaid salary for the period July 1, 2017 through September 30, 2017, payable to the Company's CEO. In this regard, under the terms of the Note and Security Purchase Agreement, including the Senior Secured Note, between the Company and Scopia Holdings LLC, effective with the first bi-monthly payroll in July 2017, the CEO agreed to the payment of a reduced salary of $4,200 per month, with the payment of the earned but not paid amount to be deferred until the earlier to occur of: (i) the date FDA 510(k) clearance is obtained for the for the Company's implantable intraosseous vascular access device (the "PortIO Product"); or, (ii) the date the borrowings due Scopia Holdings LLC are repaid-in-full - see Note 12, *Note and Securities Purchase Agreement, Senior Secured Note, and Series S Warrants*, for a discussion of the Note and Security Purchase Agreement with Scopia Holdings LLC.

The accrued board of director fees at September 30, 2017 and December 31, 2016 represent amounts payable to all non-executive members of the board of directors, including $10,000 payable to a board member deemed to be a related party, at each of September 30, 2017 and December 31, 2016.

The accrued professional fees at December 31, 2016 related to deferred offering costs incurred with respect to the Series A Preferred Stock Units private placement. See Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a discussion of the Series A Preferred Stock Units private placement transaction.

Included in accrued operating expenses at December 31, 2016, is $10,000 due to HCFP/Strategy Advisors LLC, a related party. See Note 9, *Related Party Transactions*, for further details regarding HCFP/Strategy Advisors LLC.

**Note 8 — Income Taxes**

In the nine months ended September 30, 2017 and 2016, the Company recognized a deferred tax benefit which was fully offset by a corresponding valuation allowance. As required by ASC Topic 740, a "more-likely-than-not" criterion is applied when evaluating the realization of a deferred tax asset. The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses, the Company has concluded it is more-likely-than-not the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of September 30, 2017 and December 31, 2016.

**Note 9 — Related Party Transactions**

Effective October 2015, the Company entered into a three-year management services agreement through October 2018 with HCP/Advisors LLC, an affiliate of a director of the Company. Pursuant to the HCP/Advisors LLC agreement, such entity has agreed to provide the Company with certain management services, including without limitation identifying potential corporate opportunities, general business development, corporate development, corporate governance, marketing strategy, strategic development and planning, coordination with service providers, and other advisory services as may be mutually agreed upon. The Company has agreed to pay HCP/Advisors LLC an initial monthly fee of $35,000 commencing as of November 1, 2015, and thereafter, a monthly fee of $25,000 through October 31, 2018. Under this agreement, the Company incurred fees of $75,000 and $225,000 in each of the three and nine months ended September 30, 2017 and 2016, respectively, which are included in "General and administrative expenses" in the accompanying unaudited condensed consolidated statements of operations.

Effective September 2016, the Company and HCFP/Strategy Advisors LLC, an affiliate of certain directors and officers of the Company, entered into a management consulting agreement referred to as the "HCFP Strategic Advisory Agreement", which, as discussed below, expired on May 14, 2017. Under the HCFP Strategic Advisory Agreement, HCFP/Strategy Advisors LLC had been engaged for an initial term of five months from September 14, 2016 to February 14, 2017, to provide various management consulting advisory services, including: to provide strategic business planning, to identify and assist with potential sources of financing arrangements, to promote the Company to various potential investors, and to provide strategic advisory services as reasonably requested by the Company. The HCFP Strategic Advisory Agreement provided for an initial total fee of $110,000, with $30,000 paid upon execution of the agreement and four payments of $20,000 per month from October 2016 to January 2017. Subsequently, on February 17, 2017, the Company and HCFP/Strategy Advisors LLC executed an extension of the HCFP Strategic Advisory Agreement, effective as of February 15, 2017, extending the services from February 15 to May 14, 2017, and obligating the Company to make three payments of $20,000 per month in February, March, and April 2017. The Company did not further renew the HCFP Strategic Advisory Agreement after the May 14, 2017 expiration date. Previously, at December 31, 2016, the Company recognized a $10,000 estimated accrued expense liability for HCFP/Strategy Advisors LLC asserted out-of-pocket expenses under the HCFP Strategic Advisory Agreement in effect as of December 31, 2016. Subsequently, at June 30, 2017, the Company reversed such $10,000 estimated accrued expense liability, as supporting documentation had not been provided by HCFP/Strategy Advisors LLC. At June 30, 2017, the Company had made all contractually obligated payments to, and disclaimed any further payment obligations, under the HCFP Strategic Advisory Agreement.

Separately, at June 30, 2017, the Company recognized a $10,000 accrued expense liability for a HCFP/Strategy Advisors LLC vendor invoice dated June 30, 2017, with payment of such invoice in July 2017, for professional services fees related to separate discrete discussions between the Company's management and HCFP /Strategy Advisors LLC, conducted between the period of May 15, 2017 to May 31, 2017 regarding corporate matters separate and apart from the previously expired HCFP Strategic Advisory Agreement.

The Company incurred expense of $0 and $80,000 in the three and nine months ended September 30, 2017, respectively, and $30,000 in the three and nine months ended September 30, 2016, under the HCFP Strategic Advisory Agreement and the HCFP/Strategy Advisors LLC discrete invoice dated June 30, 2017, as noted above, which is included in "General and administrative expenses" in the accompanying unaudited condensed consolidated statements of operations.

Effective September 2016, the Company also entered into a consulting agreement with Swartwood Hesse, Inc., an affiliate of HCFP/Strategy Advisors (which, as noted above, is an affiliate of certain directors and officers of the Company) (the "Swartwood Hesse Financial Advisory Agreement"). Under the Swartwood Hesse Financial Advisory Agreement, Swartwood Hesse Inc. was engaged for an initial term of five months to provide advisory services regarding potential financing arrangements, to assist the Company with its investors relations, and to provide other financial advisory services as reasonably requested by the Company. The Swartwood Hesse Financial Advisory Agreement provided for total fee payments to Swartwood Hesse of $15,000, which was previously paid and recognized as expense upon execution of the agreement.

In January 2017, the Company entered into an agreement with Xzerta Trading LLC d/b/a HCFP/Capital Markets ("HCFP/Capital Markets"), an affiliate of certain directors and officers of the Company, wherein HCFP/Capital Markets was engaged to be the Company's exclusive placement agent in an offering of securities ("the HCFP/Capital Markets Placement Agent Agreement"), including the Series A Preferred Stock Units private placement transaction. Under the HCFP /Capital Markets Placement Agent Agreement, HCFP/Capital Markets is paid a fee of 7.0% of the gross proceeds realized in the securities offering, plus reimbursement of certain out-of-pocket costs. The term of the HCFP/Capital Markets Placement Agent Agreement is from the January 2017 execution date to the completion or termination of any other potential transactions in conjunction with the Series A Preferred Stock Units private placement. The Company incurred $0 and $177,576 of fees paid to HCFP/Capital Markets in connection with the issuances of Series A Preferred Stock Units in the three and nine months ended September 30, 2017, respectively, which are included in "Loss on the issuance of preferred stock units" in the accompanying unaudited condensed consolidated statements of operations.

Effective June 30, 2017, the Company and Michael J. Glennon, Vice Chairman and a member of the Company's Board of Directors, mutually agreed to terminate the consulting agreement between the Company and Mr. Glennon (the "Glennon Consulting Agreement"). Previously, effective October 1, 2016, the Company and Mr. Glennon entered into the Glennon Consulting Agreement, under which Mr. Glennon provided the Company with services and advice relating to the successful development and commercialization of medical device products. Effective as of December 31, 2016, Mr. Glennon and the Company entered into an agreement whereby Mr. Glennon waived his right to compensation under the Glennon Consulting Agreement for the year ended December 31, 2016, and, effective as of March 31, 2017, Mr. Glennon and the Company entered into a second agreement whereby Mr. Glennon further waived his right to compensation under the Glennon Consulting Agreement for the period January 1, 2017 through June 30, 2017.

Effective November 2016, the Company entered into a consulting agreement with Patrick Glennon, a related-party who is the brother of Michael J. Glennon, Vice Chairman and a member of the Company's board of directors (the "Patrick Glennon Consulting Agreement"). Under the terms of the Patrick Glennon Consulting Agreement, Mr. Patrick Glennon will provide consulting support and advice with respect to the development and commercialization of resorbable ear tubes. The sole compensation for such services is the issuance on November 28, 2016 of stock options to purchase 20,000 shares of the Company's common stock, with an exercise price of $9.50 per share, and vesting ratably on a quarterly basis commencing December 31, 2016 through September 30, 2019.

**Note 10 — Commitments and Contingencies**

Employment Agreements & Compensation

*Chief Executive Officer Employment Agreement*

Effective November 1, 2014, the Company entered into an employment agreement with its CEO (the "CEO Employment Agreement") for a five-year term, with a current base salary of $295,000 per year. On April 28, 2016, upon consummation of the IPO, the CEO was granted a stock option to purchase 278,726 shares of the Company's common stock with an exercise price equal to $5.00 per share. Effective on January 1, 2016, the CEO Employment Agreement provides for a guaranteed bonus equal to 50% of base salary, beginning on January 1 of each year. Additionally, the CEO will also be eligible to earn discretionary annual performance bonuses upon meeting certain objectives as determined by the Board of Directors. Effective as of December 31, 2016, the CEO agreed to waive his right to the guaranteed bonus for the year ended December 31, 2016. Under the terms of the Note and Security Purchase Agreement, including the Senior Secured Note, between the Company and Scopia Holdings LLC, effective with the first bi-monthly payroll in July 2017, the CEO agreed to the payment of a reduced salary of $4,200 per month, with the payment of the earned but not paid amount to be deferred until the earlier to occur of: (i) the date FDA 510(k) clearance is obtained for the for the Company's implantable intraosseous vascular access device (the "PortIO Product"); or, (ii) the date the borrowings due Scopia Holdings LLC are repaid-in-full - see Note 12 — *Note and Securities Purchase Agreement, Senior Secured Note , and Series S Warrants*, for a discussion of the Note and Security Purchase Agreement with Scopia Holdings LLC. The CEO Employment Agreement contains provisions for the protection of the Company's intellectual property and contains non-compete restrictions in the event of his termination other than without "cause" or by the board of directors with "good reason."

*Executive Vice President and Chief Financial Officer Employment Agreement*

On March 20, 2017, the Company entered into a two year employment agreement with Dennis M. McGrath, to serve as the Company's Executive Vice President and Chief Financial Officer, with a base annual salary of $285,000, and a discretionary annual performance bonus with a target of 50% of his then current annual base salary, based upon his performance and the Company's performance over the preceding year, as determined by the compensation committee of the Board of Directors. Additionally, the Company will reimburse Mr. McGrath up to $2,250 per month for housing and travel expenses for up to 12 months. Mr. McGrath was granted a stock option to purchase up to 250,000 shares of common stock, at an exercise price of $5.95 per share. The stock option vests in 12 equal quarterly installments on the last day of each fiscal quarter, commencing on June 30, 2017 through March 31, 2020. The employment agreement with Mr. McGrath contains provisions for the protection of the Company's intellectual property and contains non-compete restrictions in the event of his termination other than without "cause" or by the board of directors with "good reason".

*Chief Medical Officer Employment Agreement*

Effective July 1, 2016, the Company entered into a five-year employment agreement with Dr. Brian J. deGuzman, M.D. to serve as the Company's CMO (the "CMO Employment Agreement") with a base annual salary of $285,000, plus an initial bonus of $50,000 for services provided before the agreement's effective date. Dr. deGuzman is eligible to earn discretionary annual performance bonuses upon meeting certain objectives as determined by the compensation committee of the Board of Directors. On April 28, 2016, upon the consummation of the IPO, Dr. deGuzman was granted a stock option to purchase 278,726 shares of the Company's common stock with an exercise price equal to $5.00 per share. The employment agreement with Dr. deGuzman contains provisions for the protection of the Company's intellectual property and contains non-compete restrictions in the event of his termination other than without "cause" or by the CEO with "good reason".

**Note 10 — Commitments and Contingencies** (continued)

Leases

The Company leases office space for its corporate office, which initially provided for two consecutive six month terms beginning on February 1, 2016, rent payments of $9,500 per month and the option to cancel the lease agreement at the end of the initial six-month term at the election of the Company. Subsequently, the lease agreement was amended to add additional office space at an additional rate of $4,400 per month, and extended the lease term through May 31, 2017. The lease agreement includes a 5% increase in monthly rent effective on each twelve month anniversary date. Effective March 1, 2017, the rented office space was reduced, resulting in a $650 per month reduction of the monthly lease payment, and effective August 1, 2017, the rented office space was further reduced, resulting in a $3,938 per month reduction of the monthly lease payment. Upon the May 31, 2017 termination date, the lease agreement converted to a month-to-month lease, which may be cancelled by the Company with three months written notice. Total rent expense incurred under the corporate office space lease arrangement was $33,863 and $117,351 for the three and nine months ended September 30, 2017, respectively, and $41,406 and $92,656 for the three and nine months ended September 30, 2016, respectively. At September 30, 2017, the Company's future minimum lease payments totaled $123,690 for the period October 1, 2017 to September 30, 2018, with respect to the lease arrangement on a month-to-month basis.

Additionally, beginning on May 1, 2015, the Company had previously rented access to a research and development facility, for monthly rent of $1,000, on a month-to-month basis under which either the landlord or the Company could cancel the rental arrangement at any time. Effective February 28, 2017, the Company ceased use of the research and development facility and canceled the rental arrangement. Total rental expense under this research and development facility rental arrangement amounted to $0 and $2,000 for the three and nine months ended September 30, 2017, respectively, and $3,000 and $9,000 for the three and nine months ended September 30, 2016, respectively.

Legal Proceedings

In the normal course of business, from time-to-time, the Company may be subject to claims in legal proceedings. However, the Company does not believe it is currently a party to any pending legal actions. Notwithstanding, legal proceedings are subject-to inherent uncertainties, and an unfavorable outcome could include monetary damages, and in such event, could result in a material adverse impact on the Company's business, financial position, results of operations, or cash flows.

**Note 11 — Stock Based Compensation**

The 2014 Long-Term Incentive Equity Plan (the "2014 Stock Plan"), adopted by the Company's board of directors and stockholders in November 2014, is designed to enable the Company to offer employees, officers, directors, and consultants, as defined, an opportunity to acquire a proprietary interest in the Company. The types of awards that may be granted under the 2014 Stock Plan include stock options, stock appreciation rights, restricted stock, and other stock-based awards subject to limitations under applicable law. All awards are subject to approval by the compensation committee of the Company's board of directors.

The 2014 Stock Plan reserves a total of 2,951,081 shares of common stock, which includes a share reservation increase of 1,000,000 shares of common stock approved by the stockholders on October 4, 2017, for issuance in accordance with the 2014 Stock Plan's terms. Stock options granted outside the 2014 Stock Plan amounted to 250,000 in the nine months ended September 30, 2017 and 250,854 on April 28, 2016. Common stock of the Company available for grant under the 2014 Stock Plan was 530,011 shares as of September 30, 2017 and, upon the stockholders approval of the share reservation increase, 1,530,011 shares as of October 4, 2017.

The following table summarizes information about stock options for the periods presented below:

| | Number Stock Options | Weighted Average Exercise Price | Aggregate Intrinsic Value |
|---|---|---|---|
| Outstanding at December 31, 2016 | 1,633,313 | $ 5.14 | |
| Granted | 365,000 | $ 5.36 | |
| Exercised | — | $ — | |
| Forfeited | (76,389) | $ 5.00 | |
| Outstanding at September 30, 2017 | 1,921,924 | $ 5.19 | $ 805,127 |
| Vested and exercisable at September 30, 2017 | 807,972 | $ 5.13 | $ 331,839 |
| Unvested at September 30, 2017 | 1,113,952 | $ 5.23 | $ 473,288 |

In March 2017, the Company granted 250,000 stock options to the Company's new Chief Financial Officer, with such stock options granted outside the 2014 Stock Plan, having a ten year contractual term from date of grant, an exercise price of $5.95 per share, and vesting ratably on a quarterly basis commencing June 30, 2017 and ending March 31, 2020. In March 2017, the Company granted 25,000 stock options to a new member of the Company's medical advisory board, with a ten year contractual term from date of grant, an exercise price of $5.01 per share, and vesting ratably on a quarterly basis commencing June 30, 2017 and ending March 31, 2020. In July 2017, the Company granted 50,000 stock options to the Company's Corporate Controller, with a ten year contractual term from date of grant, an exercise price of $4.50 per share, and vesting ratably on a quarterly basis commencing September 30, 2017 and ending June 30, 2020. In August 2017, the Company granted 40,000 stock options to a new member of the Board of Directors, with a ten year contractual term from date of grant, an exercise price of $2.98 per share, and vesting ratably on a quarterly basis commencing September 30, 2017 and ending June 30, 2020. Subsequently, in October 2017, the Company granted 15,000 stock options to a consultant, with a ten year contractual term from date of grant, and exercise price of $5.11 per share, and vesting ratably on an annual basis over a three year period commencing October 2018.

In March 2017, in connection with his separation from the Company, 76,389 stock options were forfeited which were previously granted to the Company's former Chief Financial Officer, as discussed below.

On April 28, 2016, upon the closing of the Company's IPO, a total of 1,588,313 stock options were granted, including 961,178 to management, 487,770 to members of the board of directors, and 139,365 to members of the Company's medical advisory board. The stock options granted on April 28, 2016, have a ten year contractual term from date of grant, an exercise price of $5.00 per share, and vest 3/36 on July 28, 2016, and 1/36 on each successive month thereafter from Aug 28, 2016 to April 28, 2019. In November 2016, the Company granted 25,000 stock options to a new member of the Company's medical advisory board, with a ten year contractual term from date of grant, an exercise price of $10.50 per share, and vesting ratably on a quarterly basis commencing December 31, 2016 and ending September 30, 2019. In November 2016, the Company granted 20,000 stock options to a (related party) consultant, with a ten year contractual term from date of grant, an exercise price of $9.50 per share, and vesting ratably on a quarterly basis commencing December 31, 2016 and ending September 30, 2019.

The aggregate intrinsic value is computed as the difference between the exercise price of the underlying stock options and the quoted price of the common stock on September 30, 2017, to the extent the exercise price is less than the quoted price.

The weighted average remaining contractual term of stock options outstanding was 8.6 years at September 30, 2017. The weighted average remaining contractual term of stock options vested and exercisable was 8.3 years at September 30, 2017.

**Note 11 — Stock Based Compensation** (continued)

The stock-based compensation expense related to stock options granted to employees and directors is based on the grant-date fair value, and for stock options granted to non-employees is based on the vesting date fair value, with the cost recognized on a straight-line basis over the award's requisite service period. Stock-based compensation expense for the three and nine months ended September 30, 2017 and 2016 was recognized as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| General and administrative expenses | $ 241,401 | $ 292,085 | $ 707,588 | $ 447,232 |
| Research and development expenses | 30,900 | 30,900 | 91,693 | 52,396 |
| | $ 272,301 | $ 322,985 | $ 799,281 | $ 499,628 |

Included in general and administrative expenses, is $51,389 of stock-based compensation expense resulting from the March 31, 2017 modifications to the stock option grant previously awarded to the Company's former CFO. Previously, on April 28, 2016, upon the closing of the Company's IPO, the former CFO was granted a stock option to purchase 125,000 shares of common stock with an exercise price equal to $5.00 per share. On March 31, 2017, the April 28, 2016 stock option agreement was amended wherein the stock option grant continued to vest monthly in April, May, and June 2017, and the 48,611 vested stock options are exercisable until April 28, 2019, with the remaining 76,389 stock options forfeited effective March 31, 2017.

At September 30, 2017, there was $2,098,291 of total unrecognized compensation cost related to stock options, which is expected to be recognized over the next 1.7 years, which represents the weighted average remaining requisite service periods for such awards.

The weighted average fair value of stock options granted to employees and members of the board of directors was $1.57 per share during the nine months ended September 30, 2017 and $1.32 per share during the nine months ended September 30, 2016, calculated using the following Black-Scholes valuation model assumptions:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2017 | 2016 |
| Risk free interest rate | 1.53% | 1.40% |
| Expected term of stock options (in years) | 5.8 | 5.8 |
| Expected stock price volatility | 50% | 50% |
| Expected dividend yield | 0% | 0% |

The weighted average fair value of stock options granted to non-employees was $4.32 per share at September 30, 2017 and $11.45 at September 30, 2016, with such fair values calculated using the following weighted-average Black-Scholes valuation model assumptions:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2017 | 2016 |
| Risk free interest rate | 2.19% | 1.54% |
| Expected term of stock options (in years) | 9.0 | 9.6 |
| Expected stock price volatility | 60% | 60% |
| Expected dividend yield | 0% | 0% |

The Company uses the Black-Scholes valuation model to estimate the fair value of stock options. The Black-Scholes valuation model requires the Company to make certain estimates and assumptions, including assumptions related to the expected price volatility of the Company's stock, the period during which the options will be outstanding, the rate of return on risk- free investments, and the expected dividend yield for the Company's stock. The weighted-average valuation assumptions for all stock-based awards were determined as follows:

Weighted-average risk-free interest rate: The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period commensurate with the assumed expected option term.

Expected term of options: The expected term of stock options represents the period of time options are expected to be outstanding, which for employees is the expected term derived using the simplified method and for non-employees is the contractual term.

Expected stock price volatility: The expected volatility is based on historical stock price volatilities of similar entities within the Company's industry over the period commensurate with the expected term of the stock option.

Expected dividend yield: The estimate for annual dividends is $0.00 as the Company has not historically paid, and does not expect for the foreseeable future to pay, a dividend.

**Note 12 — Note and Securities Purchase Agreement, Senior Secured Note , and Series S Warrants**

The Company and Scopia Holdings LLC ("Scopia or the Lender") entered into a Note and Security Purchase Agreement, under which, upon Scopia delivering to the Company $4.8 million in net cash proceeds by wire transfer on July 3, 2017, the Company issued to Scopia and its designees, a Senior Secured Note with an initial principal amount of $5.0 million ("Scopia Note"), and 2,660,000 Series S Warrants to purchase shares of common stock of the Company.

The Scopia Note and the Series S Warrants are freestanding financial instruments, as the Series S Warrants were immediately legally detachable from the Scopia Note and were immediately exercisable. The Series-S Warrants are classified as equity in the condensed consolidated balance sheet. See Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for further information with respect to the Series S Warrants.

The $4,842,577 of cash proceeds, net of the Lender's debt issuance costs, have been allocated to the Scopia Note and the Series S Warrants based on their respective relative fair value, resulting in an allocation of $1,408,125 to the Scopia Note and $3,434,452 to the Series S-Warrants, with the resulting difference of $3,591,875 between the Scopia Note initial principal amount and the allocated amount accounted for as debt discount, amortized as interest expense over the term of the Scopia Note. See below for issue-date fair value information.

The Scopia Note bears interest at a fixed annual rate of 15.0%, with interest payable semi-annually in arrears on June 30 and December 30 of each calendar year, commencing on December 30, 2017. The Company may elect, at its sole discretion, to defer payment of up to 50% of the semi-annual interest due, with the remaining unpaid portion added to and increasing the outstanding interest-bearing principal balance of the Scopia Note by such amount of the deferred interest payment. The aggregate remaining unpaid principal balance of the Scopia Note is due on June 30, 2019.

Interest expense recognized was $362,142, including $187,500 with respect to the semi-annual interest payment and $174,642 with respect to the amortization of debt discount, in the three and nine months ended September 30, 2017. The Scopia Note remaining unamortized debt discount is $3,417,233 at September 30, 2017.

At the discretion of the Company, the aggregate principal balance of the Scopia Note and any earned and unpaid interest may be repaid at any time without penalty or premium. Additionally, under the Scopia Note, if at the Company's discretion, it sells its implantable intraosseous vascular access device (the "PortIO Product"), then the Scopia Note holders' may require the Company to repay the then outstanding aggregate principal amount of the Scopia Note, in whole or in part, together with any accrued interest thereon, from the net cash proceeds of such PortIO Product sale, provided such principal and interest repayment is limited to the amount of the net cash proceeds from such PortIO Product sale.

The Note and Security Purchase Agreement with Scopia contains various customary negative covenants of the Company including restrictions on the Company incurring any additional indebtedness or liens or declaring or paying any dividends, subject to certain exceptions provided for in the Note and Security Purchase Agreement with Scopia, while any amount under the Scopia Note remains outstanding. The Note and Security Purchase Agreement with Scopia also contains certain affirmative covenants of the Company, including, among others:

- If the PortIO Product obtains initial FDA 510(k) clearance, then, commencing four months after such FDA 510(k) clearance, the Company will use its reasonable best efforts to attempt to sell the PortIO Product on commercially reasonable terms for an amount not less than $10.0 million. If the net cash proceeds are $10.0 million or greater from such PortIO product sale, and there are no continuing obligations imposed on the Company, which would constitute an undue burden on the Company, resulting from such PortIO Product sale transaction, then the Scopia Note holders may request the Company to repay the then aggregate remaining unpaid principal balance of the Scopia Note. Notwithstanding, such Note and Securities Purchase Agreement provision has been rendered moot, as the FDA has indicated the PortIO Product will be reviewed for approval under a regulatory pathway other than a 510(k) clearance;

- Effective with the first bi-monthly payroll in July 2017, the Company's CEO agreed to the payment of a reduced salary of $4,200 per month, with the payment of the earned but unpaid salary amount deferred until the earlier to occur of (a) the date that FDA 510(k) clearance for the PortIO Product is obtained or (b) the date the aggregate remaining unpaid principal balance of the Scopia Note is repaid in full; and,

- The Company agreed to use its commercially reasonable best efforts to file a registration statement with the U.S. Securities and Exchange Commission (SEC) registering for resale of all of the shares of common stock underlying the Series S Warrants with such registration statement having an effectiveness date on or before November 27, 2017.

**Note 12 — Note and Securities Purchase Agreement, Senior Secured Note and Series S Warrants**(continued)

Additionally, the Note and Security Purchase Agreement with Scopia provides, for so long as the Lender holds at least 50% of the aggregate remaining unpaid principal balance of the Scopia Note, the Lender shall have the ability to nominate one individual to the Company's board of directors, provided the board of directors shall have the right to reject any such Lender nominee if it determines in good faith such Lender nominee is not reasonably acceptable. In this regard, on August 3, 2017, the Lender nominee was appointed to the Company's board of directors.

Payment of all amounts due and payable under the Scopia Note are guaranteed by the Company, and the obligations under the Scopia Note are secured by all of the assets of the Company pursuant to the terms of a Note and Guaranty Security Agreement. The Lender may transfer or assign all or any part of the Scopia Note to any person with the prior written consent of the Company, provided no consent shall be required from the Company for any transfer to an affiliate of the Lender, or upon the occurrence and during the continuance of an Event of Default, as defined in the Scopia Note.

The Scopia Note issue-date fair value of $4.1 million was estimated using a discounted cash flow analysis with a required rate of return of 25.5%, with such rate of return determined through a synthetic credit rating analysis involving a comparison of market yields on publicly-traded secured corporate debentures with characteristics similar to those of the Scopia Note. The Series S Warrants issue-date fair value of $10.0 million was estimated using a Black-Scholes valuation model using the following assumptions:

| Series S Warrants | Issue Date |
|---|---|
| Exercise price per share | $ 0.01 |
| Value of common stock | $ 4.50 |
| Expected term (years) | 15.0 |
| Volatility | 48% |
| Risk free rate | 2.4% |
| Dividend yield | 0% |

**Note 13 — Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants**

**Preferred Stock**

The Company is authorized to issue 20,000,000 shares of its preferred stock, par value of $0.001 per share, with such designation, rights, and preferences as may be determined from time-to-time by the Company's board of directors. At September 30, 2017, a total of 422,838 shares of Series A Convertible Preferred Stock (classified in temporary equity), and 125,000 shares of Series A-1 Convertible Preferred Stock (classified in permanent equity), were each issued and outstanding. At December 31, 2016 there were no shares of preferred stock issued or outstanding.

*Series A Preferred Stock Units Private Placement*

The Company's Board of Directors authorized the issuance of up to a total of 1.25 million Series A Preferred Stock Units, including authorizing 500,000 units on January 21, 2017 and 750,000 units on May 10, 2017. On January 26, 2017, the Company entered into a Securities Purchase Agreement pursuant to which the Company may issue up to an aggregate of $3,000,000 (subject to increase) of Series A Preferred Stock Units at a price of $6.00 per unit, in a private placement transaction ("Series A Preferred Stock Units private placement"). At the Series A Preferred Stock Units private placement initial closing on January 26, 2017, and at subsequent closings on January 31, 2017 and March 8, 2017, a total of 422,838 Series A Preferred Stock Units were issued for aggregate gross proceeds of approximately $2.5 million and net proceeds of approximately $2.2 million, after payment of placement agent fees and closing costs.

Subsequently, on October 20, 2017, the Company initiated an exchange offer (Series A Exchange Offer), to the holders of the Series A Convertible Preferred Stock and Series A Warrants, to exchange one share Series A Convertible Preferred Stock for 1.5 shares of Series A-1 Convertible Preferred Stock; and, to exchange one Series A Warrant for one Series A-1 Warrant. The Series A Exchange Offer expires November 17, 2017. See below for a discussion of the Series A-1 Convertible Preferred Stock and Series A-1 Warrants.

The Series A Preferred Stock Unit was comprised of one share of Series A Convertible Preferred Stock and one Series A Warrant. The Series A Convertible Preferred Stock and Series A Warrants were immediately separable upon their issuance, and became convertible and exercisable, respectively, on May 21, 2017 upon stockholder approval of the Series A Preferred Stock Units private placement, with such approval obtained in accordance with Nasdaq Stock Market Rule 5635(d).

At the election of their respective holder, a share of Series A Convertible Preferred Stock is convertible into a number of shares of common stock of the Company at a prescribed exchange ratio; and, a Series A Warrant is exercisable for one share of common stock of the Company, or may be exchanged for four Series X Warrants, with each such Series X Warrant exercisable for one share of common stock of the Company - each as more fully described below.

The Series A Warrant and the Series A Convertible Preferred Stock conversion option, which is accounted for as an embedded derivative and bifurcated from its host financial instrument, were each determined to be a derivative liability under ASC 815, as discussed below.

The issuance of the Series A Preferred Stock Units resulted in the recognition of an aggregate loss of $3,124,285, resulting from the aggregate initial fair value of the Series A Warrant liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability being in excess of the Series A Preferred Stock Units issuance gross proceeds, with such excess amounting to $2,735,657, recognized as a current period expense, along with offering costs of $388,628, which were also recognized as a current period expense, as follows:

| | | Series A Preferred Stock Units Issue Dates (Aggregate) |
|---|---|---|
| Series A Preferred Stock Units issuance gross proceeds | $ | 2,537,012 |
| Less: Series A Warrants initial fair value[1] | | (4,050,706) |
| Less: Series A Convertible Preferred Stock conversion option embedded derivative liability initial fair value[1] | | (1,221,963) |
| Excess of initial fair value over gross proceeds | | (2,735,657) |
| Offering costs of the issuance of the Series A Preferred Stock Units | | (388,628) |
| Loss on issuance of Series A Preferred Stock Units | $ | (3,124,285) |

(1) See Note 3, *Financial Instruments Fair Value Measurements*, for information with respect to the fair value of the Series A Convertible Preferred Stock embedded derivative liability and the Series A Warrants liability.

**Preferred Stock** (continued)

*Series A Preferred Stock Units Private Placement (continued)*

The Company has filed an effective registration statement on Form S-1 (File No. 333-216963) registering for resale the maximum number of the Company's shares of common stock issuable upon conversion of the Series A Convertible Preferred Shares and the exercise of the Series A Warrants, or if exchanged, the Series X Warrants. Such registration statement also registers the resale of the Series X Warrants, and the initial issuance of the shares of common stock of the Company underlying the Series X Warrants to the extent the Series X Warrants are publicly sold prior to the exercise of such Series X Warrants. The Company timely filed the initial registration statement with the SEC on March 27, 2017, and such registration statement became effective on June 23, 2017, with such dates consistent with the requirements of the registration rights agreement entered into in connection with the Series A Preferred Stock Units private placement. If such registration statement effectiveness is not maintained, then, the Company is required to make payments to the investors of 2% of their Series A Preferred Stock Units subscription amount on the date of such event, and every thirty days thereafter until the effectiveness is cured.

*Series A Convertible Preferred Stock*

The Series A Convertible Preferred Stock has a par value of $0.001 per share, no voting rights, a stated value of $6.00 per share, and became convertible on May 21, 2017 upon stockholder approval of the Series A Preferred Stock Units private placement, with such approval obtained in accordance with Nasdaq Stock Market Rule 5635(d). At the holders' election, a share of Series A Convertible Preferred Stock is convertible into a number of shares of common stock of the Company at a conversion ratio equal to its stated value divided by a conversion price of $4.99 per share, subject to further adjustment. The Series A Convertible Preferred Stock conversion price is subject to further reduction by a prescribed formula should any subsequent issuances of convertible securities by the Company be at a price lower than such conversion price immediately prior to such new issuance. In this regard, at issuance, the Series A Convertible Preferred Stock conversion price was initially $6.00 per share, and was subsequently adjusted to $5.00 per share upon the issuance of the Series S Warrants on July 3, 2017, and then to $4.99 per share upon the issuance of the Series A-1 Preferred Stock Units on August 4, 2017, with such conversion price subject to further adjustment as noted above.

As of September 30, 2017, there were 422,838 shares of Series A Convertible Preferred Stock issued and outstanding. Subsequently, in November 2017, at the election of the holder, 8,334 shares of Series A Convertible Preferred Stock were converted into 10,021 shares of common stock of the Company.

The Series A Convertible Preferred Stock conversion option is accounted for as an embedded derivative and bifurcated from Series A Convertible Preferred Stock host financial instrument, under ASC 815, as, along with other provisions, the conversion price is subject to potential adjustment resulting from future financing transactions, under certain conditions. The Series A Convertible Preferred Stock conversion option embedded derivative is classified as a current liability on the unaudited condensed consolidated balance sheet, initially measured at fair value at the time of issuance and subsequently remeasured at fair value at each reporting period, with changes in its fair value recognized as other income or expense in the unaudited condensed consolidated statement of operations. See Note 3, *Financial Instruments Fair Value Measurements*, for further detail regarding the fair value of the Series A Convertible Preferred Stock conversion option embedded derivative liability.

The Series A Convertible Preferred Stock has a carrying value of $0 resulting from the issuance date initial fair values of the Series A Warrant derivative liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability being in excess of the Preferred Stock Units issuance gross proceeds, with such excess recognized as a current period loss in the unaudited condensed consolidated statement of operations, as discussed above.

The Series A Convertible Preferred Stock provides for dividends at an 8% annual rate, compounded quarterly, accumulate, and are payable in arrears upon being declared by the Company's Board of Directors. The Series A Convertible Preferred Stock dividends from April 1, 2017 through April 1, 2021 are payable-in-kind ("PIK") in additional shares of Series A Convertible Preferred Stock. The dividends may be settled after April 1, 2021, at the option of the Company, through any combination of the issuance of additional Series A Convertible Preferred Stock, shares of common stock, and /or cash payment. As of September 30, 2017, Series A Convertible Preferred Stock dividends totaling $130,010 or a payment-in-kind of 21,711 shares of Series A Convertible Preferred Stock, were earned, accumulated, and in arrears, as the Company's Board of Directors had not declared such dividends payable, and, as such, the Company has not recognized a Series A Convertible Preferred Stock dividend payable liability as of September 30, 2017, and will not recognize such dividend payable liability until they are declared by the Company's Board of Directors. Notwithstanding, the Company has presented such dividend value as a component of the loss attributable to common stockholders in the calculation of basic and diluted net loss per share.

**Note 13 — Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants** (continued)

**Preferred Stock** (continued)

*Series A Convertible Preferred Stock (Continued)*

In the event of a Deemed Liquidation Event, as defined in the Certificate of Designation of Preferences, Rights, and Limitations of the Series A Convertible Preferred Stock, the Series A Convertible Preferred Stock can become redeemable at the election of at least two-thirds of holders of the then number of issued and outstanding Series A Convertible Preferred Stock, if the Company fails to effect a dissolution of the Company under the Delaware General Corporation Law within ninety (90) days after such Deemed Liquidation Event. In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company or a Deemed Liquidation Event, as defined, the holders of the Series A Convertible Preferred Stock then outstanding are entitled to be paid out the assets of the Company available for distribution to its stockholders before any payment shall be made to the holders of the common stock, an amount per share equal to the greater of (i) the stated value, plus any dividends accrued but unpaid, or (ii) such amount per share as would have been payable had all the shares of Series A Convertible Preferred Stock been converted into shares of common stock prior to such liquidation, dissolution, winding up, or Deemed Liquidation Event, as defined. As the Deemed Liquidation Event, as defined, is a contingent event, the Series A Convertible Preferred Stock is classified outside of stockholders' equity in temporary ("mezzanine") equity. Further, as the Series A Convertible Preferred Stock is not currently redeemable and redemption is not probable, as a Deemed Liquidation Event, as defined, has not occurred and is not probable, the Series A Convertible Preferred Stock will not be measured at fair value until such time as a redemption trigger occurs which causes redemption to be probable.

*Series A-1 Preferred Stock Units Private Placement*

On August 3, 2017, the Company's Board of Directors authorized the issuance of up to 150,000 Series A-1 Preferred Stock Units, and on August 4, 2017, the Company entered into a Securities Purchase Agreement pursuant to which the Company may issue up to an aggregate of $600,000 (subject to increase) of Series A-1 Preferred Stock Units at a price of $4.00 per unit, in a private placement transaction (Series A-1 Preferred Stock Units private placement). On the August 4, 2017 closing of the Series A-1 Preferred Stock Units private placement, a total of 125,000 Series A-1 Preferred Stock Units were issued for cash proceeds of $500,000 - the Company did not incur placement agent fees in connection with the August 4, 2017 closing.

Subsequently, on October 18, 2017, upon approval by the unanimous vote of the Series A-1 Preferred Stock Units holders, the Series A-1 Preferred Stock Units private placement transaction documents were amended: to remove the requirement for the Company to file with the SEC an initial registration statement within sixty days of the August 4, 2017 closing date; to provide for the exchange of one Series A-1 Warrant for five Series W Warrants; to exchange one Series A-1 Warrant for four Series X-1 Warrants, with such Series X-1 Warrants replacing the Series X Warrants. The Series X-1 Warrants are substantively equivalent to the Series X Warrants with respect to material contractual terms and conditions, including the same $6.00 per share exercise price, and dates of exercisability and expiry. The Series X-1 Warrant also confirms such warrants are not subject to redemption, and under no circumstances will the Company be required to net cash settle the Series X-1 Warrants, for any reason, nor to pay any liquidated damages or other payments, resulting from a failure to satisfy any obligations under the Series X-1 Warrant, notwithstanding such provisions were applicable to the Series X Warrant through the operation of the Series A-1 Preferred Stock Units Securities Purchase Agreement. Additionally, as the Company's Series A Warrants can be exchanged for four Series X Warrants, the Series X-1 Warrants were instituted for issuance upon the exchange of the corresponding Series A-1 Warrant. See below for a discussion of the Series W Warrants or Series X-1 Warrants issued upon the exchange of the Series A-1 Warrants, and the Series X Warrants issued upon the exchange of the Series A Warrants.

The Series A-1 Preferred Stock Unit was comprised of one share of Series A-1 Convertible Preferred Stock and one Series A-1 Warrant - as more fully described below. At their issuance, the Series A-1 Convertible Preferred Stock and the Series A-1 Warrant were immediately separable, and each was immediately convertible and exercisable, respectively.

**Preferred Stock** (continued)

*Series A-1 Preferred Stock Units Private Placement (continued)*

The Series A-1 Preferred Stock Units private placement cash proceeds of $500,000 were allocated as $189,550 to the Series A-1 Convertible Preferred Stock and $310,450 to the Series A-1 Warrants, based on their respective relative fair value. The issue-date fair value of the Series A-1 Convertible Preferred Stock was determined using a combination of the Series A-1 Convertible Preferred Stock's present value of its cash flows and incorporating a required rate of return determined through a synthetic credit rating analysis and the Black-Scholes valuation model; and the fair value of the Series A-1 Warrants was determined using a Black-Scholes valuation model and assuming the exchange of one Series A-1 Warrant for four Series X Warrants, using the following assumptions:

| Series A-1 Convertible Preferred Stock | | Issue Date |
|---|---|---|
| Aggregate fair value | $ | 189,550 |
| Required rate of return | | 27.0% |
| Series A-1 Convertible Preferred Stock shares | | 125,000 |
| Conversion ratio | | 1.0x |
| Stated Value per share - conversion ratio numerator | $ | 4.00 |
| Conversion price per share - conversion ratio denominator | $ | 4.00 |
| Value of common stock | $ | 2.98 |
| Expected term (years) | | 6.74 |
| Volatility | | 52% |
| Risk free rate | | 2.0% |
| Dividend yield | | 0% |

| Series A-1 Convertible Preferred Stock | | Issue Date |
|---|---|---|
| Aggregate fair value | $ | 310,450 |
| Series A-1 Warrants | | 125,000 |
| Exercise price per share | $ | 6.00 |
| Value of common stock | $ | 2.98 |
| Expected term (years) | | 6.74 |
| Volatility | | 52% |
| Risk free rate | | 2.0% |
| Dividend yield | | 0% |

The registration rights agreement, as amended, entered into in connection with the Series A-1 Preferred Stock Units private placement, requires the Company to file with the SEC a registration statement registering for resale the maximum number of common shares issuable upon conversion of the Series A-1 Convertible Preferred Shares and the exercise of the Series A-1 Warrants or, the Series W or Series X-1 Warrants issued in exchange for the Series A-1 Warrants (as discussed below). The Company expects such registration statement to also register the resale of the Series W Warrants and the Series X-1 Warrants, and will register the initial issuance of shares of common stock of the Company underlying the Series W Warrants and the Series X-1 Warrants to the extent each such warrants are publicly sold prior to their respective exercise. Such registration rights agreement requires the Company to use commercially reasonable best efforts to have such registration statement declared effective no later than one hundred and fifty (150) days from the August 4, 2017 closing date. If such registration statement is not effective by the contractually agreed upon date or such registration statement effectiveness is not maintained, then, the Company is required to make payments to the investors of 2% of their Series A-1 Preferred Stock Units subscription amount on the date of such events, and every thirty days thereafter until the effectiveness is cured.

**Preferred Stock** (continued)

*Series A-1 Convertible Preferred Stock*

The Series A-1 Convertible Preferred Stock has a par value of $0.001 per share, no voting rights, a stated value of $4.00 per share, was immediately convertible upon its issuance, and, at the election of the holders, is convertible into a number of shares of common stock at a conversion ratio equal to its stated value divided by a conversion price of $4.00 per share, with such conversion price not subject to further adjustment, except for the effect of stock dividends, stock splits or similar events affecting the Company's common stock. The Series A-1 Convertible Preferred Stock shall not be redeemed for cash and under no circumstances shall the Company be required to net cash settle the Series A-1 Convertible Preferred Stock. As of September 30, 2017, there were 125,000 shares of Series A-1 Convertible Preferred Stock issue and outstanding.

The Series A-1 Preferred Stock Units private placement cash proceeds allocated to the Series A-1 Convertible Preferred Stock, as discussed above, of $189,550 resulted in an effective conversion price below the issue-date fair value of the underlying shares of common stock, resulting in a $182,500 beneficial conversion feature, which was accounted for as an implied discount on the Series A-1 Convertible Preferred Stock. The Series A-1 Convertible Preferred Stock does not have a stated redemption date and was immediately convertible upon issuance, resulting in the full accretion of the beneficial conversion feature as a deemed dividend paid to the Series A-1 Convertible Preferred Stock on the August 4, 2017 issue date.

The Series A-1 Convertible Preferred Stock provides for dividends at an 8% annual rate, compounded quarterly, accumulate, and are payable in arrears upon being declared by the Company's Board of Directors. The Series A-1 Convertible Preferred Stock dividends from October 1, 2017 through October 1, 2021 are payable-in-kind ("PIK") in additional shares of Series A-1 Convertible Preferred Stock. The dividends may be settled after October 1, 2021, at the option of the Company, through any combination of the issuance of additional Series A-1 Convertible Preferred Stock, shares of common stock, and /or cash payment. As of September 30, 2017, Series A-1 Convertible Preferred Stock dividends totaling $6,196 or a payment-in-kind of 1,551 shares of Series A-1 Convertible Preferred Stock, were earned, accumulated, and in arrears, as the Company's Board of Directors had not declared such dividends payable, and, as such, the Company has not recognized a Series A-1 Convertible Preferred Stock dividend payable liability as of September 30, 2017, and will not recognize such dividend payable liability until they are declared by the Company's Board of Directors. Notwithstanding, the Company has presented such dividend value as a component of the loss attributable to common stockholders in the calculation of basic and diluted net loss per share.

**Common Stock**

The Company is authorized to issue 50,000,000 shares of common stock with a par value of $0.001 per share. There were 13,343,061 and 13,330,811 shares of common stock outstanding as of September 30, 2017 and December 31, 2016, respectively.

*Pre-Initial Public Offering*

In connection with the organization of the Company in June 2014, a total of 8,083,049 shares of the Company's common stock and 8,710,181 warrants (of which 627,133 warrants were subsequently returned to the Company in October 2014) ("Founders' Warrants") were sold to the Company's founders (the "Founders") for an aggregate purchase price of $3,212.

In June 2014 and July 2014, in a private placement (Private Placement 1), a total of 418,089 units, consisting of one share of common stock and one warrant, were sold to the initial investor investors ("Initial Investors") for an aggregate purchase price of $75,000 less offering costs of $7,500. In November 2014, the Company completed another private placement (Private Placement 2) of 2,355,233 units, consisting of one share of common stock and one warrant, raising $845,000 in gross offering proceeds less offering costs of $46,500. Taken together, the Private Placement 1 warrants and Private Placement 2 warrants are referred to collectively as the "Private Placement Warrants". Subsequently, in September 2015, 1,393,629 shares of common stock were issued as a result of the exercise of 1,393,629 Private Placement Warrants for cash proceeds of $1.25 million.

In August 2015, the Company issued 97,554 warrants to an outside advisor in exchange for services.

The 9,560,295 remaining unexercised warrants discussed above, were subsequently converted into identical Series W Warrants issued in the Company's April 28, 2016 initial public offering ("IPO"), and are therefore aggregated with the Series W Warrants issued in the IPO, and together are collectively referred to as "Series W Warrants" - see below for a further discussion of the Series W Warrants.

*Initial Public Offering*

Under a registration statement on Form S-1 (File No. 333-203569) declared effective January 29, 2016, the Company's IPO was consummated on April 28, 2016, resulting in $4.2 million of net cash proceeds, after deducting cash selling agent discounts and commissions and offering expenses, from the issuance of 1,060,000 units at an offering price of $5.00 per unit, with each such unit comprised of one share of common stock of the Company and one warrant to purchase a share of common stock of the Company, with such warrant referred to as a "Series W Warrant" - see below for a discussion of the Series W Warrant. The Company estimated the fair value of its common stock issued in the IPO using the guideline transaction method of the market approach and arrived at an estimated fair value of common stock of $3.50.

The units issued in the IPO were initially listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "PAVMU", until July 27, 2016, when the PAVMU units ceased to be quoted and traded on Nasdaq, and the underlying shares of common stock and the Series W Warrants began separate trading on Nasdaq, under their respective individual symbols of "PAVM" for the shares of common stock and "PAVMW" for the Series W Warrants - see below for a discussion of the Series W Warrant.

*Post-Initial Public Offering*

In March 2017 and September 2017, 400 shares and 11,850 shares of common stock were issued, resulting from a corresponding number of Series W Warrants exercised for $2,000 and $59,250 of cash proceeds, respectively.

In November 2016 and December 2016, 20,732 and 79 shares of common stock were issued, resulting from the cashless exercise of 40,000 and 200 Series W Warrants, respectively.

Subsequently, in October 2017, 532,000 shares of common stock were issued, resulting from a corresponding number of Series S Warrants exercised for $5,320 of cash proceeds; and, in November 2017 122,080 shares of common stock were issued, resulting from the cashless exercise of 122,360 Series S Warrants.

Subsequently, in November 2017, 10,021 shares of common stock were issued, resulting from, at the election of the holder, the conversion of 8,334 shares of Series A Convertible Preferred Stock.

**Note 13 — Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants**(continued)

**Warrants**

The accounting for warrants issued to purchase shares of common stock of the Company is based on the specific terms of the respective warrant agreement. Generally, warrants are classified as equity, but may be classified as a derivative liability if the warrant agreement provides for cash settlement or has certain exercise price adjustment provisions.

The following table summarizes outstanding warrants to purchase common stock at the dates indicated:

| | Warrants Exercisable at | | | | |
|---|---|---|---|---|---|
| | September 30, 2017 | Weighted Average Exercise Price /Share | December 31, 2016 | Weighted Average Exercise Price | Expiration Date |
| Equity classified warrants | | | | | |
| Series W Warrants | 10,567,845 | $ 5.00 | 10,580,095 | $ 5.00 | January 2022 |
| Unit Purchase Options | | | | | |
| Series W Warrants | 53,000 | $ 5.00 | 53,000 | $ 5.00 | January 2022 |
| Series S Warrants | 2,660,000 | $ 0.01 | — | $ — | June 2032 |
| Series A-1 Warrants | 125,000 | $ 6.67 | — | $ — | April 2024 |
| Liability classified warrants | | | | | |
| Series A Warrants | 422,838 | $ 6.65 | — | $ — | April 2024 |
| Total | 13,828,683 | $ 4.11 | 10,580,095 | $ 5.00 | |

*Equity-Classified Warrants*

*Series W Warrants*

The Series W Warrants have an exercise price of $5.00 per share, with such exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock, and became exercisable on October 28, 2016 and expire on January 29, 2022 or earlier upon redemption by the Company, as discussed below.

As discussed above, a total of 1,060,000 Series W Warrants were issued in the Company's IPO, and the remaining previously issued (pre-IPO) 9,560,295 unexercised warrants outstanding on the April 28, 2016 date of the Company's IPO were automatically converted into identical Series W Warrants issued in the Company's IPO, and are therefore aggregated with the 1,060,000 Series W Warrants issued in the IPO, and together are collectively referred to as Series W Warrants.

As discussed below, a Series A-1 Warrant, at the election of the holder, may be exchanged for five Series W Warrants or four Series X-1 Warrants. As of September 30, 2017, no Series A-1 Warrants had been exchanged for Series W Warrants nor Series X-1 Warrants.

In March 2017 and September 2017, 400 and 11,850 Series W Warrants were exercised for cash proceeds of $2,000 and $59,250, respectively, resulting in the issuances of a corresponding number of shares of common stock. In November and December 2016, 40,000 and 200 Series W Warrants were exercised on a cashless basis, resulting in the issuance of 20,732 and 79 shares of common stock, respectively.

Commencing April 28, 2017, the Company may redeem the outstanding Series W Warrants (other than those outstanding prior to the IPO held by the Company's management, founders, and members thereof, but including the warrants held by the initial investors), at the Company's option, in whole or in part, at a price of $0.01 per warrant: at any time while the warrants are exercisable; upon a minimum of 30 days' prior written notice of redemption; if, and only if, the volume weighted average price of the Company's common stock equals or exceeds $10.00 (subject-to adjustment) for any 20 consecutive trading days ending three business days before the Company issues its notice of redemption, and provided the average daily trading volume in the stock is at least 20,000 shares per day; and, if, and only if, there is a current registration statement in effect with respect to the shares of common stock underlying such warrants. The right to exercise will be forfeited unless the IPO Warrants are exercised prior to the date specified in the notice of redemption. On and after the redemption date, a record holder of an IPO Warrant will have no further rights except to receive the redemption price for such holder's IPO Warrant upon surrender of such warrant.

**Note 13 — Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants**(continued)

**Warrants** (continued)

*Series W Warrants (continued)*

The Company filed a Registration Statement on Form S-1 (File No. 333-214288), declared effective February 3, 2017, (the "February 2017 Form S-1") to register the issuance of 1,020,000 shares of the Company's common stock upon the exercise of 1,020,000 remaining unexercised Series W Warrants, along with the registration of (i) the issuance of 1,062,031 shares of the Company's common stock upon the exercise of 1,062,031 of the unexercised IPO Warrants (issued prior to the IPO), but only in the event such warrants are publicly transferred pursuant to Rule 144 prior to exercise, or (ii) the resale of such shares of common stock, but only in the event such warrants are exercised prior to being publicly transferred pursuant to Rule 144. Separately, in January 2017, the Company's CEO purchased 25,000 IPO Warrants (issued prior to the IPO) from a shareholder who had previously purchased shares of common stock and warrants in the Company's private financings prior to its IPO, with shares of common stock underlying such IPO Warrants purchased by the CEO not included in the February 2017 Form S-1.

*Series S Warrants*

The Company and Scopia Holdings LLC ("Scopia or the Lender") entered into a Note and Security Purchase Agreement under which, on July 3, 2017, the Company issued to Scopia and its designees, a Senior Secured Note ("Scopia Note"), and 2,660,000 Series S Warrants to purchase shares of common stock of the Company. The Series S Warrants were immediately exercisable upon issuance, have an exercise price of $0.01 per share, with such exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock, may be exercised for cash or on a cashless basis, and expire June 30, 2032, with any Series S Warrants outstanding on their expiration date will be automatically exercised on a cashless basis.

The Scopia Note and the Series S Warrants are freestanding financial instruments, as the Series S Warrants were immediately legally detachable from the Scopia Note and were immediately exercisable. The Series-S Warrants are classified as equity in the condensed consolidated balance sheet. The Scopia Note net cash proceeds were allocated to the Scopia Note and the Series S Warrants based on their respective relative fair value, resulting in an allocation of $1,408,125 to the Scopia Note and $3,434,452 to the Series S-Warrants. See Note 12, *Note and Securities Purchase Agreement, Senior Secured Note, and Series S Warrants*, for further information regarding the Note and Security Purchase Agreement with Scopia, including the non-recurring issue-date fair values of the Scopia Note and Series S Warrants.

As of September 30, 2017, there were 2,660,000 Series S Warrants issued and outstanding. Subsequently, in October 2017, 532,000 Series S Warrants were exercised for cash proceeds of $5,320, resulting in the issuance of a corresponding number of shares of common stock; and, in November 2017, 122,360 Series S Warrants were exercised on a cashless basis, resulting in the issuance of 122,080 shares of common stock.

*Series A-1 Warrants*

The Series A-1 Warrants were exercisable upon their issuance and expire after the close of business on April 30, 2024, and each may be exercised for one share of common stock at an exercise price of $6.67 per share, with such exercise price not subject to further adjustment, except for the effect of stock dividends, stock splits or similar events affecting the common stock. Additionally, as a result of the October 18, 2017 amendment discussed above, through April 30, 2024, each Series A-1 Warrant, at the option of the holder, may be exchanged into five Series W Warrants or four Series X-1 Warrants. The Series W Warrants or Series X-1 Warrants issued upon the exchange of a Series A-1 Warrant are discussed below. As of September 30, 2017, no Series A-1 Warrants had been exchanged for Series W Warrants nor Series X-1 Warrants.

The Series A-1 Warrants are not subject to redemption, and under no circumstances will the Company be required to net cash settle the Series A-1 Warrants. The Series A-1 Warrants have been accounted for as equity-classified warrants, with an issue-date allocated fair value of $310,450, as discussed above.

A Series A-1 Warrant may be exercised for one share of common stock at an exercise price of $6.67 per share, with such exercise price not subject to further adjustment, except for the effect of stock dividends, stock splits or similar events affecting the common stock. Additionally, as a result of the October 18, 2017 amendment discussed above, through April 30, 2024, each Series A-1 Warrant, at the option of the holder, may be exchanged into five Series W Warrants or four Series X-1 Warrants. The Series W Warrants or Series X-1 Warrants issued upon the exchange of a Series A-1 Warrant are discussed below. As of September 30, 2017, no Series A-1 Warrants had been exchanged for Series W Warrants nor Series X-1 Warrants.

If at any time after the six month anniversary of the Series A-1 Preferred Stock Units August 4, 2017 closing date, there is not an effective registration statement registering, or no current prospectus available for, the resale of the shares underlying the Series A-1 Warrants, then the Series A-1 Warrants may be exercised, in whole or in part, at such time by means of a "cashless exercise". During the time the Series A-1 Warrants are outstanding, the holders will be entitled to participate in dividends or other distributions on a pro rata basis based upon the equivalent number of common shares that would have been outstanding had the warrants been fully exercised.

**Warrants** (continued)

*Series W Warrants and Series X-1 Warrants Issued Upon Exchange of Series A-1 Warrants*

As discussed above, a Series A-1 Warrant, at the election of the holder, may be exchange for five Series W Warrants or four Series X-1 Warrants. As of September 30, 2017, no Series A-1 Warrants had been exchanged for Series W Warrants nor Series X-1 Warrants. Notwithstanding, the 125,000 Series A-1 Warrants issued and outstanding at September 30, 2017, if exchanged, would result in the issuance of 625,000 such Series W Warrants or the issuance of 500,000 such Series X-1 Warrants.

As more fully discussed above, the Series W Warrants issued upon the exchange of a Series A-1 Warrant have an exercise price of $5.00 per share, with such exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock, and became exercisable on October 28, 2016 and expire on January 29, 2022 or earlier upon redemption by the Company, as discussed above.

The Series X-1 Warrants issued upon exchange of a Series A-1 Warrant, are exercisable for one share of common stock of the Company at $6.00 per share, with such Series X-1 Warrant exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock. The Series X-1 Warrants are exercisable commencing on the first trading day following October 31, 2018 - as it is the later of (i) the May 21, 2017 stockholder approval in accordance with Nasdaq Stock Market Rule 5635(d) of the Series A Preferred Stock Units private placement; or (ii) October 31, 2018. The Series X-1 Warrants may be exercised until their April 30, 2024 expiration date, or earlier upon redemption by the Company, as discussed below. At their expiration date, provided the closing price of the Company's common stock is greater than $6.00 /per share, any such outstanding Series X-1 Warrants will be automatically exercised via a cashless exercise.

The Company may redeem all, but not less than all, of the issued and outstanding Series X-1 Warrants, at any time after April 30, 2019, at a price of $0.01 per Series X-1 Warrant, if the volume weighted average price per share of the common stock of the Company has been for twenty trading days out of the thirty trading day period ending three business days prior to the notice of redemption, at least $18.00, with such price adjusted for stock splits, stock dividends, or similar events occurring after the August 4, 2017 closing date of the Series A-1 Preferred Stock Units private placement.

*Series X Warrants Issued Upon Exchange of Series A Warrants*

A Series A Warrant, as discussed below, at the election of the holder, may be exchanged for four Series X Warrants. As of September 30, 2017, no Series A Warrants had been exchanged for Series X Warrants. Notwithstanding, the 422,838 Series A Warrants issued and outstanding at September 30, 2017, if exchanged, would result in the issuance of 1,691,352 such Series X Warrants.

The Series X Warrants issued upon exchange of a Series A Warrant are exercisable for one share of common stock at $6.00 per share, with such Series X Warrant exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock. The Series X Warrants are exercisable commencing on the first trading day following October 31, 2018 - as it is the later of (i) the May 21, 2017 stockholder approval in accordance with Nasdaq Stock Market Rule 5635(d) of the Series A Preferred Stock Units private placement; or (ii) October 31, 2018. The Series X Warrants may be exercised until their April 30, 2024 expiration date, or earlier upon redemption by the Company, as discussed below. At their expiration date, provided the closing price of the Company's common stock is greater than $6.00 per share, any such outstanding Series X Warrants will be automatically exercised via a cashless exercise.

The Company may redeem all, but not less than all, of the issued and outstanding Series X Warrants, at any time after April 30, 2019, at a price of $0.01 per Series X Warrant, if the volume weighted average price per share of the common stock of the Company has been for twenty trading days out of the thirty trading day period ending three business days prior to the notice of redemption, at least $18.00, with such price adjusted for stock splits, stock dividends, or similar events occurring after the January 26, 2017 initial closing date of the Series A Preferred Stock Units private placement.

**Warrants** (continued)

*Liability-Classified Warrants*

Common stock warrants are accounted for as derivative liabilities if the warrants allow for cash settlement or provide for modification of the warrant exercise price in the event subsequent sales of common stock are at a lower price per share than the then-current warrant exercise price, as is the case for the Series A Warrants. The Company classifies derivative warrant liabilities on the condensed consolidated balance sheet as a current liability, initially measured at its issue-date fair value, with such fair value subsequently remeasured at each reporting period, with the resulting fair value adjustment recognized as other income or expense on the condensed consolidated statement of operations. If upon the occurrence of an event resulting in the warrant liability or the embedded derivative liability to be subsequently classified as equity, the fair value will be adjusted on such date-of-occurrence, with such date-of-occurrence fair value adjustment recognized as other income or expense, and then it will be classified as equity at such date-of-occurrence adjusted fair value.

*Series A Warrants*

The Series A Warrants became exercisable on May 21, 2017 upon stockholder approval of the Series A Preferred Stock Units private placement, with such approval obtained in accordance with Nasdaq Stock Market Rule 5635(d), and expire after the close of business on April 30, 2024. The Series A Warrants are not subject to redemption.

The Series A Warrants may be exercised for one share of common stock at an exercise price of $6.65 per share, with such exercise price initially $8.00 per share at issuance, and subsequently adjusted to $6.67 per share upon the issuance of the Series S Warrants on July 3, 2017, and then to $6.65 per share upon the issuance of the Series A-1 Preferred Stock Units on August 4, 2017. Additionally, through April 30, 2024, each Series A Warrant, at the election of the holder, may be exchanged for four Series X Warrants, with such Series X Warrants discussed above.

The Series A Warrant exercise price is subject to further reduction by a prescribed formula on a weighted average basis in the event the Company issues common stock, options, or convertible securities at a price lower than the exercise price of Series A Warrants immediately prior to such securities issuance.

During the time the Series A Warrants are outstanding, the holders will be entitled to participate in dividends or other distributions on a pro rata basis based upon the equivalent number of common shares that would have been outstanding had the warrants been fully exercised.

As noted above, the Series A Warrants are accounted for as a derivative liability under FASB ASC 815, as, along with other provisions, the conversion price is subject to potential adjustment resulting from future financing transactions, under certain conditions. The Series A Warrant is classified as a current liability on the unaudited condensed consolidated balance sheet, initially measured at its issue-date fair value, with such fair value subsequently remeasured at each reporting period, with the resulting fair value adjustment recognized as other income or expense on the condensed consolidated statement of operations. See Note 3, *Financial Instruments Fair Value Measurements*, for further detail regarding the fair value of the Series A Warrants liability.

**Unit Purchase Options**

On April 28, 2016, the Company issued 53,000 unit purchase options to the selling agents in the Company's IPO ("UPO"), with such unit purchase options enabling the holder to purchase at an exercise price of $5.50 per unit, with each such unit being identical to the unit issued in the Company's IPO, and thus comprised of one share of common stock and one Series W Warrant to purchase a share of common stock of the Company at an exercise price of $5.00 per share, as discussed above. The estimated the fair value of such unit purchase options was $105,100, which was accounted for as offering costs of the Company's IPO, and was determined using a Black-Scholes option pricing model with the following assumptions: fair value of the underlying unit of $5.00, expected volatility of 50%, risk free rate of 1.28%, remaining contractual term of 4.6 years, and a dividend yield of 0%.

**Note 14 —Loss Per Share**

The following table sets forth basic and diluted net loss per share - as reported and net loss per share attributable to common stockholders for the periods indicated:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| **Numerator** | | | | |
| Net loss - as reported | $ (5,129,318) | $ (1,928,722) | $ (10,389,113) | $ (3,940,337) |
| Series A Convertible Preferred Stock undeclared and accumulated dividends[1] | (52,299) | — | (130,010) | — |
| Series A-1 Convertible Preferred Stock undeclared and accumulated dividends[2] | (6,196) | — | (6,196) | — |
| Deemed dividend Series A-1 Convertible Preferred Stock[3] | (182,500) | | (182,500) | — |
| Net loss attributable to common stockholders[4] | $ (5,370,313) | $ (1,928,722) | $ (10,707,819) | $ (3,940,337) |
| **Denominator** | | | | |
| Weighted-average common shares outstanding | 13,332,629 | 13,310,000 | 13,331,585 | 12,855,714 |
| **Loss per share** | | | | |
| Basic and diluted[5] | | | | |
| - Net loss - as reported | $ (0.38) | $ (0.14) | $ (0.78) | $ (0.31) |
| - Net loss attributable to common stockholders | $ (0.40) | $ (0.14) | $ (0.80) | $ (0.31) |

(1) The Series A Convertible Preferred Stock provides for dividends at an 8% annual rate, compounded quarterly, accumulate, and are payable in arrears upon being declared by the Company's Board of Directors. The Series A Convertible Preferred Stock dividends from April 1, 2017 through April 1, 2021 are payable-in-kind ("PIK") in additional shares of Series A Convertible Preferred Stock. The dividends may be settled, after April 1, 2021, at the election of the Company, through any combination of the issuance of additional Series A Convertible Preferred Stock, common shares, and /or cash payment. As of September 30, 2017, Series A Convertible Preferred Stock dividends totaling $130,010 or a payment-in-kind of 21,711 shares of Series A Convertible Preferred Stock, were earned, accumulated, and in arrears, as the Company's Board of Directors had not declared such dividends payable, and, as such, the Company has not recognized a Series A Convertible Preferred Stock dividend payable liability as of September 30, 2017, and will not recognize such dividend payable liability until they are declared by the Company's Board of Directors.

(2) The Series A-1 Convertible Preferred Stock provides for dividends at an 8% annual rate, compounded quarterly, accumulate, and are payable in arrears upon being declared by our Board of Directors. The Series A-1 Convertible Preferred Stock dividends from October 1, 2017 through October 1, 2021 are payable-in-kind ("PIK") in additional shares of Series A-1 Convertible Preferred Stock. The dividends may be settled, after October 1, 2021, at the election of the Company, through any combination of the issuance of additional Series A-1 Convertible Preferred Stock, common shares, and /or cash payment. As of September 30, 2017, Series A-1 Convertible Preferred Stock dividends totaling $6,196 or a payment-in-kind of 1,551 shares of Series A-1 Convertible Preferred Stock, were earned, accumulated, and in arrears, as the Company's Board of Directors had not declared such dividends payable, and, as such, the Company has not recognized a Series A-1 Convertible Preferred Stock dividend payable liability as of September 30, 2017, and will not recognize such dividend payable liability until they are declared by the Company's Board of Directors. .

(3) The Series A-1 Preferred Stock Units cash proceeds allocated to the Series A-1 Convertible Preferred Stock resulted in an effective conversion price below the issue date fair value of the underlying shares of common stock, resulting in a $182,500 beneficial conversion feature, which was accounted for as an implied discount on the Series A-1 Convertible Preferred Stock. The Series A-1 Convertible Preferred Stock does not have a stated redemption date and was immediately convertible upon issuance, resulting in the full accretion of the beneficial conversion feature as a deemed dividend paid to the Series A-1 Convertible Preferred Stock on the Series A-1 Preferred Stock Units August 4, 2017 issue date.

(4) The holders of the Series A Warrants and the Series A-1 Warrants have the same rights to receive dividends as the holders of common stock. As such, the Series A Warrants and Series A-1 Warrants are considered participating securities under the two-class method of calculating net loss per share. The Company has incurred net losses to-date, and as the holders of the Series A Warrants and the Series A-1 Warrants are not contractually obligated to share in the losses, there is no impact on the Company's net loss per share calculation for the periods indicated.

(4) Basic net loss per share is calculated by dividing the loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive common shares. As the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share as the inclusion of incremental shares resulting from common stock equivalents would be anti-dilutive.

**Note 14 —Loss Per Share (continued)**

The following common stock equivalents have been excluded from the computation of diluted weighted average shares outstanding as their inclusion would be anti-dilutive:

| | September 30, | |
|---|---|---|
| | 2017 | 2016 |
| Stock Options | 1,921,924 | 1,588,313 |
| Unit purchase options as to shares of common stock | 53,000 | 53,000 |
| Unit purchase options as to shares underlying Series W Warrants | 53,000 | 53,000 |
| Series W Warrants[8] | 10,567,845 | 10,620,295 |
| Series A Convertible Preferred Stock[5] | 422,838 | — |
| Series A Warrants[6] | 422,838 | — |
| Series X Warrants[6] | — | — |
| Series A-1 Convertible Preferred Stock[7] | 125,000 | — |
| Series A-1 Warrants[8] | 125,000 | — |
| Series X-1 Warrants[8] | — | — |
| Series S Warrants | 2,660,000 | — |
| Total | 16,351,445 | 12,314,608 |

(5) The 422,838 shares of Series A Convertible Preferred Stock, at the election of the holder, if-converted into a number of shares of common stock at a conversion ratio equal to its $6.00 per share stated value divided by a conversion price of $4.99 per share, with such conversion price subject to further reduction, would result in 508,422 incremental shares of newly-issued common stock at September 30, 2017.

(6) The 422,838 Series A Warrants, at the election of the holder, may be exchanged for four Series X Warrants under the terms of the Series A Warrant agreement. The Series X Warrants issued in exchange for the Series A Warrants are exercisable commencing on the first trading day following October 31, 2018, and are therefore not exercisable for shares of common stock at September 30, 2017, and would not result in common stock equivalent incremental shares for purposes of diluted weighted average shares outstanding at such date. At September 30, 2017, no Series A Warrants had been exchanged for Series X Warrants.

(7) The 125,000 shares of Series A-1 Convertible Preferred Stock, at the election of the holder, if-converted into a number of shares of common stock at a conversion ratio equal to its $4.00 per share stated value divided by a conversion price of $4.00 per share, with such conversion price not subject to further adjustment, would result in 125,000 incremental shares of newly-issued common stock at September 30, 2017.

(8) The 125,000 Series A-1 Warrants, at the election of the holder, may be exchanged for five Series W Warrants or four Series X-1 Warrants under the terms of the Series A-1 Warrant agreement. The Series W Warrants issued in exchange for the Series A-1 Warrants would be exercisable upon their issuance. The Series X-1 Warrants issued upon the exchange of the Series A-1 Warrants are exercisable commencing on the first trading day following October 31, 2018, and are therefore not exercisable for shares of common stock at September 30, 2017, and would not result in common stock equivalent incremental shares for purposes of diluted weighted average shares outstanding at such date. At September 30, 2017, no Series A-1 Warrants had been exchanged for Series W Warrants or Series X1 Warrants.

**Note 15 — Subsequent Events**

*Other Matters*

Except as otherwise noted herein, the Company has evaluated subsequent events through the date of filing of this Quarterly Report on Form 10-Q, and determined there to be no events requiring adjustments to the unaudited condensed consolidated financial statements or disclosures therein.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The following discussion and analysis of our consolidated financial condition and results of operations should be read together with our Annual Report on Form 10-K for the year ended December 31, 2016 as filed with the SEC. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements involving risks and uncertainties and should be read together with the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2016 as filed with the SEC for a discussion of important factors which could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

**Forward-looking statements**

This Quarterly Report on Form 10-Q, including the following discussion and analyses of our consolidated financial condition and results of operations, contains forward-looking statements. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, as well as "Risk Factors" section of the Annual Report on Form 10-K for the year ended December 31, 2016, including statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- our limited operating history;
- our financial performance, including our ability to generate revenue;
- ability of our products to achieve market acceptance;
- success in retaining or recruiting, or changes required in, our officers, key employees or directors;
- reliance upon additional financings to fund ongoing operating losses;
- potential ability to obtain additional financing;
- ability to sustain status as a going concern;
- ability to protect our intellectual property;
- ability to complete strategic acquisitions;
- ability to manage growth and integrate acquired operations;
- potential liquidity and trading of our securities;
- regulatory or operational risks;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- our expectations regarding the time during which we will be an emerging growth company ("EGC") under the JOBS Act.

These forward-looking statements involve substantial risks and uncertainties. You should refer to the "Risk Factors" section of the Annual Report on Form 10-K for the year ended December 31, 2016 for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Quarterly Report on Form 10-Q and the Annual Report on Form 10-K for the year ended December 31, 2016, and the documents we have filed as exhibits to this Quarterly Report on Form 10-Q and the Annual Report on Form 10-K for the year ended December 31, 2016, completely and with the understanding our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by applicable law.

**Overview**

We are a highly-differentiated multi-product medical device company organized to advance a broad pipeline of innovative medical technologies from concept to commercialization. We employ a business model focused on capital efficiency and speed to market. Since our inception on June 26, 2014, our activities have focused on advancing the lead products in our pipeline towards regulatory approval and commercialization, while protecting our intellectual property, and strengthening our corporate infrastructure and management team.

Since our inception in June 2014, we have financed our operations principally through equity and debt financings, including: approximately $2.1 million of net proceeds from private offerings of common stock and warrants issued prior our 2016 initial public offering ("IPO"); approximately $4.2 million of net cash proceeds resulting from the Company's IPO on April 28, 2016; and, to-date during 2017, approximately $7.5 million of aggregate net cash proceeds resulting from: a Note and Security Purchase Agreement with Scopia Holdings LLC, including the issuance of a Senior Secured Note and Series S Warrants; the Series A-1 Preferred Stock Units private placement; and the Series A Preferred Stock Units private placement, as further discussed herein below.

The following is a brief overview of the products currently in our pipeline, including: CarpX, PortIO, NextCath, DisappEAR, NextFlo, and Caldus - among other things, we have:

- filed final nonprovisional patent applications for PortIO, CarpX, NextCath, and Caldus and acquired a patent and related patent applications (one of which was subsequently granted) for NextFlo and entered into a licensing agreement with a group of academic centers securing the worldwide rights in perpetuity to a family of patents and patent applications underlying the DisappEAR product;

- advanced, in partnership with our design and contract manufacturing partners, our CarpX product from concept to working prototypes, completed successful benchtop and cadaver testing confirming the device consistently cuts the transverse carpal ligament, as well as commercial design and development, and performed pre-submission verification and validation testing; we are in the final stages of testing and assembling our application with the FDA for marketing clearance under rule 510(k) to allow for commercialization of the CarpX product;

- advanced, in partnership with our design and contract manufacturing partners, our PortIO product from concept to working prototypes, benchtop, animal, and cadaver testing, commercial design and development, verification and validation testing, and an initial submission to the FDA for 510(k) market clearance for use in patients requiring 24-hour emergency type vascular access. After further discussion with the FDA, we have decided to pursue a broader clearance for use in patients with a need for vascular access up to seven days under section 513(f)2 of the Federal Food, Drug and Cosmetic Act, also referred to as de novo classification. We have filed with the FDA a pre-submission package and requested an in-person meeting regarding the submission and review. As we await a date, we will continue our planning and development of an initial commercialization strategy, in partnership with our medical advisors, focused on short-term applications in patients with poor venous access and future regulatory strategy focused on expanded, longer-term indications and other clinical applications;

- engaged a design and contract manufacturing firm to design and develop the DisappEAR product in collaboration with our academic partners at Tufts University and Harvard Medical School; initiated transfer of laboratory process for creating silk ear tubes into a commercial setting, and begun testing and optimization of manufacturing processes;

- engaged design and contract manufacturing firms with experience in extrusions which has completed initial design work on the first product in the NextCath product, and completed head-to-head testing of retention forces, comparing our working prototype to several competing products, which has validated our approach and advanced the commercial design and development process focusing on optimizing the self-anchoring helical portion as well as cost of materials and manufacturing processes;

- advanced the design and development of the NextFlo device, including a redesign which dramatically simplifies the product, lowers the projected cost of goods and expands its application to routine inpatient infusion sets, and completed benchtop testing of a working prototype demonstrating constant flows across the range of pressures encountered in clinical situations;

- we are evaluating which initial applications for our Caldus disposable tissue ablation technology to pursue from a clinical and commercial point-of-view, and will reinitiate development activity on this product once resources are available; in collaboration with our design, engineering and manufacturing partners we have completed proof of principle testing demonstrating we can deliver temperatures of >90C to a balloon catheter for at least 20 minutes of ablation time and histologically confirmed tissue necrosis in a wide variety of tissues and organs in a pig model; we are currently optimizing the design of the renal denervation balloon and catheter and enhancing the design of the infusion device to higher specifications including temperatures up to 140C and significantly higher flow rates;

- we remain actively engaged with our full-service regulatory consulting partner who is working closely with our contract design, engineering and manufacturing partners as our products advance towards regulatory submission, clearance, and commercialization;

**Overview** (continued)

- we are evaluating a number of product opportunities and intellectual property covering a spectrum of clinical conditions, which have been presented to us by clinician innovators and academic medical centers, for consideration of a partnership to develop and commercialize these products; we are also exploring opportunities to partner with larger medical device companies to commercialize our lead products as they move towards regulatory clearance and commercialization; we are evaluating strategic merger and acquisition opportunities which synergize with our growth strategy; and,

- we are exploring other opportunities to grow our business and enhance shareholder value through the acquisition of pre-commercial or commercial stage products and /or companies with potential strategic corporate and commercial synergies.

***Recent Developments***

*Regulatory*

On December 17, 2016, we filed a 510(k) premarket notification submission with the FDA for our first product, the PortIO™ Intraosseous Infusion System relying upon substantial equivalence to a previously approved predicate device with an indication for use for up to 24 hours. The Company has been engaged with the FDA on the issue of substantial equivalence, including an in-person meeting in July 2017, and had submitted a response based on the FDA's feedback which included narrower indications and inclusion of a needle in the kit. Despite these modifications, the FDA determined that PortIO is not substantially equivalent to the proposed predicate and encouraged the Company to instead pursue classification under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act, also referred to as de novo classification. The Company has decided to follow the FDA's encouragement and pursue a de novo classification for PortIO under a broader indication, for up to seven days. In this regard, the Company filed its de novo pre-submission package with the FDA for PortIO on October 30, 2017.

*Financing*

*Note and Security Purchase Agreement with Scopia Holdings LLC*

The Company and Scopia Holdings LLC ("Scopia" or the "Lender") entered into a Note and Security Purchase Agreement, under which, upon Scopia delivering to the Company $4.8 million in net cash proceeds by wire transfer on July 3, 2017, the Company issued to Scopia and its designees, a Senior Secured Note with an initial principal amount of $5.0 million ("Scopia Note"), and 2,660,000 Series S Warrants to purchase shares of common stock of the Company.

The Series S Warrants were immediately exercisable upon issuance, have an exercise price of $0.01 per share, with such exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock, and may be exercised for cash or on a cashless basis. The Series S Warrants expire June 30, 2032, with any warrants outstanding on such date will be automatically exercised on a cashless basis.

The Scopia Note bears interest at a fixed annual rate of 15.0%, with interest payable semi-annually in arrears on June 30 and December 30 of each calendar year, commencing on December 30, 2017. The Company may elect, at its sole discretion, to defer payment of up to 50% of the semi-annual interest, with the remaining unpaid portion added to and increasing the outstanding interest-bearing principal balance of the Scopia Note by such amount of the deferred interest payment. The aggregate remaining unpaid principal balance of the Scopia Note is due on June 30, 2019.

See *Liquidity and Capital Resources* herein below for further information regarding the Note and Security Purchase Agreement with Scopia Holdings LLC.

***Recent Developments*** *(continued)*

*Financing (continued)*

*Series A-1 Preferred Stock Units Private Placement*

On August 3, 2017, the Company's Board of Directors authorized the issuance of up to 150,000 Series A-1 Preferred Stock Units, and on August 4, 2017, the Company entered into a Securities Purchase Agreement pursuant to which the Company may issue up to an aggregate of $600,000 (subject to increase) of Series A-1 Preferred Stock Units at a price of $4.00 per unit, in a private placement transaction ("Series A-1 Preferred Stock Units private placement"). On the August 4, 2017 closing of the Series A-1 Preferred Stock Units private placement, a total of 125,000 Series A-1 Preferred Stock Units were issued for cash proceeds of $500,000 - the Company did not incur placement agent fees in connection with the August 4, 2017 closing.

Subsequently, on October 18, 2017, upon approval by the unanimous vote of the Series A-1 Preferred Stock Units holders, the Series A-1 Preferred Stock Units private placement transaction documents were amended: to provide for the election to exchange one Series A-1 Warrant for five Series W Warrants; to remove the requirement for the Company to file with the SEC an initial registration statement within sixty days of the August 4, 2017 closing date; and, to provide for the election to exchange one Series A-1 Warrant for four Series X-1 Warrants, with such Series X-1 Warrants replacing the Series X Warrants. In this regard, while the Series X-1 Warrants are substantively equivalent to the Series X Warrants with respect to material contractual terms and conditions, including the same $6.00 per share exercise price, and dates of exercisability and expiry, the Series X-1 Warrant confirms the Series X-1 Warrant are not subject to redemption, and under no circumstances will the Company be required to net cash settle the Series X-1 Warrants, for any reason, nor to pay any liquidated damages resulting from a failure to satisfy any obligations under the Series X-1 Warrant, notwithstanding such provisions were applicable to the Series X Warrant through the operation of the Series A-1 Preferred Stock Units Securities Purchase Agreement. Additionally, as the Company's Series A Warrants can be exchanged for four Series X Warrants, the Series X-1 Warrants were developed for issuance upon the exchange of the corresponding Series A-1 Warrant. See below for a discussion of the Series X Warrants and the Series X-1 Warrants.

A Series A-1 Preferred Stock Unit was comprised of one share of Series A-1 Convertible Preferred Stock and one Series A-1 Warrant - as more fully described below. At their issuance, the Series A-1 Convertible Preferred Stock and the Series A-1 Warrant were immediately separable, and each was immediately convertible and exercisable, respectively. The Series A-1 Preferred Stock Units private placement cash proceeds of $500,000 were allocated as $189,550 to the Series A-1 Convertible Preferred Stock and $310,450 to the Series A-1 Warrants, based on their respective relative fair value.

A Series A-1 Warrant may be exercised for one share of common stock at an exercise price of $6.67 per share, with such exercise price not subject to further adjustment, except for the effect of stock dividends, stock splits or similar events affecting the common stock, and expire after the close of business on April 30, 2024.

Additionally, through April 30, 2024, each Series A-1 Warrant, at the election of the holder, may be exchanged into five Series W Warrants or four Series X-1 Warrants. As of September 30, 2017, no Series A-1 Warrants had been exchanged for Series W Warrants nor Series X-1 Warrants. Notwithstanding, the 125,000 Series A-1 Warrants issued and outstanding at September 30, 2017, if exchanged would result in the issuance of 625,000 Series W Warrants or the issuance of 500,000 Series X-1 Warrants.

The Series W Warrants issued upon the exchange of a Series A-1 Warrant have an exercise price of $5.00 per share, with such exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock, and became exercisable on October 28, 2016 and expire on January 29, 2022 or earlier upon redemption by the Company, under certain conditions. Such Series W Warrants were issued in our initial public offering as described below.

The Series X-1 Warrants issued upon exchange of a Series A-1 Warrant, are exercisable for one share of common stock of the Company at $6.00 per share, with such Series X-1 Warrant exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock. The Series X-1 Warrants are exercisable commencing on the first trading day following October 31, 2018.The Series X-1 Warrants may be exercised until their April 30, 2024 expiration date, or earlier upon redemption by the Company, as discussed below. At their expiration date, provided the closing price of the Company's common stock is greater than $6.00 per share, any such outstanding Series X-1 Warrants will be automatically exercised via a cashless exercise.

See *Liquidity and Capital Resources* herein below for further information regarding the Series A-1 Preferred Stock Units private placement, Series A-1 Convertible Stock, and Series A-1 Warrants.

***Recent Developments*** *(continued)*

*Financing (continued)*

*Series A Preferred Stock Units Private Placement*

The Company's Board of Directors authorized the issuance of up to a total of 1.25 million Series A Preferred Stock Units, including authorizing 500,000 units on January 21, 2017 and 750,000 units on May 10, 2017. On January 26, 2017, the Company entered into a Securities Purchase Agreement pursuant to which the Company may issue up to an aggregate of $3,000,000 (subject to increase) of Series A Preferred Stock Units at a price of $6.00 per unit, in a private placement transaction (Series A Preferred Stock Units private placement). At the Series A Preferred Stock Units private placement initial closing on January 26, 2017, and at subsequent closings on January 31, 2017 and March 8, 2017, a total of 422,838 Series A Preferred Stock Units were issued for aggregate gross proceeds of approximately $2.5 million and net proceeds of approximately $2.2 million, after payment of placement agent fees and closing costs.

On October 20, 2017, the Company initiated an exchange offer, which expires on November 17, 2017, for holders of the Series A Convertible Preferred Stock to exchange on a 1.0:1.5 exchange ratio for shares of Series A-1 Convertible Preferred Stock; and, for the holders of the Series A Warrants to exchange on a 1.0:1.0 exchange ratio for Series A-1 Warrants. A total of 634,257 shares Series A-1 Convertible Preferred Stock and 422,838 Series A-1 Warrants would be issued if all such shares and warrants are exchanged, respectively. See above for a discussion of the Series A-1 Convertible Preferred Stock and Series A-1 Warrants.

A Series A Preferred Stock Unit was comprised of one share of Series A Convertible Preferred Stock and one Series A Warrant, with each, at the election of the holder, convertible into and exercisable for, respectively, a share of the Company's common stock - as more fully described below. The Series A Convertible Preferred Stock and Series A Warrants were immediately separable upon their issuance, and became convertible and exercisable, respectively, on May 21, 2017 upon stockholder approval of the Series A Preferred Stock Units private placement, with such approval obtained in accordance with Nasdaq Stock Market Rule 5635(d).

The Series A Convertible Preferred Stock has a par value of $0.001 per share, no voting rights, a stated value of $6.00 per share, and, at the holders' election, is convertible into a number of shares of common stock at a conversion ratio equal to its stated value divided by a conversion price of $4.99 per share, with such conversion price initially $6.00 per share at issuance, and subsequently adjusted to $5.00 per share upon the issuance of the Series S Warrants on July 3, 2017, and then to $4.99 per share upon the issuance of the Series A-1 Preferred Stock Units on August 4, 2017; and, with such conversion price subject to further reduction.

The Series A Warrants may be exercised for one share of common stock at an exercise price of $6.65 per share, with such exercise price initially $8.00 per share at issuance, and subsequently adjusted to $6.67 per share upon the issuance of the Series S Warrants on July 3, 2017, and then to $6.65 per share upon the issuance of the Series A-1 Preferred Stock Units on August 4, 2017, with such exercise price subject to further reduction.

Additionally, through their April 30, 2024 expiration date, each Series A Warrant, at the election of the holder, may be exchanged into four Series X Warrants. As of September 30, 2017, no Series A Warrants has been exchanged for Series X Warrants. Notwithstanding, the 422,838 Series A Warrants issued and outstanding at September 30, 2017, if exchanged would result in the issuance of 1,691,352 Series X Warrants. The Series X Warrants issued upon exchange of a Series A Warrant are exercisable for one share of common stock at $6.00 per share, with such Series X Warrant exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock. The Series X Warrants are exercisable commencing on the first trading day following October 31, 2018, and have an April 30, 2024 expiration date, or earlier upon redemption by the Company.

See *Liquidity and Capital Resources* herein below for further information regarding the Series A-1 Preferred Stock Units private placement, Series A-1 Convertible Stock, and Series A-1 Warrants.

***Recent Developments*** *(continued)*

*Initial Public Offering*

Under a registration statement on Form S-1 (File No. 333-203569) declared effective January 29, 2016, the Company's initial public offering ("IPO") was consummated on April 28, 2016, resulting in $4.2 million of net cash proceeds, after deducting cash selling agent discounts and commissions and offering expenses, from the issuance of 1,060,000 units at an offering price of $5.00 per unit, referred to as an "IPO Unit", comprised of one share of the Company's common stock and one warrant to purchase a share of common stock of the Company, with such warrant referred to as a "Series W Warrant". The IPO Units were initially listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "PAVMU", until July 27, 2016, when the PAVMU IPO Units ceased to be quoted and traded on Nasdaq, and the shares of common stock and the Series W Warrants which comprised the PAVMU IPO Units, began separate trading on Nasdaq, under their own individual symbols of "PAVM" for the shares of common stock and "PAVMW" for the Series W Warrants.

The Series W Warrants have an exercise price of $5.00 per share, with such exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock, and became exercisable on October 28, 2016 and expire on January 29, 2022 or earlier upon redemption by the Company, under certain conditions, as discussed below.

Commencing April 28, 2017, the Company may redeem the outstanding Series W Warrants (other than those outstanding prior to the IPO held by the Company's management, founders, and members thereof, but including the warrants held by the initial investors), at the Company's election, in whole or in part, at a price of $0.01 per warrant: at any time while the warrants are exercisable; upon a minimum of 30 days' prior written notice of redemption; if, and only if, the volume weighted average price of the Company's common stock equals or exceeds $10.00 (subject-to adjustment) for any 20 consecutive trading days ending three business days before the Company issues its notice of redemption, and provided the average daily trading volume in the stock is at least 20,000 shares per day; and, if, and only if, there is a current registration statement in effect with respect to the shares of common stock underlying such warrants. The right to exercise will be forfeited unless the IPO Warrants are exercised prior to the date specified in the notice of redemption. On and after the redemption date, a record holder of an IPO Warrant will have no further rights except to receive the redemption price for such holder's IPO Warrant upon surrender of such warrant.

*Tufts Patent License Agreement - Antibiotic-Eluting Resorbable Ear Tubes*

In November 2016, we executed the Tufts Patent License Agreement with the Licensors. Pursuant to the Tufts Patent License Agreement, the Licensors granted us the exclusive right and license to certain patents owned or controlled by the Licensors in connection with the development and commercialization of antibiotic-eluting resorbable ear tubes based on a proprietary aqueous silk technology. Upon execution of the Tufts Patent License Agreement, we paid the Licensors a $50,000 up-front non-refundable payment. The Tufts Patent License Agreement also provides for payments by us to the Licensors upon the achievement of certain product development and regulatory clearance milestones as well as royalty payments on net sales upon the commercialization of products developed utilizing the licensed patents.

*Going Concern*

The provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements - Going Concern* (ASC Topic 205-40) requires management to assess an entity's ability to continue as a going concern within one year of the date of the financial statements are issued. In each reporting period (including interim periods), an entity is required to assess conditions known and reasonably knowable as of the financial statement issuance date to determine whether it is probable an entity will not meet its financial obligations within one year from the financial statement issuance date. Substantial doubt about an entity's ability to continue as a going concern exists when conditions and events, considered in the aggregate, indicate it is probable the entity will be unable to meet its financial obligations as they become due within one year after the date the financial statements are issued.

We are an early stage and emerging growth company and have not generated any revenues to date. As such, we are subject to all of the risks associated with early stage and emerging growth companies. Since inception, we have incurred losses and negative cash flows from operating activities. We do not expect to generate positive cash flows from operating activities in the near future until such time, if at all, the Company completes the development process of its products, including regulatory approvals, and thereafter begins to commercialize and achieve substantial acceptance in the marketplace for the first series of products in its medical device portfolio.

We incurred a net loss attributable to common stockholders of $10,707,819 and had net cash flows used in operating activities of $5,021,134 for the nine months ended September 30, 2017. At September 30, 2017, we had an accumulated deficit of $18,273,448, working capital of $1,681,246, adjusted to exclude the Series A Warrants liability of $4,731,557 and the Series A Convertible Preferred Stock embedded conversion option derivative liability of $1,298,113. In the near future, we anticipate incurring operating losses and do not expect to experience positive cash flows from operating activities and may continue to incur operating losses for the next several years as we complete the development of our products, seek regulatory approvals, and begin to market such products. These factors raise substantial doubt about our ability to continue as a going concern within one year after the date our unaudited condensed consolidated financial statements are issued.

We estimate our current cash resources absent any additional sources of cash, is sufficient to fund our operations into the quarter ended June 30, 2018. Accordingly, we do not have sufficient cash resources to fund our anticipated operating losses beyond the twelve months after the date our unaudited condensed consolidated financial statements are issued. Therefore, we must raise additional cash to support our operating and capital needs beyond the quarter ended June 30, 2018.

Our ability to fund our operations is dependent upon management's plans, which include raising additional capital, obtaining regulatory approvals for its products currently under development, commercializing and generating revenues from products currently under development, and continuing to control expenses. However, there is no assurance we will be successful in these efforts.

A failure to raise sufficient capital, obtain regulatory approvals of our products, generate sufficient product revenues, or control expenditures, among other factors, will adversely impact our ability to meet its financial obligations as they become due and payable and to achieve its intended business objectives and therefore raises substantial doubt of our ability to continue as a going concern within one year after the date our unaudited condensed consolidated financial statements are issued.

Our unaudited condensed consolidated financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities should we be unable to continue as a going concern.

**Financial Results of Operations**

**Revenue**

To date, we have not generated any revenues from product sales. Our ability to generate product revenue and become profitable depends upon our ability to successfully develop and commercialize our products.

**General and administrative expenses**

General and administrative expenses consist primarily of salaries and related costs for personnel, including travel expenses for our employees in executive and research and development functions, facility-related costs, professional fees, accounting and legal services, consultants and expenses associated with obtaining and maintaining patents within our intellectual property portfolio.

We anticipate our general and administrative expenses will increase in the future as we increase our headcount to support our continued potential commercialization of our products. We also anticipate increased expenses related to being a public company, including audit, legal, regulatory and tax-related services associated with maintaining compliance as a public company, director and officer insurance premiums and investor relations costs. Additionally, prior to the potential regulatory approval of our first product, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial operations, especially as it relates to sales and marketing.

**Research and development expenses**

Research and development expenses costs are expensed as incurred and consist principally of internal and external costs incurred for the development of our products and include:

- consulting costs charged to us by various external contract research organizations we contract with to conduct preclinical studies and engineering studies;
- salary and benefit costs associated with our chief medical officer;
- costs associated with regulatory filings;
- patent license fees;
- cost of laboratory supplies and acquiring, developing and manufacturing preclinical prototypes;
- product design engineering studies; and
- rental expense for facilities maintained solely for research and development purposes.

We incurred approximately $4.3 million in research and development costs from June 26, 2014 (inception) through September 30, 2017. We plan to increase our research and development expenses for the foreseeable future as we continue development of our products. Our current research and development activities are focused principally on obtaining FDA clearance and initializing commercialization of the lead products in our pipeline, PortIO and CarpX, and advancing our DisappEAR product through its initial development phase, with research and development activities on our other portfolio products commensurate with available sufficient capital resources. These planned research and development activities include the following:

- completion of engineering design studies for our products;
- finalization of engineering designs and documentation supporting our products;
- additional engineering and preclinical studies through our contract research partners;
- preparation and filing of regulatory submissions with the FDA for our products; and
- establishing and documenting manufacturing processes for our products.

The successful development of our products is highly uncertain and subject to numerous risks including, but not limited to:

- the scope, rate of progress and expense of our research and development activities;
- the scope, terms and timing of obtaining regulatory clearances;
- the expense of filing, prosecuting, defending and enforcing patent claims;
- the continued access to expertise through outsourced suppliers for engineering and manufacturing; and
- the cost, timing and our ability to manufacture sufficient prototype and commercial supplies for our products.

**Financial Results of Operations** (continued)

**Income Taxes**

We provide for federal and state income taxes currently payable, as well as those deferred resulting from temporary differences between reporting income and expenses for financial statement purposes versus income tax purposes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recoverable. The effect of the change in the tax rate is recognized as income or expense in the period of the enacted change in tax rate. A valuation allowance is established, when necessary, to reduce deferred income taxes to the amount that is more-likely-than-not to be realized.

In assessing the recoverability of deferred tax assets, we consider whether it is more-likely-than-not some portion or all of the deferred tax assets will not be realized. If we determine it is more-likely-than-not certain future tax benefits may not be realized, a valuation allowance reserve is recognized for the amount of the deferred tax asset unlikely to be realized. Realization of the remaining deferred tax assets will depend on the generation of sufficient taxable income in the appropriate jurisdiction, the reversal of deferred tax liabilities, tax planning strategies, and other factors prior to the expiration date of the tax carryforwards. A change in the estimates used to make this determination could require a reduction in the valuation allowance for deferred tax assets if they become realizable. At September 30, 2017 and December 31, 2016, we concluded a full valuation allowance is necessary for our deferred tax assets.

**Financial Results of Operations** (continued)

***Comparison of the three months ended September 30, 2017 and 2016.***

| | Three Months Ended September 30, | |
|---|---|---|
| | 2017 | 2016 |
| Revenue | $ — | $ — |
| Operating expense | | |
| General and administrative expenses | 1,263,122 | 1,350,248 |
| Research and development expenses | 704,866 | 578,474 |
| Total operating expenses | 1,967,988 | 1,928,722 |
| Loss from operations | (1,967,988) | (1,928,722) |
| | | |
| Other income (expense) | | |
| Interest expenses | (362,142) | — |
| Loss on the issuance of Series A Preferred Stock Units | — | — |
| Change in fair value of Series A Warrants | (2,215,671) | — |
| Change in fair value of derivative liability | (583,517) | — |
| Other income (expense), net | (3,161,330) | — |
| | | |
| Loss before income tax | (5,129,318) | (1,928,722) |
| Income tax | — | — |
| Net loss | (5,129,318) | (1,928,722) |
| | | |
| Series A Convertible Preferred Stock dividends | (52,299) | — |
| Series A-1 Convertible Preferred Stock dividends | (6,196) | — |
| Deemed dividend Series A-1 Convertible Preferred Stock | (182,500) | — |
| | | |
| Net loss attributable to common stockholders | $ (5,370,313) | $ (1,928,722) |

**Revenue**

We have not generated any revenues to date. Our ability to generate product revenue and become profitable depends upon our ability to successfully commercialize products.

**Financial Results of Operations** (continued)

**General and administrative expense**

The following table summarizes our general and administrative expense incurred during the three months ended September 30, 2017 and 2016:

| | Three Months Ended September 30, 2017 | Three Months Ended September 30, 2016 | $ Change | %Change |
|---|---|---|---|---|
| Compensation and related personnel costs | $ 251,434 | $ 238,869 | $ 12,565 | 5% |
| Stock-based compensation | 241,401 | 292,084 | (50,683) | -17% |
| Outside professional services | 578,952 | 608,806 | (29,854) | -5% |
| Facility related costs | 38,838 | 48,721 | (9,883) | -20% |
| Board of directors related costs | 79,167 | 72,500 | 6,667 | 9% |
| Other operating costs | 73,330 | 89,268 | (15,938) | -18% |
| Total general and administrative expenses | $ 1,263,122 | $ 1,350,248 | $ (87,126) | -6% |

General and administrative expenses incurred for the three months ended September 30, 2017 were $1,263,122, a decrease of $87,126 as compared to $1,350,248 incurred for the prior year period. The decreased general and administrative expenses for the current year period is principally due to decreased expenses related to stock-based compensation expense of $50,683, outside professional services of $29,854, facility related costs of $9,883, and other operating expenses of $15,938; offset by higher expenses related to compensation and related personnel costs of $12,565 and board of directors related costs of $6,667.

The increased compensation and related personnel costs expense of $12,565 in the three months ended September 30, 2017 as compared to the prior year period, principally resulted from higher salary expense related to additional personnel offset by lower accrued bonus payable expense. In the three months ended September 30, 2017, the accrued bonus payable expense recognized represents the pro rata amount of the guaranteed bonus under the Chief Executive Officer ("CEO") employment agreement, as compared to the prior year period, for which accrued bonus payable expense was incurred for the CEO guaranteed bonus and a discretionary bonus.

The decrease in stock-based compensation expense of $50,683 in the three months ended September 30, 2017 as compared to the prior year period, principally resulted from a decrease in non-employee stock-based compensation expense, associated with lower stock option vesting date fair value corresponding to lower share price of the underlying common stock on such dates in the current year period as compared to the prior year period, offset by higher employee stock-based compensation expense resulting from additional stock option grants to new employees, along with additional stock-based compensation expense related to stock options granted after September 30, 2016, for which there was no expense recognized in the three months ended September 30, 2016.

The outside professional services expense, includes fees incurred under consulting agreements with entities and /or individuals affiliated with certain of our officers and directors, including: $75,000 incurred for each of the three months ended September 30, 2017 and 2016 under the HCP/Advisors consulting agreement; $0 and $30,000 incurred in the three months ended September 30, 2017 and 2016, respectively, related to the previous (expired) HCFP/Strategy Advisors consulting agreement; and, $0 and $15,000 incurred in the three months ended September 30, 2017 and 2016, respectively, related to the previous (expired) Swartwood Hesse consulting agreement; along with $0 and $37,500 incurred in the three months ended September 30, 2017 and 2016, respectively, related to the initial payment incurred under the previous (cancelled) consulting agreement with Michael J. Glennon - see "Contractual Obligations" below for further details on these related party agreements. Additionally, in the current year period as compared to the prior year period, there were lower expenses of $78,455 related to investor and public relations, offset by higher expenses of $74,323 associated with professional fees for information technology, legal, accounting, auditing, SEC reporting, and public company requirements; $15,026 of increased expenses related to regulatory consulting fees, and, $42,109 of increased expenses related to intellectual property matters.

The decrease in facility related costs of $9,883 in the three months ended September 20, 2017 as compared to the prior year period, was from lower rent expense resulting from the reduction of leased corporate office space.

The board of director related costs includes expense incurred for the services of non-executive members of $79,167 for the three months ended September 30, 2017, as compared to $72,500 for the prior year period, with the increase resulting from the addition of a new member of the board of directors in August 2017.

The decrease in other operating expenses of $15,938 in the three months ended September 30, 2017 as compared to the prior year period, principally resulted from lower travel and related costs of $36,285, offset by higher director and officers insurance premiums of $12,438.

**Financial Results of Operations** (continued)

**Research and development expenses**

The following table summarizes our research and development expenses incurred during the three months ended September 30, 2017 and 2016:

| | Three Months Ended September 30, 2017 | Three Months Ended September 30, 2016 | $ Change | % Change |
|---|---|---|---|---|
| Compensation and related personnel costs | $ 80,257 | $ 111,238 | $ (30,981) | -28% |
| Stock-based compensation | 30,900 | 30,900 | — | 0% |
| Outside professional services | 593,709 | 436,336 | 157,373 | 36% |
| Total research and development expenses | $ 704,866 | $ 578,474 | $ 126,392 | 22% |

In general, the increased research and development expenses incurred during the three months ended September 30, 2017, resulted from increased research and development activities in support of advancing our products toward FDA submittals as compared with limited research and development activities on certain of the products during the prior year period.

Research and development expenses incurred for the three months ended September 30, 2017 were $704,866, an increase of $126,392 as compared to $578,474 incurred for the prior year period. The increase in research and development expenses for the current year period is principally due to increased outside professional services of $157,373, offset by decreased compensation and related personnel costs of $30,981.

Compensation and related personnel cost classified as research and development expense is related to the services provided by our Chief Medical Officer ("CMO"), with the decrease in such expense principally resulting from the absence in the current year period of expense related to accrued discretionary bonus expense incurred in the prior year period. The stock-based compensation expense relates to CMO stock options. The increase in outside professional services expense in the current year period as compared to the prior year period, resulted principally from increase research and development work on the Company's lead product candidates.

**Financial Results of Operations** (continued)

**Other Income and Expense**

The following is a discussion of other income and expense for the three months ended September 30, 2017 and 2016.

*Interest Expense*

The Company and Scopia Holdings LLC ("Scopia" or the "Lender") entered into a Note and Security Purchase Agreement, under which the Company issued to Scopia and its designees, a Senior Secured Note with an initial principal amount of $5.0 million ("Scopia Note"), and 2,660,000 Series S Warrants to purchase shares of common stock of the Company.

The $4,842,577 of cash proceeds, net of the Lender's debt issuance costs, have been allocated to the Scopia Note and the Series S Warrants based on their respective relative fair value, resulting in an allocation of $1,408,125 to the Scopia Note and $3,434,452 to the Series S-Warrants, with the resulting difference of $3,591,875 between the Scopia Note initial principal amount and the allocated amount accounted for a debt discount amortized as interest expense over the term of the Scopia Note.

The Scopia Note bears interest at a fixed annual rate of 15.0%, with interest payable semi-annually in arrears on June 30 and December 30 of each calendar year, commencing on December 30, 2017. The Company may elect, at its sole discretion, to defer payment of up to 50% of the semi-annual interest due, with the remaining unpaid portion added to and increasing the outstanding interest-bearing principal balance of the Scopia Note by such amount of the deferred interest payment. The aggregate remaining unpaid principal balance of the Scopia Note is due on June 30, 2019.

In the three months ended September 30, 2017, interest expense recognized was $362,142, including $187,500 with respect to the 15% semi-annual interest payment and $174,642 with respect to the amortization of debt discount. The Scopia Note remaining unamortized debt discount is $3,417,233 at September 30, 2017.

*Change in fair value of Series A Warrant liability and Series A Convertible Preferred Stock conversion option embedded derivative liability*

The Series A Preferred Stock Units were issued in three closings in the three months ended March 31, 2017, with each such unit comprised of one share of Series A Convertible Preferred Stock and one Series A Warrant, with each, at the option of the holder, convertible into and exercisable for, respectively, a share of common stock of the Company.

The Series A Convertible Preferred Stock conversion option, which is accounted for as an embedded derivative and bifurcated from the Series A Convertible Preferred Stock host instrument, and the Series A Warrant, were determined to be derivatives under ASC 815, as, along with other provisions, their conversion price and exercise price, respectively, are subject to potential adjustment resulting from future financing transactions, under certain conditions.

The Series A Warrants and the Series A Convertible Preferred Stock conversion option embedded derivative are each classified as a current liability on the unaudited condensed consolidated balance sheet, and were initially measured at fair value at the time of issuance and are subsequently remeasured at fair value at each reporting period, with changes in fair value recognized as other income or expense in the unaudited condensed consolidated statement of operations.

A reconciliation of the Series A Warrants liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability for the three months ended September 30, 2017 is a follows:

| | Series A Warrant Liability | Series A Convertible Preferred Stock Conversion Option Embedded Derivative Liability |
|---|---|---|
| Balance at June 30, 2017 | $ 2,515,886 | $ 714,596 |
| Change in fair value | 2,215,671 | 583,517 |
| Balance at September 30, 2017 | $ 4,731,557 | $ 1,298,113 |

In the three months ended September 30, 2017, the change in fair values resulted in the recognition of: an expense of $2,215,671 with respect to the Series A Warrants liability; and an expense of $583,517 with respect to the Series A Convertible Preferred Stock conversion option embedded derivative liability. As the Series A Preferred Stock Units, which were comprised of the Series A Convertible Preferred Stock and the Series A Warrants, were issued in the three months ended March 31, 2017, there was no comparable amount in the prior year period.

**Financial Results of Operations** (continued)

**Other Income and Expense** (continued)

The fair value of the Series A Warrants liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability was determined using a Monte Carlo simulation valuation model, with such valuation model using the Company's common stock price and certain other inputs to take into account the probabilities of certain events occurring over the life of the respective financial instrument. The resulting estimated fair value is subjective and is affected by changes in inputs to the valuation model including the Company's common stock price, and the assumptions regarding the estimated volatility in the value of the Company's common stock price; the Company's dividend yield; the likelihood and timing of dilutive transactions; and, the risk-free rates based on U.S. Treasury security yields. Changes in these assumptions can materially affect the estimated fair value of each financial instrument. The Series A Warrants liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability estimated fair value and the underlying assumptions as of the dates indicated, are as follows:

| Series A Warrants Liability | September 30, 2017 | June 30, 2017 |
|---|---|---|
| Fair value per Series A Warrant | $ 11.19 | $ 5.95 |
| Series A Warrants outstanding | 422,838 | 422,838 |
| Calculated aggregate fair value | $ 4,731,557 | $ 2,515,886 |
| Value of common stock | $ 5.43 | $ 4.50 |
| Exercise price per share | $ 6.65 | $ 8.00 |
| Expected term (years) | 6.59 | 6.84 |
| Volatility | 53% | 49% |
| Risk free rate | 2.1% | 2.1% |
| Dividend yield | 0% | 0% |

| Series A Convertible Preferred Stock Conversion Option Embedded Derivative Liability | September 30, 2017 | June 30, 2017 |
|---|---|---|
| Fair value per conversion option | $ 3.07 | $ 1.69 |
| Series A Convertible Preferred Stock shares outstanding | 422,838 | 422,838 |
| Calculated aggregate fair value | $ 1,298,113 | $ 714,596 |
| Value of common stock | $ 5.43 | $ 4.50 |
| Conversion price per share | $ 4.99 | $ 6.00 |
| Expected term (years) | 6.59 | 6.84 |
| Volatility | 53% | 49% |
| Risk-free interest rate | 2.1% | 2.1% |
| Dividend yield | 0% | 0% |

**Financial Results of Operations** (continued)

***Comparison of the nine months ended September 30, 2017 and 2016.***

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2017 | 2016 |
| Revenue | $ — | $ — |
| Operating expense | | |
| General and administrative expenses | 4,082,366 | 2,827,721 |
| Research and development expenses | 2,063,319 | 1,112,616 |
| Total operating expenses | 6,145,685 | 3,940,337 |
| Loss from operations | (6,145,685) | (3,940,337) |
| | | |
| Other income (expense) | | |
| Interest expenses | (362,142) | — |
| Loss on the issuance of Series A Preferred Stock Units | (3,124,285) | — |
| Change in fair value of Series A Warrants | (680,851) | — |
| Change in fair value of derivative liability | (76,150) | — |
| Other income (expense), net | (4,243,428) | — |
| | | |
| Loss before income tax | (10,389,113) | (3,940,337) |
| Income tax | — | — |
| Net loss | (10,389,113) | (3,940,337) |
| | | |
| Series A Convertible Preferred Stock dividends | (130,010) | — |
| Series A-1 Convertible Preferred Stock dividends | (6,196) | — |
| Deemed dividend Series A-1 Convertible Preferred Stock | (182,500) | — |
| | | |
| Net loss attributable to common stockholders | $ (10,707,819) | $ (3,940,337) |

**Revenue**

We have not generated any revenues to date. Our ability to generate product revenue and become profitable depends upon our ability to successfully commercialize products.

**Financial Results of Operations** (continued)

**General and administrative expense**

The following table summarizes our general and administrative expense incurred during the nine months ended September 30, 2017 and 2016:

| | Nine Months Ended September 30, 2017 | Nine Months Ended September 30, 2016 | $ Change | %Change |
|---|---|---|---|---|
| Compensation and related personnel costs | $ 729,174 | $ 709,441 | $ 19,733 | 3% |
| Stock-based compensation | 707,588 | 447,232 | 260,356 | 58% |
| Outside professional services | 2,087,392 | 1,189,599 | 897,793 | 75% |
| Facility related costs | 133,270 | 116,588 | 16,682 | 14% |
| Board related costs | 224,167 | 120,833 | 103,334 | 86% |
| Other operating costs | 200,775 | 244,028 | (43,253) | -18% |
| Total general and administrative expenses | $ 4,082,366 | $ 2,827,721 | $ 1,254,645 | 44% |

General and administrative expenses incurred for the nine months ended September 30, 2017 were $4,082,366, an increase of $1,254,645 as compared to $2,827,721 incurred for the prior year period. The increased general and administrative expenses for the current year period is principally due to increased expenses related to compensation and related personnel costs of $19,733, stock-based compensation expense of $260,356, outside professional services of $897,793, facility related costs of $16,682, and, board of directors related costs of 103,334; offset by a decrease of $43,253 in other operating costs.

The increase in stock-based compensation expense of $260,356 in the nine months ended September 30, 2017 as compared to the prior year period, principally resulted from a full nine months of employee stock-based compensation expense recognized in the nine months ended September 30, 2017 as compared to a partial period expense recognized in the prior year period, as the stock options were granted effective with the April 28, 2016 IPO. Additional stock based compensation expense in the nine months ended September 30, 2017 includes $51,389 related to the March 31, 2017 modifications to the stock option grant previously awarded to the Company's former Chief Financial Officer, as well as, employee stock options granted after September 30, 2016, for which there was no expense recognized in the nine months ended September 30, 2016. The increased employee stock-based compensation expense was offset by lower non-employee stock based compensation expense, resulting principally from a decrease in non-employee stock-based compensation expense, associated with lower stock option vesting date fair value corresponding to lower share price of the underlying common stock on such dates in the current year period as compared to the prior year period,

The outside professional services expense includes fees incurred under consulting agreements with entities and /or individuals affiliated with certain of our officers and directors, including: $225,000 incurred for each of the nine months ended September 30, 2017 and 2016 under the HCP/Advisors consulting agreement; $80,000 and $30,000 incurred in the nine months ended September 30, 2017 and 2016, respectively, related to the previous (expired) HCFP/Strategy Advisors consulting agreement; and, $0 and $15,000 incurred in the nine months ended September 30, 2017 and 2016, respectively, related to the previous (expired) Swartwood Hesse consulting agreement; along with $0 and $37,500 incurred in the nine months ended September 30, 2017 and 2016, respectively, related to the initial payment incurred under the previous (cancelled) consulting agreement with Michael J. Glennon - see "Contractual Obligations" below for further details on these related party agreements. Additionally, in the current year period as compared to the prior year period, there were higher expenses of: $626,052 associated with professional fees for information technology, legal, accounting, auditing, SEC reporting, and public company requirements; $64,144 of increased expenses related to regulatory consulting fees; $43,037 of increased expenses related to intellectual property matters; and, $167,057 of increased expenses related to investor and public relations.

The increase in facility related costs of $16,682 in the nine months ended September 20, 2017 as compared to the prior year period, principally resulted from a higher quantity of space leased for our corporate offices in the current year period as compared to the prior year period and incurring rent expense for nine months in 2017 as compared to eight months in 2016. Notwithstanding, effective August 1, 2017, the Company reduced the quantity of leased space, resulting in a decrease in the monthly rent expense.

The board of director related costs includes member compensation expense incurred for the services of non-executive members of $224,167 for the nine months ended September 30, 2017, as compared to $120, 833 for the prior year period, with the increase resulting from the addition of a new member of the board of directors in August 2017 and, in the prior year period, board of directors compensation expense commenced from the IPO closing date of April 28, 2016.

The decrease in other operating expenses of $43, 253 in the nine months ended September 20, 2017 as compared to the prior year period, principally resulted from lower travel and related costs of $104,341 offset by higher director and officers insurance premiums of $55,898.

**Financial Results of Operations** (continued)

**Research and development expenses**

The following table summarizes our research and development expenses incurred during the nine months ended September 30, 2017 and 2016:

| | Nine Months Ended September 30, 2017 | Nine Months Ended September 30, 2016 | $ Change | %Change |
|---|---|---|---|---|
| Compensation and related personnel costs | $ 242,111 | $ 168,388 | $ 73,723 | 44% |
| Stock-based compensation | 91,693 | 52,396 | 39,297 | 75% |
| Outside professional services | 1,729,515 | 891,832 | 837,683 | 94% |
| Total research and development expenses | $ 2,063,319 | $ 1,112,616 | $ 950,703 | 85% |

In general, the increased research and development expenses incurred during the nine months ended September 30, 2017, resulted from increased research and development activities in support of advancing our products toward FDA submittals as compared with limited research and development activities on certain of the products during the prior year period.

Research and development expenses incurred for the nine months ended September 30, 2017 were $2,063,319, an increase of $950,703 as compared to $1,112,616 incurred for the prior year period. The increase in research and development expenses for the current year period is principally due to increased outside professional services of $837,683, along with compensation and related personnel costs of $73,723 and stock-based compensation of 39,297.

Compensation and related personnel cost classified as research and development expense is related to the services provided by our Chief Medical Officer ("CMO"), with such expense incurred for nine months in the current year period as compared to a partial period of time in the prior year period. In this regard, upon the commencement of the CMO employment agreement on July 1, 2016, the CMO was paid an initial bonus of $50,000 for services provided before the employment agreement effective date, with such payment and related employer payroll taxes recognized as an accrued expense at June 30, 2016. Additionally, the increase was offset from the absence in the current year of expense related to accrued discretionary bonus expense as compared to the prior year period when such expense was incurred. The stock-based compensation expense related to stock options granted to the CMO increase of $39,297 in the nine months ended September 30, 2017 as compared to the prior year period, resulted from a full nine months of stock-based compensation expense recognized in the current year period as compared to a partial period expense recognized in the prior year period, as the stock options were granted on the IPO date of April 28, 2016. The increase in outside professional services expense in the current year period as compared to the prior year period, resulted principally from increase research and development work on the Company's lead product candidates.

**Financial Results of Operations** (continued)

**Other Income and Expense**

The following is a discussion of other income and expense for the nine months ended September 30, 2017 and 2016.

*Interest Expense*

The Company and Scopia Holdings LLC ("Scopia" or the "Lender") entered into a Note and Security Purchase Agreement, under which the Company issued to Scopia and its designees, a Senior Secured Note with an initial principal amount of $5.0 million ("Scopia Note"), and 2,660,000 Series S Warrants to purchase shares of common stock of the Company.

The $4,842,577 of cash proceeds, net of the Lender's debt issuance costs, have been allocated to the Scopia Note and the Series S Warrants based on their respective relative fair value, resulting in an allocation of $1,408,125 to the Scopia Note and $3,434,452 to the Series S-Warrants, with the resulting difference of $3,591,875 between the Scopia Note initial principal amount and the allocated amount accounted for a debt discount amortized as interest expense over the term of the Scopia Note.

The Scopia Note bears interest at a fixed annual rate of 15.0%, with interest payable semi-annually in arrears on June 30 and December 30 of each calendar year, commencing on December 30, 2017. The Company may elect, at its sole discretion, to defer payment of cash pay up to 50% of the semi-annual interest due, with the remaining unpaid portion added to and increasing the outstanding interest-bearing principal balance of the Scopia Note by such amount of the deferred interest payment. The aggregate remaining unpaid principal balance of the Scopia Note is due on June 30, 2019.

In the nine months ended September 30, 2017, interest expense recognized was $362,142, including $187,500 with respect to the 15% semi-annual interest payment and $174,642 with respect to the amortization of debt discount. The Scopia Note remaining unamortized debt discount is $3,417,233 at September 30, 2017.

*Loss Related to issuance of Series A Preferred Stock Units and change in fair value of Series A Convertible Preferred Stock conversion option embedded derivative liability and Series A Warrant liability*

The Series A Preferred Stock Units were issued in three closings in the three months ended March 31, 2017, with each such unit comprised of one share of Series A Convertible Preferred Stock and one Series A Warrant, with each, at the option of the holder, convertible into and exercisable for, respectively, a share of common stock of the Company.

The Series A Convertible Preferred Stock conversion option, which is accounted for as an embedded derivative and bifurcated from the Series A Convertible Preferred Stock host instrument, and the Series A Warrant, were determined to be derivatives under ASC 815, as, along with other provisions, their conversion price and exercise price, respectively, are subject to potential adjustment resulting from future financing transactions, under certain conditions.

The Series A Warrants and the Series A Convertible Preferred Stock conversion option embedded derivative are each classified as a current liability on the unaudited condensed consolidated balance sheet, and were initially measured at fair value at the time of issuance and are subsequently remeasured at fair value at each reporting period, with changes in fair value recognized as other income or expense in the unaudited condensed consolidated statement of operations.

The issuance of the Series A Preferred Stock Units resulted in the recognition of a $3,124,285 loss in the nine months ended September 30, 2017, resulting from the aggregate issue dates' fair value of the Series A Warrant liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability being in excess of the Series A Preferred Stock Units aggregate issuance gross proceeds, with such excess amounting to $2,735,657, along with offering costs of $388,628 which were also recognized as a current period expense, summarized as follows:

| | Series A Preferred Stock Units Issue Dates (Aggregate) |
|---|---|
| Series A Preferred Stock Units issuance gross proceeds | $ 2,537,012 |
| Less: Series A Warrants initial fair value | (4,050,706) |
| Less: Conversion option embedded derivative liability initial fair value | (1,221,963) |
| Excess of fair value over gross proceeds | (2,735,657) |
| Offering costs | (388,628) |
| Loss on issuance of Series A Preferred Stock Units | $ (3,124,285) |

**Financial Results of Operations** (continued)

**Other Income and Expense** (continued)

A reconciliation of the Series A Warrants liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability for the nine months ended September 30, 2017 is a follows:

| | Series A Warrants Liability | Series A Convertible Preferred Stock Conversion Option Embedded Derivative Liability |
|---|---|---|
| Balance at December 31, 2016 | $ — | $ — |
| Initial fair value on dates of issuance | 4,050,706 | 1,221,963 |
| Change in fair value | 680,851 | 76,150 |
| Balance at September 30, 2017 | $ 4,731,557 | $ 1,298,113 |

In the nine months ended September 30, 2017, the change in fair values resulted in the recognition of: an expense of $680,851 with respect to the Series A Warrants liability; and, an expense of $76,150 with respect to the Series A Convertible Preferred Stock conversion option embedded derivative liability. As the Series A Preferred Stock Units, which were comprised of the Series A Convertible Preferred Stock and the Series A Warrants, were issued in the three months ended March 31, 2017, there was no comparable amount in the prior year period.

The fair value of the Series A Warrants liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability was determined using a Monte Carlo simulation valuation model, with such valuation model using the Company's common stock price and certain other inputs to take into account the probabilities of certain events occurring over the life of the respective financial instrument. The resulting estimated fair value is subjective and is affected by changes in inputs to the valuation model including the Company's common stock price, and the assumptions regarding the estimated volatility in the value of the Company's common stock price; the Company's dividend yield; the likelihood and timing of dilutive transactions; and, the risk-free rates based on U.S. Treasury security yields. Changes in these assumptions can materially affect the estimated fair value of each financial instrument. The Series A Warrants liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability estimated fair value and the underlying assumptions as of the dates indicated, are as follows:

| Series A Warrants Liability | September 30, 2017 | Issue Dates' Aggregated Weighted Average |
|---|---|---|
| Fair value per Series A Warrant | $ 11.19 | $ 9.58 |
| Series A Warrants outstanding | 422,838 | 422,838 |
| Calculated aggregate fair value | $ 4,731,557 | $ 4,050,706 |
| Value of common stock | $ 5.43 | $ 5.73 |
| Exercise price per share | $ 6.65 | $ 8.00 |
| Expected term (years) | 6.59 | 7.21 |
| Volatility | 53% | 47% |
| Risk free rate | 2.1% | 2.3% |
| Dividend yield | 0% | 0% |

| Series A Convertible Preferred Stock Conversion Option Embedded Derivative Liability | September 30, 2017 | Issue Dates' Aggregated Weighted Average |
|---|---|---|
| Fair value per conversion option | $ 3.07 | $ 2.89 |
| Series A Convertible Preferred Stock shares outstanding | 422,838 | 422,838 |
| Calculated aggregate fair value | $ 1,298,113 | $ 1,221,963 |
| Value of common stock | $ 5.43 | $ 5.73 |
| Conversion price per share | $ 4.99 | $ 6.00 |
| Expected term (years) | 6.59 | 7.21 |
| Volatility | 53% | 47% |
| Risk-free interest rate | 2.1% | 2.3% |
| Dividend yield | 0% | 0% |

**Financial Results of Operations** (continued)

**Non-GAAP Financial Measures**

The factors described above resulted in net loss attributable to common stockholders of $5,370,313 and $10,707,819 for the three and nine months ended September 30, 2017, respectively, as compared to net loss attributable to common stockholders of $1,928,722 and $3,940,337 for the three and nine months ended September 30, 2016, respectively.

To supplement our condensed consolidated financial statements presented in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") within this Quarterly Report on Form 10-Q, management provides certain non-GAAP financial measures ("NGFM") of the Company's financial results, including net loss before interest, taxes, depreciation, and amortization ("EBITDA") and non-GAAP Adjusted Loss, which further adjusts EBITDA for stock-based compensation expense, loss on the issuance of the Series A Preferred Stock Units, the change in fair value of the Series A Warrant liability, and the change in fair value of the Series A Convertible Preferred Stock conversion option embedded derivative liability. The foregoing NGFM measures of EBITDA and non-GAAP Adjusted Loss are not recognized terms under U.S. GAAP.

The NGFM are presented with the intent of providing greater transparency to information used by us in our financial performance analysis and operational decision-making. We believe these NGFM provide meaningful information to assist investors, shareholders, and other readers of our unaudited condensed consolidated financial statements in making comparisons to our historical financial results, and analyzing the underlying performance of our financial results of operations. These NGFM are not intended to be, and should not be, a substitute for, considered superior to, considered separately from, or as an alternative to, the most directly comparable GAAP financial measures.

The NGFM are provided to enhance readers' overall understanding of our current financial results and to provide further information for comparative purposes. Management believes the NGFM provide useful information to management and investors by isolating certain expenses, gains and losses that may not be indicative of our operating financial results and business outlook. Specifically, the presentation of the NGFM of non-GAAP adjusted loss is intended to help the reader understand the effect of the loss on the issuance of the Series A Preferred Stock Units and the corresponding derivative accounting for non-cash charges on financial performance. In addition, management believes the NGFM enhance the comparability of results between the current year period and the prior year period.

**Financial Results of Operations** (continued)

**Non-GAAP Financial Measures** (continued)

A reconciliation to the most directly comparable GAAP measure of NGFM, as discussed above, included in this report for the three months ended September 30, 2017 and 2016, is as follows:

| | Three Months Ended September 30, | | |
|---|---|---|---|
| | 2017 | 2016 | $ Change |
| Net loss attributable to common stockholders | $ (5,370,313) | $ (1,928,722) | $ (3,441,591) |
| Series A Convertible Preferred Stock dividends | 52,299 | — | 52,299 |
| Series A-1 Convertible Preferred Stock dividends | 6,196 | — | 6,196 |
| Deemed dividend Series A-1 Convertible Stock | 182,500 | — | 182,500 |
| Net loss - as reported | (5,129,318) | (1,928,722) | (3,200,596) |
| | | | |
| Adjustments | | | |
| Depreciation expense(1) | 1,802 | 1,478 | 324 |
| Interest expense | 362,142 | — | — |
| Income tax provision | — | — | — |
| | | | |
| EBITDA | (4,765,374) | (1,927,244) | (2,838,130) |
| | | | |
| Stock-based compensation expense(2) | 272,301 | 322,085 | (50,684) |
| Loss on the issuance of Series A Preferred Stock Units(3) | — | — | — |
| Change in fair value of Series A Warrants(4) | 2,215,671 | — | 2,215,671 |
| Change in fair value of derivative liability(5) | 583,517 | — | 583,517 |
| | | | |
| Non-GAAP adjusted loss | $ (1,693,885) | $ (1,604,259) | $ (89,626) |

(1) Included in general and administrative expenses in the condensed consolidated statement of operations.

(2) Stock-based compensation expense of $241,401 and $292,085 is included in general administrative expenses and, $30,900 and $30,900 is included in research and development expenses, in the condensed consolidated statement of operations, in the three months ended September 30, 2017 and 2016, respectively.

(3) The issuance of the Series A Preferred Stock Units resulted in the recognition of a current period loss in the three months ended March 31, 2017 of $3,124,285, resulting from the aggregate fair value of the Series A Warrants liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability being in excess of the Series A Preferred Stock Units issuance gross proceeds, with such excess amounting to $2,735,657, along with offering costs of $388,628 also recognized as a current period expense in the unaudited condensed consolidated statement of operations. The Series A Preferred Stock Units were issued in the three months ended March 31, 2017, and therefore there was no comparable amount in the prior year period.

(4) The Series A Warrants are initially measured at the issue date fair value with such fair value subsequently adjusted at each reporting period, with the resulting adjustment recognized as other income or expense in the condensed consolidated statement of operations. If upon the occurrence of an event resulting in the Series A Warrant to be subsequently classified as equity, the Series A Warrant fair value will be adjusted on such date-of-occurrence, with such fair value adjustment recognized as other income or expense, and then classified as equity at such date-of-occurrence adjusted fair value. The Series A Preferred Stock Units, which were comprised of the Series A Warrants and the Series A Convertible Preferred Stock, were issued in the three months ended March 31, 2017, and therefore there was no comparable amount in the prior year period.

(5) The Series A Convertible Preferred Stock conversion option is accounted for as a bifurcated embedded derivative liability, initially measured at the issue date fair value with such fair value subsequently adjusted at each reporting period, with the resulting adjustment recognized as other income or expense in the condensed consolidated statement of operations. If upon the occurrence of an event resulting in the Series A Convertible Preferred Stock conversion option embedded derivative to be subsequently classified as equity, the Series A Convertible Preferred Stock conversion option embedded derivative fair value will be adjusted on such date-of-occurrence, with such fair value adjustment recognized as other income or expense, and then classified as equity at such date-of-occurrence adjusted fair value. The Series A Preferred Stock Units, which were comprised of the Series A Convertible Preferred Stock and the Series A Warrants, were issued in the three months ended March 31, 2017, and therefore there was no comparable amount in the prior year period.

**Financial Results of Operations** (continued)

**Non-GAAP Financial Measures** (continued)

A reconciliation to the most directly comparable GAAP measure of NGFM, as discussed above, included in this report for the nine months ended September 30, 2017 and 2016, is as follows:

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| | 2017 | 2016 | $ Change |
| Net loss attributable to common stockholders | $ (10,707,819) | $ (3,940,337) | $ (6,767,482) |
| Series A Convertible Preferred Stock dividends | 130,010 | — | 130,010 |
| Series A-1 Convertible Preferred Stock dividends | 6,196 | — | 6,196 |
| Deemed dividend Series A-1 Convertible Stock | 182,500 | — | 182,500 |
| Net loss - as reported | (10,389,113) | (3,940,337) | (6,448,776) |
| | | | |
| Adjustments | | | |
| Depreciation expense(1) | 5,307 | 2,315 | 2,992 |
| Interest expense | 362,142 | — | 362,142 |
| Income tax provision | — | — | — |
| | | | |
| EBITDA | (10,021,664) | (3,938,022) | (6,083,642) |
| | | | |
| Stock-based compensation expense(2) | 799,281 | 499,628 | 299,653 |
| Loss on the issuance of Series A Preferred Stock Units(3) | 3,124,285 | — | 3,124,285 |
| Change in fair value of Series A Warrants(4) | 680,851 | — | 680,851 |
| Change in fair value of derivative liability(5) | 76,150 | — | 76,150 |
| | | | |
| Non-GAAP adjusted loss | $ (5,341,097) | $ (3,438,394) | $ (1,902,703) |

(1) Included in general and administrative expenses in the condensed consolidated statement of operations.

(2) Stock-based compensation expense of $707,588 (which includes $51,389 of stock-based compensation expense related to the stock option modifications at March 31, 2017 to the stock option grant previously awarded to the Company's former Chief Financial Officer) and $447,232 is included in general administrative expenses; and, $91,693 and $52,396 is included in research and development expenses, in the condensed consolidated statement of operations, for the nine months ended September 30, 2017 and 2016, respectively. There was no stock-based compensation expense in the three months ended March 31, 2016, as the stock options were granted in April 2016.

(3) The issuance of the Series A Preferred Stock Units resulted in the recognition of a current period loss in the nine months ended September 30, 2017 of $3,124,285, resulting from the aggregate fair value of the Series A Warrants liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability being in excess of the Series A Preferred Stock Units issuance gross proceeds, with such excess amounting to $2,735,657, along with offering costs of $388,628 also recognized as a current period expense in the unaudited condensed consolidated statement of operations. The Series A Preferred Stock Units were issued in the three months ended March 31, 2017, and therefore there was no comparable amount in the prior year period.

(4) The Series A Warrants are initially measured at the issue date fair value with such fair value subsequently adjusted at each reporting period, with the resulting adjustment recognized as other income or expense in the condensed consolidated statement of operations. If upon the occurrence of an event resulting in the Series A Warrant to be subsequently classified as equity, the Series A Warrant fair value will be adjusted on such date-of-occurrence, with such fair value adjustment recognized as other income or expense, and then classified as equity at such date-of-occurrence adjusted fair value. The Series A Preferred Stock Units, which were comprised of the Series A Warrants and the Series A Convertible Preferred Stock, were issued in the three months ended March 31, 2017, and therefore there was no comparable amount in the prior year period.

(5) The Series A Convertible Preferred Stock conversion option is accounted for as a bifurcated embedded derivative liability, initially measured at the issue date fair value with such fair value subsequently adjusted at each reporting period, with the resulting adjustment recognized as other income or expense in the condensed consolidated statement of operations. If upon the occurrence of an event resulting in the Series A Convertible Preferred Stock conversion option embedded derivative to be subsequently classified as equity, the Series A Convertible Preferred Stock conversion option embedded derivative fair value will be adjusted on such date-of-occurrence, with such fair value adjustment recognized as other income or expense, and then classified as equity at such date-of-occurrence adjusted fair value. The Series A Preferred Stock Units, which were comprised of the Series A Convertible Preferred Stock and the Series A Warrants, were issued in the three months ended March 31, 2017, and therefore there was no comparable amount in the prior year period.

**Liquidity and Capital Resources**

We are an early stage and emerging growth company and have not generated any revenues to date. As such, we are subject to all of the risks associated with early stage and emerging growth companies. Since inception, the Company has incurred losses and negative cash flows from operating activities. We do not expect to generate positive cash flows from operating activities as we complete the development process of our products, including regulatory approvals, and thereafter, begin to commercialize and achieve substantial acceptance in the marketplace for the first of a series of products in its medical device portfolio, which is not expected to occur in the near future, if at all.

We have incurred a net loss attributable to common stockholders of $5,370,313 and $1,928,722 in the three months ended September 30, 2017 and 2016, respectively, and $10,707,819 and $3,940,337 in the nine months ended September 30, 2017 and 2016, respectively. We had net cash flows used in operating activities of $5,021,134 and $3,251,887 in the nine months ended September 30, 2017 and 2016, respectively. At September 30, 2017, we had an accumulated deficit of $18,273,448, working capital of $1,681,246, adjusted to exclude the Series A Warrants liability of $4,731,557 and the Series A Convertible Preferred Stock conversion option derivative liability of 1,298,113. In the near future, we anticipate incurring operating losses and do not expect to experience positive cash flows from operating activities, and may continue to incur operating losses for the next several years as we complete the development of our products, file for and request regulatory approvals of our products, and begin to market our products. These factors raise substantial doubt of the Company's ability to continue as a going concern within one year after the date our unaudited condensed consolidated financial statements are issued.

We estimate our current cash resources, absent any additional sources of cash, is sufficient to fund our operations through the quarter ended June 30, 2018. Accordingly, we do not have sufficient cash resources to fund our anticipated operating losses for the next twelve months and we must raise additional funds to support our operating and capital needs beyond the quarter ended June 30, 2018.

Our ability to fund our operations is dependent upon management's plans, which include raising additional capital, obtaining regulatory approvals for our products currently under development, commercializing and generating revenues from products currently under development, if any, and continuing to control expenses. However, there is no assurance we will be successful in these efforts.

A failure to raise sufficient capital, obtain regulatory approvals for our products, generate sufficient product revenues, or control expenditures, among other factors, will adversely impact our ability to meet our financial obligations as they become due and payable and to achieve our intended business objectives and therefore raises substantial doubt of our ability to continue as a going concern within one year after the date our unaudited condensed consolidated financial statements are issued. Our unaudited condensed consolidated financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities should we be unable to continue as a going concern.

Since our inception in June 2014, we have financed our operations principally through issuances of common stock, preferred stock, warrants, and debt. Prior to our April 2016 IPO, we raised approximately $2.1 million of net cash proceeds from private offerings of our common stock and warrants. Our April 28, 2016 IPO resulted in approximately $4.2 million of net cash proceeds. To-date, during 2017, we have raised a total of approximately $7.5 million of net cash proceeds from: a Note and Security Purchase Agreement with Scopia Holdings LLC, including the issuance of a $5.0 million Senior Secured Note and Series S Warrants; the Series A-1 Preferred Stock Units private placement; and the Series A Preferred Stock Units private placement, each as discussed below.

*Note and Security Purchase Agreement with Scopia Holdings LLC*

We entered into a Note and Security Purchase Agreement with Scopia Holdings LLC ("Scopia" or the "Lender"), under which, upon Scopia delivering to the Company $4.8 million in net cash proceeds by wire transfer on July 3, 2017, we issued to Scopia and its designees, a Senior Secured Note with an initial principal amount of $5.0 million ("Scopia Note"), and 2,660,000 Series S Warrants to purchase shares of common stock of the Company, as discussed below.

The $4,842,577 of cash proceeds, which was net amount of cash remitted to us, after deduction of the Lender's debt issuance costs, were allocated for accounting purposes to the Scopia Note and the Series S Warrants based on their respective relative fair value, resulting in an allocation of $1,408,125 to the Scopia Note and $3,434,452 to the Series S-Warrants, with the resulting difference of $3,591,875 between the Scopia Note initial principal amount and the allocated amount accounted for a debt discount amortized as interest expense over the term of the Scopia Note.

*Note and Security Purchase Agreement with Scopia Holdings LLC (continued)*

The Scopia Note bears interest at a fixed annual rate of 15.0%, with interest payable semi-annually in arrears on June 30 and December 30 of each calendar year, commencing on December 30, 2017. We may elect, at our sole discretion, to defer payment of up to 50% of the semi-annual interest due, with the remaining unpaid portion added to and increasing the outstanding interest-bearing principal balance of the Scopia Note by such amount of the deferred interest payment. The aggregate remaining unpaid principal balance of the Scopia Note is due on June 30, 2019.

Interest expense recognized was $362,142, including $187,500 with respect to the 15% semi-annual interest payment and $174,642 with respect to the amortization of debt discount, in the three and nine months ended September 30, 2017. The Scopia Note remaining unamortized debt discount is $3,417,233 at September 30, 2017.

At our discretion, the aggregate principal balance of the Scopia Note and any earned and unpaid interest may be repaid at any time without penalty or premium. Additionally, under the Scopia Note, if we sell our implantable intraosseous vascular access device (the "PortIO Product"), then the Scopia Note holders' may require us to repay the then outstanding aggregate principal amount of the Scopia Note, in whole or in part, together with any accrued interest thereon, from the proceeds of such PortIO Product sale, provided such principal and interest payment is limited to the amount of the net cash proceeds from such PortIO Product sale.

The Note and Security Purchase Agreement with Scopia contains various customary negative covenants of the Company including restrictions on incurring any additional indebtedness or liens or declaring or paying any dividends, subject to certain exceptions provided for in the Note and Security Purchase Agreement with Scopia, while any amount under the Scopia Note remains outstanding. The Note and Security Purchase Agreement with Scopia also contains certain affirmative covenants of the Company, including, among others:

- If the PortIO Product obtains initial FDA 510(k) clearance, then, commencing four months after such FDA 510(k) clearance, we will use our reasonable best efforts to attempt to sell the PortIO Product on commercially reasonable terms for an amount not less than $10.0 million. If the net cash proceeds are $10.0 million or greater from such PortIO product sale, and there are no continuing obligations imposed on the Company, which would constitute an undue burden on the Company, resulting from such PortIO Product sale transaction, then the Scopia Note holders may request us to repay the then aggregate remaining unpaid principal balance of the Scopia Note. Notwithstanding, such Note and Securities Purchase Agreement provision has been rendered moot, as the FDA has indicated the PortIO Product will be reviewed for approval under a regulatory pathway other than a 510(k) clearance;

- Effective with the first bi-monthly payroll in July 2017, our CEO agreed to the payment of a reduced salary of $4,200 per month, with the payment of the earned but unpaid salary amount deferred until the earlier to occur of (a) the date that FDA 510(k) clearance for the PortIO Product is obtained or (b) the date the aggregate remaining unpaid principal balance of the Scopia Note is repaid in full; and,

- We agreed to use its commercially reasonable best efforts to file a registration statement with the U.S. Securities and Exchange Commission (SEC) registering for resale of all of the shares of common stock underlying the Series S Warrants with such registration statement having an effectiveness date on or before November 27, 2017.

Additionally, the Note and Security Purchase Agreement with Scopia provides, for so long as the Lender holds at least 50% of the aggregate remaining unpaid principal balance of the Scopia Note, the Lender shall have the ability to nominate one individual to the Company's board of directors, provided the board of directors shall have the right to reject any such Lender nominee if it determines in good faith such Lender nominee is not reasonably acceptable. In this regard, on August 3, 2017, the Lender nominee was appointed to the Company's board of directors.

The Series S Warrants were immediately exercisable upon issuance, have an exercise price of $0.01 per share, with such exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock, may be exercised for cash or on a cashless basis, and expire June 30, 2032, with any Series S Warrants outstanding on the expiration date will be automatically exercised on a cashless basis.

As of September 30, 2017, there were 2,660,000 Series S Warrants issued and outstanding. Subsequently, in October 2017, 532,000 Series S Warrants were exercised for cash proceeds of $5,320, resulting in the issuance of a corresponding number of shares of common stock; and, in November 2017, 122,360 Series S Warrants were exercised on a cashless basis, resulting in the issuance of 122,080 shares of common stock.

See our unaudited condensed consolidated financial statements Note 12,*Note and Securities Purchase Agreement, Senior Secured Note, and Series S Warrants*, for a further discussion of the Note and Security Purchase Agreement with Scopia; and, Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for further information regarding the Series S Warrants.

**Liquidity and Capital Resources** (continued)

*Series A-1 Preferred Stock Units Private Placement*

On August 3, 2017, our Board of Directors authorized the issuance of up to 150,000 Series A-1 Preferred Stock Units, and on August 4, 2017, we entered into a Securities Purchase Agreement pursuant to which we may issue up to an aggregate of $600,000 (subject to increase) of Series A-1 Preferred Stock Units at a price of $4.00 per unit, in a private placement transaction (Series A-1 Preferred Stock Units private placement). At the August 4, 2017 closing of the Series A-1 Preferred Stock Units private placement, a total of 125,000 Series A-1 Preferred Stock Units were issued for aggregate proceeds of $500,000. We did not incur placement agent fees in connection with the Series A-1 Preferred Stock Units private placement.

Subsequently, on October 18, 2017, upon approval by the unanimous vote of the Series A-1 Preferred Stock Units holders, the Series A-1 Preferred Stock Units private placement transaction documents were amended: to provide for the election to exchange one Series A-1 Warrant for five Series W Warrants; to remove the requirement for the Company to file with the SEC an initial registration statement within sixty days of the August 4, 2017 closing date; and, to provide for the election to exchange one Series A-1 Warrant for four Series X-1 Warrants, with such Series X-1 Warrants replacing the Series X Warrants. In this regard, while the Series X-1 Warrants are substantively equivalent to the Series X Warrants with respect to material contractual terms and conditions, including the same $6.00 per share exercise price, and dates of exercisability and expiry, the Series X-1 Warrant confirms the Series X-1 Warrant are not subject to redemption, and under no circumstances will the Company be required to net cash settle the Series X-1 Warrants, for any reason, nor to pay any liquidated damages resulting from a failure to satisfy any obligations under the Series X-1 Warrant, notwithstanding such provisions were applicable to the Series X Warrant through the operation of the Series A-1 Preferred Stock Units Securities Purchase Agreement. Additionally, as the Company's Series A Warrants can be exchanged for four Series X Warrants, the Series X-1 Warrants were developed for issuance upon the exchange of the corresponding Series A-1 Warrant. See below for a discussion of the Series X Warrants and the Series X-1 Warrants.

A Series A-1 Preferred Stock Unit was comprised of one share of Series A-1 Convertible Preferred Stock and one Series A-1 Warrant - as more fully described below. At their issuance, the Series A-1 Convertible Preferred Stock and the Series A-1 Warrant were immediately separable, and each was immediately convertible and exercisable, respectively. The Series A-1 Preferred Stock Units private placement cash proceeds of $500,000 were allocated as $189,550 to the Series A-1 Convertible Preferred Stock and $310,450 to the Series A-1 Warrants, based on their respective relative fair value.

The Series A-1 Convertible Preferred Stock has a par value of $0.001 per share, no voting rights, a stated value of $4.00 per share, is classified as permanent equity in the condensed consolidated balance sheet, and, at the holders' election, is convertible into a number of shares of common stock at a conversion ratio equal to its stated value divided by a conversion price of $4.00 per share, with such conversion price not subject to further adjustment, except for the effect of stock dividends, stock splits or similar events affecting the Company's common stock. The Series A-1 Convertible Preferred Stock was immediately convertible upon its issuance. The Series A-1 Convertible Preferred Stock shall not be redeemed for cash and under no circumstances shall the Company be required to net cash settle the Series A-1 Convertible Preferred Stock.

The Series A-1 Preferred Stock Units cash proceeds allocated to the Series A-1 Convertible Preferred Stock, as discussed above, of $189,550 resulted in an effective conversion price below the issue-date fair value of the underlying shares of common stock, resulting in a $182,500 beneficial conversion feature, which was accounted for as an implied discount on the Series A-1 Convertible Preferred Stock. The Series A-1 Convertible Preferred Stock does not have a stated redemption date and was immediately convertible upon issuance, resulting in the full accretion of the beneficial conversion feature as a deemed dividend paid to the Series A-1 Convertible Preferred Stock on the August 4, 2017 issue date.

The Series A-1 Convertible Preferred Stock provides for dividends at an 8% annual rate, compounded quarterly, accumulate, and are payable in arrears upon being declared by the Company's Board of Directors. The Series A-1 Convertible Preferred Stock dividends from October 1, 2017 through October 1, 2021 are payable-in-kind ("PIK") in additional shares of Series A-1 Convertible Preferred Stock. The dividends may be settled after October 1, 2021, at the option of the Company, through any combination of the issuance of additional Series A-1 Convertible Preferred Stock, shares of common stock, and /or cash payment. As of September 30, 2017, Series A-1 Convertible Preferred Stock dividends totaling $6,196 or a payment-in-kind of 1,551 shares of Series A-1 Convertible Preferred Stock, were earned, accumulated, and in arrears, as the Company's Board of Directors had not declared such dividends payable, and, as such, the Company has not recognized a Series A-1 Convertible Preferred Stock dividend payable liability as of September 30, 2017, and will not recognize such dividend payable liability until they are declared by the Company's Board of Directors. Notwithstanding, the Company has presented such dividend value as a component of the loss attributable to common stockholders in the calculation of basic and diluted net loss per share.

A Series A-1 Warrant may be exercised for one share of common stock at an exercise price of $6.67 per share, with such exercise price not subject to further adjustment, except for the effect of stock dividends, stock splits or similar events affecting the common stock, and expire after the close of business on April 30, 2024. Additionally, through April 30, 2024, each Series A-1 Warrant, at the option of the holder, may be exchanged into five Series W Warrants or four Series X1 Warrants - as discussed below. As of September 30, 2017, no Series A-1 Warrants had been exchanged for Series W Warrants nor Series X-1 Warrants. Notwithstanding, the 125,000 Series A-1 Warrants issued and outstanding at September 30, 2017, if exchanged would result in the issuance of 625,000 Series W Warrants or the issuance of 500,000 Series X-1 Warrants.

**Liquidity and Capital Resources** (continued)

*Series A-1 Preferred Stock Units Private Placement (continued)*

The Series W Warrants issued upon the exchange of a Series A-1 Warrant have an exercise price of $5.00 per share, with such exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock, and became exercisable on October 28, 2016 and expire on January 29, 2022 or earlier upon redemption by the Company, under certain conditions. Such Series W Warrants were issued in our initial public offering as described above.

The Series X-1 Warrants issued upon exchange of a Series A-1 Warrant, are exercisable for one share of common stock of the Company at $6.00 per share, with such Series X-1 Warrant exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock. The Series X-1 Warrants are exercisable commencing on the first trading day following October 31, 2018, and may be exercised through their April 30, 2024 expiration date, or earlier upon redemption by the Company. At their expiration date, provided the closing price of the Company's common stock is greater than $6.00 per share, any such outstanding Series X-1 Warrants will be automatically exercised via a cashless exercise.

The registration rights agreement, as amended, entered into in connection with the Series A-1 Preferred Stock Units private placement, requires the Company to file with the SEC a registration statement registering for resale the maximum number of common shares issuable upon conversion of the Series A-1 Convertible Preferred Shares and the exercise of the Series A-1 Warrants or, the Series W or Series X1 Warrants issued in exchange for the Series A-1 Warrants (as discussed above). The Company expects such registration statement to also register the resale of the Series W Warrants and the Series X-1 Warrants, and will register the initial issuance of shares of common stock of the Company underlying the Series W Warrants and the Series X-1 Warrants to the extent each such warrants are publicly sold prior to their respective exercise. Such registration rights agreement requires the Company to use commercially reasonable best efforts to have such registration statement declared effective no later than one hundred and fifty (150) days from the August 4, 2017 closing date. If such registration statement is not effective by the contractually agreed upon date or such registration statement effectiveness is not maintained, then, the Company is required to make payments to the investors of 2% of their Series A-1 Preferred Stock Units subscription amount on the date of such events, and every thirty days thereafter until the effectiveness is cured.

See our unaudited condensed consolidated financial statements Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a discussion of the Series A-1 Preferred Stock Units private placement, the Series A-1 Convertible Preferred Stock, the Series A-1 Warrants, and the Series W Warrants or Series X-1 Warrants which may be issued upon the exchange of Series A-1 Warrants.

*Series A Preferred Stock Units Private Placement*

The Company's Board of Directors previously authorized the issuance of up to a total of 1.25 million Series A Preferred Stock Units, including authorizing 500,000 units on January 21, 2017 and 750,000 units on May 10, 2017. On January 26, 2017, the Company entered into a Securities Purchase Agreement pursuant to which the Company may issue up to an aggregate of $3,000,000 of Series A Preferred Stock Units at a price of $6.00 per unit, in a private placement transaction ("Series A Preferred Stock Units private placement"). At the Series A Preferred Stock Units private placement initial closing on January 26, 2017, and at subsequent closings on January 31, 2017 and March 8, 2017, a total of 422,838 Series A Preferred Stock Units were issued for aggregate gross proceeds of approximately $2.5 million and net proceeds of approximately $2.2 million, after payment of placement agent fees and closing costs.

Subsequently, on October 20, 2017, the Company initiated an exchange offer, which expires on November 17, 2017, for holders of the Series A Convertible Preferred Stock to exchange on a 1.0:1.5 exchange ratio for shares of Series A-1 Convertible Preferred Stock; and, for the holders of the Series A Warrants to exchange on a 1.0:1.0 exchange ratio for Series A-1 Warrants. A total of 634,257 shares Series A-1 Convertible Preferred Stock and 422,838 Series A-1 Warrants would be issued if all such shares and warrants are exchanged, respectively. See above for a discussion of the Series A-1 Convertible Preferred Stock and Series A-1 Warrants.

A Series A Preferred Stock Unit was comprised of one share of Series A Convertible Preferred Stock and one Series A Warrant. The Series A Convertible Preferred Stock and Series A Warrants were immediately separable upon their issuance, and became convertible and exercisable, respectively, on May 21, 2017 upon stockholder approval of the Series A Preferred Stock Units private placement, with such approval obtained in accordance with Nasdaq Stock Market Rule 5635(d). At the election of their respective holder, a share of Series A Convertible Preferred Stock is convertible into a number of shares of common stock of the Company at a prescribed exchange ratio; and, a Series A Warrant is exercisable for one share of common stock of the Company, or may be exchanged for four Series X Warrants, with each such Series X Warrant exercisable of one share of common stock of the Company, each as more fully described below.

**Liquidity and Capital Resources** (continued)

*Series A Preferred Stock Units Private Placement (continued)*

The Series A Warrant and the Series A Convertible Preferred Stock conversion option, which is accounted for as an embedded derivative and bifurcated from its host financial instrument, are accounted for as a derivative liability under FASB ASC 815, as, along with other provisions, the conversion price and exercise price, respectively, are subject to potential adjustment resulting from future financing transactions, under certain conditions. The Series A Convertible Preferred Stock conversion option embedded derivative and the Series A Warrant are classified as a current liability on the unaudited condensed consolidated balance sheet, initially measured at their issue-date fair value, with such fair value subsequently remeasured at each reporting period, with the resulting fair value adjustment recognized as other income or expense on the condensed consolidated statement of operations.

The issuance of the Series A Preferred Stock Units resulted in the recognition of an issue-date loss of $3,124,285, resulting from the aggregate initial fair value of the Series A Warrant liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability being in excess of the Series A Preferred Stock Units issuance gross proceeds, with such excess, amounting to $2,735,657, recognized as a current period expense, along with offering costs of $388,628, which were also recognized as a current period expense.

The Series A Convertible Preferred Stock has a par value of $0.001 per share, no voting rights, a stated value of $6.00 per share, and became convertible on May 21, 2017 upon stockholder approval of the Series A Preferred Stock Units private placement, with such approval obtained in accordance with Nasdaq Stock Market Rule 5635(d). At the holders' election, a share of Series A Convertible Preferred Stock is convertible into a number of shares of common stock of the Company at a conversion ratio equal to its stated value divided by a conversion price of $4.99 per share, subject to further adjustment. The Series A Convertible Preferred Stock conversion price is subject to further reduction by a prescribed formula should any subsequent issuances of convertible securities by the Company be at a price lower than such conversion price immediately prior to such new issuance. In this regard, at the time of issuance, the Series A Convertible Preferred Stock conversion price was initially $6.00 per share, and subsequently adjusted to $5.00 per share upon the issuance of the Series S Warrants on July 3, 2017, and then to $4.99 per share upon the issuance of the Series A-1 Preferred Stock Units on August 4, 2017, with such conversion price subject to further adjustment as noted above.

At September 30, 2017, there were 422,838 shares of Series A Convertible Preferred Stock issue and outstanding. Subsequently, in November 2017, at the election of the holder, 8,334 shares of Series A Convertible Preferred Stock were converted into 10,021 shares of common stock of the Company.

The Series A Convertible Preferred Stock provides for dividends at an 8% annual rate, compounded quarterly, accumulate, and are payable in arrears upon being declared by the Company's Board of Directors. The Series A Convertible Preferred Stock dividends from April 1, 2017 through April 1, 2021 are payable-in-kind ("PIK") in additional shares of Series A Convertible Preferred Stock. The dividends may be settled after April 1, 2021, at the option of the Company, through any combination of the issuance of additional Series A Convertible Preferred Stock, shares of common stock, and /or cash payment. As of September 30, 2017, Series A Convertible Preferred Stock dividends totaling $130,010 or a payment-in-kind of 21,711 shares of Series A Convertible Preferred Stock, were earned, accumulated, and in arrears, as the Company's Board of Directors had not declared such dividends payable, and, as such, the Company has not recognized a Series A Convertible Preferred Stock dividend payable liability as of September 30, 2017, and will not recognize such dividend payable liability until they are declared by the Company's Board of Directors. Notwithstanding, the Company has presented such dividend value as a component of the loss attributable to common stockholders in the calculation of basic and diluted net loss per share.

The Series A Warrants may be exercised for one share of common stock at an exercise price of $6.65 per share, with such exercise price initially $8.00 per share at issuance, and subsequently adjusted to $6.67 per share upon the issuance of the Series S Warrants on July 3, 2017, and then to $6.65 per share upon the issuance of the Series A-1 Preferred Stock Units on August 4, 2017. The Series A Warrant exercise price is subject to further reduction by a prescribed formula on a weighted average basis in the event the Company issues common stock, options, or convertible securities at a price lower than the exercise price of Series A Warrants immediately prior to such securities issuance. The Series A Warrants expire after the close of business on April 30, 2024. The Series A Warrants are not subject to redemption.

Additionally, through their April 30, 2024 expiration date, each Series A Warrant, at the election of the holder, may be exchanged into four Series X Warrants. As of September 30, 2017, no Series A Warrants have been exchanged for Series X Warrants. Notwithstanding, the 422,838 Series A Warrants issued and outstanding at September 30, 2017, if exchanged would result in the issuance of 1,691,352 Series X Warrants. The Series X Warrants issued upon exchange of a Series A Warrant are exercisable for one share of common stock at $6.00 per share, with such Series X Warrant exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock. The Series X Warrants are exercisable commencing on the first trading day following October 31, 2018, and have a an April 30, 2024 expiration date, or earlier upon redemption by the Company.

During the time the Series A Warrants are outstanding, the holders will be entitled to participate in dividends or other distributions on a pro rata basis based upon the equivalent number of common shares that would have been outstanding had the warrants been fully exercised.

**Liquidity and Capital Resources** (continued)

*Series A Preferred Stock Units Private Placement (continued)*

The Company has filed an effective registration statement on Form S-1 (File No. 333-216963) registering for resale the maximum number of the Company's shares of common stock issuable upon conversion of the Series A Convertible Preferred Shares and the exercise of the Series A Warrants, or if exchanged, the Series X Warrants. Such registration statement also registered the resale of the Series X Warrants, and the initial issuance of the shares of common stock of the Company underlying the Series X Warrants to the extent the Series X Warrants are publicly sold prior to the exercise of such Series X Warrants. The Company timely filed the initial registration statement with the SEC on March 27, 2017, and such registration statement became effective on June 23, 2017, with such dates consistent with the requirements of the registration rights agreement entered into in connection with the Series A Preferred Stock Units private placement. If such registration statement effectiveness is not maintained, then, the Company is required to make payments to the investors of 2% of their Series A Preferred Stock Units subscription amount on the date of such event, and every thirty days thereafter until the effectiveness is cured.

See our unaudited condensed consolidated financial statements Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a discussion of the Series A Preferred Stock Units private placement, the Series A Convertible Stock, the Series A Warrants, and the Series X Warrants which may be issued upon the exchange of Series A Warrants, and Note 3, *Financial Instruments Fair Value Measurements*, for further detail regarding the fair value of the Series A Convertible Preferred Stock conversion option embedded derivative liability and the Series A Warrants liability.

*Cash flows and liquidity*

The following table sets forth the primary sources and uses of cash flows for each period set forth below:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2017 | 2016 |
| Net cash flows (used in) or provided by: | | |
| Operating activities | $ (5,021,134) | $ (3,251,887) |
| Investing activities | (5,301) | (21,793) |
| Financing activities | 7,552,211 | 4,295,062 |
| Net increase (decrease) in cash | 2,525,776 | 1,021,382 |
| Cash, beginning of period | 585,680 | 767,268 |
| Cash, end of period | $ 3,111,456 | $ 1,788,650 |

*Net cash flows used in operating activities*

The net cash flows used in operating activities in the nine months ended September 30, 2017 were $5,021,134 and consisted of a net loss of $10,389,113, adjusted for the $3,124,285 loss related to the issuance of Series A Preferred Stock Units, $680,851 resulting from the change in fair value of the Series A Warrants liability, and $76,150 resulting from the change in fair value of the Series A Convertible Preferred Stock conversion option embedded derivative liability, along with accrued interest payable of $187,500 and amortization of debt discount of $174,642, and, depreciation expense of $5,307, stock based compensation of $799,281, and a net increase of $319,963 in operating assets and liabilities, including a net decrease in prepaid expenses and other current assets of $52,218; and a net increase of $267,745 in accounts payable and accrued expenses.

The net cash flows used in operating activities for the nine months ended September 30, 2016 were $3,251,887 and consisted of a net loss of $3,940,337, adjusted for depreciation expense of $2,315, stock based compensation of $499,628, and a net increase of $186,507 in operating assets and liabilities, including a net increase of $355,564 in accounts payable and accrued expenses, offset by an increase of $169,057 in prepaid expenses and other current assets.

*Net cash flows used in investing activities*

Net cash flows used in investing activities in the nine months ended September 30, 2017 and 2016, related to the purchases of computer and research equipment, totaling $5,301 and $21,793, respectively.

*Net cash flows provided by financing activities*

Net cash flows provided by financing activities in the nine months ended September 30, 2017, were $7,552,211, comprised of $2,537,012, offset by $388,628 of offering costs, from the Series A Preferred Stock Units private placement, $500,000 from the Series A-1 Private Placement, $4,842,577 from the Scopia Note and Security Purchase Agreement, each as discussed herein above, along with $61,250 of cash proceeds from the exercise of IPO Warrants.

Net cash flows provided by financing activities in the nine months ended September 30, 2016, were $4,295,062, comprised of $5,300,00 of gross proceeds, offset by $1,004,938 of offering costs, from the issuance of units in our April 28, 2016 IPO.

**Critical Accounting Policies and Significant Judgments and Estimates**

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reported period. In accordance with U.S. GAAP, we base our estimates on historical experience and on various other assumptions we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

*Research and Development Expense*

Research and development expenditures are charged to research and development expense as incurred. Research and development costs include costs related to our various outside professional service providers and suppliers, engineering studies, supplies, outsourced testing and consulting as well as rental costs for access to certain facilities at one of our contract research suppliers.

*Stock Based Compensation*

The Company issues stock-based awards to employees, members of its board of directors, and non-employees. Stock-based awards to employees and members of its board of directors are accounted for in accordance with FASB ASC Topic 718, Stock Compensation, and stock based awards to non-employees are accounted for in accordance with FASB ASC Topic 505-50, Equity-Based Payments to Non-Employees.

The Company measures the compensation expense of stock-based awards granted to employees and members of its board of directors using the grant-date fair value of the award and recognizes compensation expense for stock-based awards on straight-line basis over the requisite service period, which is generally the vesting period of the respective stock option award.

The Company measures the expense of stock-based awards granted to non-employees on a vesting date basis, fixing the fair value of vested non-employee stock options as of the their respective vesting date, The fair value of vested non-employee stock options is not subject-to-change at subsequent reporting dates. The estimated fair value of the unvested non-employee stock options are remeasured to then current fair value at each subsequent reporting date. The expense of non-employee stock options is recognized on a straight-line basis over the service period, which is generally the vesting period of the respective non-employee stock option award.

*Fair Value Measurements*

FASB ASC Topic 820, *Fair Value* Measurement, (ASC 820) defines fair value as the price which would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at a transaction measurement date. The ASC 820 three-tier fair value hierarchy prioritizes the inputs used in the valuation methodologies, as follows:

Level 1 Valuations based on quoted prices for identical assets and liabilities in active markets.

Level 2 Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets which are not active, or other inputs observable or can be corroborated by observable market data.

Level 3 Valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

The carrying values of cash, accounts payable, and accrued expenses, approximate their respective fair value due to the short-term nature of these financial instruments at September 30, 2017 and December 31, 2016.

At September 30, 2017, the Series A Convertible Preferred Stock conversion option embedded derivative liability and the Series A Warrants liability were initially and are subsequently measured at fair value in accordance with ASC 820, using a Monte Carlo simulation valuation model, using the Company's common stock price and certain Level 3 inputs to take into account the probabilities of certain events occurring over the life of the respective financial instrument. At December 31, 2016 the Company did not have any assets or liabilities required to be measured at fair value on a recurring basis in accordance with ASC 820.

**Critical Accounting Policies and Significant Judgments and Estimates** (continued)

*Financial Instruments - Warrant Liability and Embedded Conversion Option Derivative Liability*

The Company evaluates its financial instruments to determine if those instruments or any potential embedded components of those instruments qualify as derivatives that need to be separately accounted for in accordance with FASB ASC Topic 815, *Derivatives and Hedging* (ASC 815). Warrants are classified as either equity or a derivative liability depending on the specific terms of the respective warrant agreement. Generally, warrants with cash settlement or certain exercise price adjustment provisions, are accounted for as a derivative liability. A warrant classified as a liability, or a bifurcated embedded derivative classified as a liability, is initially measured at its issue-date fair value, with such fair value subsequently adjusted at each reporting period, with the resulting adjustment recognized as other income or expense. If upon the occurrence of an event resulting in the warrant liability or the embedded derivative liability to be subsequently classified as equity, the fair value will be adjusted on such date-of-occurrence, with such date-of-occurrence fair value adjustment recognized as other income or expense, and then it will be classified as equity at such date-of-occurrence adjusted fair value.

The Series A Warrant and the Series A Convertible Preferred Stock conversion option, which is accounted for as an embedded derivative and bifurcated from its host financial instrument, were determined to be derivatives under ASC 815, as, along with other provisions, their conversion price and exercise price, respectively, are subject to potential adjustment resulting from future financing transactions, under certain conditions. The Series A Warrants and the Series A Convertible Preferred Stock conversion option embedded derivative are each classified as a current liability on the unaudited condensed consolidated balance sheet, and were initially measured at fair value at the time of issuance and are subsequently remeasured at fair value at each reporting period, with changes in fair value recognized as other income or expense in the unaudited condensed consolidated statement of operations.

The fair value of the Series A Warrants liability and the Series A Convertible Preferred Stock conversion option embedded derivative liability was determined using a Monte Carlo simulation valuation model - using the Company's common stock price and certain other Level-3 inputs to take into account the probabilities of certain events occurring over the life of the respective financial instrument. The resulting estimated fair value is subjective and is affected by changes in inputs to the valuation model including the Company's common stock price, and the assumptions regarding the estimated volatility in the value of the Company's common stock price; the Company's dividend yield; the likelihood and timing of dilutive transactions; and, the risk-free rates based on U.S. Treasury security yields. Changes in these assumptions can materially affect the estimated fair value of each financial instrument.

*Income Taxes*

The Company accounts for income taxes using the asset and liability method. Current tax liabilities or receivables are recognized for the amount of taxes estimated to be payable or refundable for the current year. Deferred tax assets and liabilities are recognized for estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, along with net operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company assesses the likelihood its deferred tax assets will be recovered from future taxable income, and to the extent it deems reasonable, based on available evidence, it is more-likely-than-not all or a portion of the deferred tax assets will not be realized, a valuation allowance reserve is established through a charge to income tax expense. To-date, the Company has recognized a full valuation allowance on its deferred tax assets.

*Going Concern*

The provisions of FASB ASC Topic 205-40, *Presentation of Financial Statements - Going Concern* (ASC Topic 205-40) requires management to assess an entity's ability to continue as a going concern within one year of the date of the financial statements are issued. In each reporting period (including interim periods), an entity is required to assess conditions known and reasonably knowable as of the financial statement issuance date to determine whether it is probable an entity will not meet its financial obligations within one year from the financial statement issuance date. Substantial doubt about an entity's ability to continue as a going concern exists when conditions and events, considered in the aggregate, indicate it is probable the entity will be unable to meet its financial obligations as they become due within one year after the date the financial statements are issued. We have incorporated specific disclosures within our financial statements stating there is substantial doubt regarding the Company's ability to continue as a going concern within one year from the financial statement issuance date. See Liquidity and Capital Resources above for a discussion of our liquidity and going concern status.

The Company's unaudited condensed consolidated financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities should the Company be unable to continue as a going concern.

**Recently Issued Accounting Standards**

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) - Part I - Accounting for Certain Financial Instruments with Down-Round Features, and Part II - Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* Principally, ASU 2017-11 amendments simplify the accounting for certain financial instruments with down-round features. The amendments require companies to disregard the down-round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. Companies that provide earnings per share (EPS) data will adjust their basic EPS calculation for the effect of the down-round feature when triggered (i.e., when the exercise price of the related equity-linked financial instrument is adjusted downward because of the down-round feature) and will also recognize the effect of the trigger within equity. Additionally, ASU 2017-11 also addresses "navigational concerns" within the FASB ASC related to an indefinite deferral available to private companies with mandatorily redeemable financial instruments and certain noncontrolling interests, which has resulted in the existence of significant "pending content" in the ASC. The FASB decided to reclassify the indefinite deferral as a scope exception, which does not have an accounting effect. The guidance of ASU 2017-11 is effective for public business entities, as defined in the ASC Master Glossary, for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and for all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Earlier adoption is permitted for all entities as of the beginning of an interim period for which financial statements (interim or annual) have not been issued or have not been made available for issuance. The Company is evaluating the impact of this guidance on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718) - Scope of Modification Accounting*. In ASU 2017-09, the FASB provides guidance on determining which changes to the terms and conditions of stock-based compensation arrangements require the application of "modification accounting" under ASC 718. Generally, ASC 718 modification accounting is not applicable if the stock-based arrangement immediately before and after the modification has the same fair value, vesting conditions, and balance sheet classification. The guidance of ASU 2017-09 is effective for all entities for annual periods, and interim periods within those annual periods, beginning December 15, 2017. Early adoption is permitted, including adoption in any interim period, for public business entities, as defined in the ASC Master Glossary, for periods for which financial statements have not yet been issued, and for all other entities for reporting periods for which financial statements have not yet been made available for issuance. The Company adopted this guidance as of April 1, 2017, and it did not have an effect on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, which amends the guidance of FASB ASC Topic 805, Business Combinations (ASC 805) adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (disposals) of assets or businesses. The objective of ASU 2017-01 is to narrow the definition of what qualifies as a business under Topic 805 and to provide guidance for streamlining the analysis required to assess whether a transaction involves the acquisition (disposal) of a business. ASU 2017-01 provides a screen to assess when a set of assets and processes do not qualify as a business under Topic 805, reducing the number of transactions that need to be considered as possible business acquisitions. ASU 2017-01 also narrows the definition of output under Topic 805 to make it consistent with the description of outputs under Topic 606. The guidance of ASU 2017-01 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years and early adoption is permitted under certain circumstances. The Company is evaluating the impact of this guidance on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, which amended the guidance of FASB ASC Topic 230, Statement of Cash Flows (ASC 230) on the classification of certain cash receipts and payments. The primary purpose of ASU 2016-15 is to reduce the diversity in practice which has resulted from a lack of consistent principles on this topic. The amendments of ASU 2016-15 add or clarify guidance on eight specific cash flow issues, including debt prepayment or debt extinguishment costs, settlement of zero-coupon debt instruments, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees, beneficial interests in securitization transactions, and separately identifiable cash flows and application of the predominance principle. The guidance of ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company is evaluating the impact of this guidance on its consolidated financial statements.

In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing* ("ASU 2016-10"). The amendments in ASU 2016-10 clarify the following two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. The amendments do not change the core principle of the guidance in Topic 606. The effective date and transition requirements for the amendments are the same as the effective date and transition requirements in Topic 606. The guidance is effective for the Company beginning January 1, 2018, although early adoption is permitted beginning January 1, 2017. The Company is currently evaluating the impact of this guidance on its consolidated financial position, results of operations and cash flows.

In March 2016, the FASB issued ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations* ("ASU 2016-08"). The amendments are intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations by amending certain existing illustrative examples and adding additional illustrative examples to assist in the application of the guidance. The effective date and transition requirements for the amendments are the same as the effective date and transition requirements in Topic 606. The guidance is effective for the Company beginning January 1, 2018, although early adoption is permitted beginning January 1, 2017. The Company is currently evaluating the impact of this guidance on its consolidated financial position, results of operations and cash flows.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"), which establishes a right-of-use (ROU) model requiring a lessee to recognize a ROU asset and a lease liability for all leases with terms greater-than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods with those fiscal years. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of this guidance on its consolidated financial position, results of operations, and cash flows.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606) and subsequently issued additional updates amending the guidance contained in Topic 606 thereby affecting the guidance contained in ASU 2014-09. ASU 2014-09 and the subsequent Topic 606 updates will supersede and replace nearly all existing U.S. GAAP revenue recognition guidance. The core principle of ASU 2014-09 is to recognize revenue when promised goods or services are transferred to customers in an amount equal to the consideration to which the entity expects to be entitled for those goods and services. ASU 2014-09 defines a five step process to achieve this core principle, and in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The standard is effective for annual periods beginning after December 15, 2017, including interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting the standard recognized at the date of adoption (which includes additional footnote disclosures). The Company is evaluating the guidance in ASU 2014-09 and the subsequent Topic 606 updates and has not yet determined what, if any, effect this guidance will have on its results of operations or financial condition.

**Contractual Obligations**

We entered into a Note and Security Purchase Agreement with Scopia Holdings LLC ("Scopia or the Lender"), under which, upon Scopia delivering to the Company $4.8 million in net cash proceeds by wire transfer on July 3, 2017, we issued to Scopia and its designees, a Senior Secured Note with an initial principal amount of $5.0 million ("Scopia Note"), and 2,660,000 Series S Warrants to purchase shares of common stock of the Company.

The Series S Warrants were immediately exercisable upon issuance, have an exercise price of $0.01 per share, with such exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock, and may be exercised for cash or on a cashless basis. The Series S Warrants expire June 30, 2032, with any warrants outstanding on such date will be automatically cashless exercised.

The Scopia Note bears interest at a fixed annual rate of 15.0%, with interest payable semi-annually in arrears on June 30 and December 30 of each calendar year, commencing on December 30, 2017. We may elect, at our sole discretion, to defer payment of up to 50% of the semi-annual interest due, with the remaining unpaid portion added to and increasing the outstanding interest-bearing principal balance of the Scopia Note by such amount of the deferred interest payment. The aggregate remaining unpaid principal balance of the Scopia Note is due on June 30, 2019.

At our discretion, the aggregate principal balance of the Scopia Note and any earned and unpaid interest may be repaid at any time without penalty or premium. Additionally, under the Scopia Note, if we sell our implantable intraosseous vascular access device (the "PortIO Product"), then the Scopia Note holders' may require us to repay the then outstanding aggregate principal amount of the Scopia Note, in whole or in part, together with any accrued interest thereon, from the proceeds of such PortIO Product sale, provided such principal and interest payment is limited to the amount of the net cash proceeds from such PortIO Product sale.

The Note and Security Purchase Agreement with Scopia contains various customary negative covenants of the Company including restrictions on incurring any additional indebtedness or liens or declaring or paying any dividends, subject to certain exceptions provided for in the Note and Security Purchase Agreement with Scopia while any amount under the Scopia Note remains outstanding, and also contains certain affirmative covenants of the Company, including, among others:

- If the PortIO Product obtains initial FDA 510(k) clearance, then, commencing four months after such FDA 510(k) clearance, we will use our reasonable best efforts to attempt to sell the PortIO Product on commercially reasonable terms for an amount not less than $10.0 million. If the net cash proceeds are $10.0 million or greater from such PortIO product sale, and there are no continuing obligations imposed on the Company, which would constitute an undue burden on the Company, resulting from such PortIO Product sale transaction, then the Scopia Note holders may request us to repay the then aggregate remaining unpaid principal balance of the Scopia Note. Notwithstanding, such Note and Securities Purchase Agreement provision has been rendered moot, as the FDA has indicated the PortIO Product will be reviewed for approval under a regulatory pathway other than a 510(k) clearance;

- Effective with the first bi-monthly payroll in July 2017, our CEO agreed to the payment of a reduced salary of $4,200 per month, with the payment of the earned but unpaid salary amount deferred until the earlier to occur of (a) the date that FDA 510(k) clearance for the PortIO Product is obtained or (b) the date the aggregate remaining unpaid principal balance of the Scopia Note is repaid in full; and,

- We agreed to use its commercially reasonable best efforts to file a registration statement with the U.S. Securities and Exchange Commission (SEC) registering for resale of all of the shares of common stock underlying the Series S Warrants with such registration statement having an effectiveness date on or before November 27, 2017.

Additionally, the Note and Security Purchase Agreement with Scopia provides, for so long as the Lender holds at least 50% of the aggregate remaining unpaid principal balance of the Scopia Note, the Lender shall have the ability to nominate one individual to the Company's board of directors, provided the board of directors shall have the right to reject any such Lender nominee if it determines in good faith such Lender nominee is not reasonably acceptable. In this regard, on August 3, 2017, the Lender nominee was appointed to the Company's board of directors.

Payment of all amounts due and payable under the Scopia Note are guaranteed by the Company, and the obligations under the Scopia Note are secured by all of the assets of the Company pursuant to the terms of a Note and Guaranty Security Agreement. The Lender may transfer or assign all or any part of the Scopia Note to any person with the prior written consent of the Company, provided no consent shall be required from the Company for any transfer to an affiliate of the Lender, or upon the occurrence and during the continuance of an Event of Default, as defined in the Scopia Note.

**Contractual Obligations** (continued)

The Company leases office space for its corporate office, which initially provided for two consecutive six month terms beginning on February 1, 2016, rent payments of $9,500 per month and the option to cancel the lease agreement at the end of the initial six-month term at the election of the Company. Subsequently, the lease agreement was amended to add additional office space at an additional rate of $4,400 per month, and extended the lease term through May 31, 2017. The lease agreement includes a 5% increase in monthly rent effective on each twelve month anniversary date. Effective March 1, 2017, the rented office space was reduced, resulting in a $650 per month reduction of the monthly lease payment, and effective August 1, 2017, the rented office space was further reduced, resulting in a $3,938 per month reduction of the monthly lease payment. Upon the May 31, 2017 termination date, the lease agreement converted to a month-to-month lease, which may be cancelled by the Company with three months written notice. Total rent expense incurred under the corporate office space lease arrangement was $33,863 and $117,351 for the three and nine months ended September 30, 2017, respectively, and $41,406 and $92,656 for the three and nine months ended September 30, 2016, respectively. At September 30, 2017, the Company's future minimum lease payments totaled $123,690 for the period October 1, 2017 to September 30, 2018, with respect to the lease arrangement on a month-to-month basis.

Effective October 2015, the Company entered into a three-year management services agreement through October 2018 with HCP/Advisors LLC, an affiliate of a director of the Company. Pursuant to the HCP/Advisors LLC agreement, such entity has agreed to provide the Company with certain management services, including without limitation identifying potential corporate opportunities, general business development, corporate development, corporate governance, marketing strategy, strategic development and planning, coordination with service providers, and other advisory services as may be mutually agreed upon. The Company has agreed to pay HCP/Advisors LLC an initial monthly fee of $35,000 commencing as of November 1, 2015, and thereafter, a monthly fee of $25,000 through October 31, 2018. Under this agreement, the Company incurred fees of $75,000 and $225,000 in each of the three and nine months ended September 30, 2017 and 2016, respectively.

Effective September 2016, the Company and HCFP/Strategy Advisors LLC, an affiliate of certain directors and officers of the Company, entered into a management consulting agreement referred to as the "HCFP Strategic Advisory Agreement", which, as discussed below, expired on May 14, 2017. Under the HCFP Strategic Advisory Agreement, HCFP/Strategy Advisors LLC had been engaged for an initial term of five months from September 14, 2016 to February 14, 2017, to provide various management consulting advisory services, including: to provide strategic business planning, to identify and assist with potential sources of financing arrangements, to promote the Company to various potential investors, and to provide strategic advisory services as reasonably requested by the Company. The HCFP Strategic Advisory Agreement provided for an initial total fee of $110,000, with $30,000 paid upon execution of the agreement and four payments of $20,000 per month from October 2016 to January 2017. Subsequently, on February 17, 2017, the Company and HCFP/Strategy Advisors LLC executed an extension of the HCFP Strategic Advisory Agreement, effective as of February 15, 2017, extending the services from February 15 to May 14, 2017, and obligating the Company to make three payments of $20,000 per month in February, March, and April 2017. The Company did not further renew the HCFP Strategic Advisory Agreement after the May 14, 2017 expiration date. Previously, at December 31, 2016, the Company recognized a $10,000 estimated accrued expense liability for HCFP/Strategy Advisors LLC asserted out-of-pocket expenses under the HCFP Strategic Advisory Agreement in effect as of December 31, 2016. Subsequently, at June 30, 2017, the Company reversed such $10,000 estimated accrued expense liability, as supporting documentation had not been provided by HCFP/Strategy Advisors LLC. As of June 30, 2017, the Company has made all contractually obligated payments to, and has disclaimed any further payment obligations, under the HCFP Strategic Advisory Agreement.

Separately, at June 30, 2017, the Company recognized a $10,000 accrued expense liability in connection with a HCFP/Strategy Advisors LLC vendor invoice dated June 30, 2017 in the amount of $10,000 for professional services fees related to separate discrete discussions between the Company's management and HCFP /Strategy Advisors LLC conducted between the period of May 15, 2017 to May 31, 2017 regarding corporate matters. Such discussions were separate and apart from the previously expired HCFP Strategic Advisory Agreement.

The Company incurred expense of $0 and $80,000 in the three and nine months ended September 30, 2017, respectively, and $30,000 in the three and nine months ended September 30, 2016, under the HCFP Strategic Advisory Agreement and the HCFP/Strategy Advisors LLC discrete invoice dated June 30, 2017, as noted above.

In January 2017, the Company entered into an agreement with Xzerta Trading LLC d/b/a HCFP/Capital Markets ("HCFP/Capital Markets"), an affiliate of certain directors and officers of the Company, wherein HCFP/Capital Markets was engaged to be the Company's exclusive placement agent in an offering of securities ("the HCFP/Capital Markets Placement Agent Agreement"), including the Series A Preferred Stock Units private placement transaction. Under the HCFP /Capital Markets Placement Agent Agreement, HCFP/Capital Markets is paid a fee of 7.0% of the gross proceeds realized in the securities offering, plus reimbursement of certain out-of-pocket costs. The term of the HCFP/Capital Markets Placement Agent Agreement is from the January 2017 execution date to the completion or termination of any other potential transactions in conjunction with the Series A Preferred Stock Units private placement. The Company incurred $0 and $177,576 of fees paid to HCFP/Capital Markets in connection with the issuances of Series A Preferred Stock Units in the three and nine months ended September 30, 2017, respectively, which are included in "Loss on the issuance of preferred stock units" in the accompanying unaudited condensed consolidated statements of operations.

**Contractual Obligations** (continued)

Effective November 1, 2014, the Company entered into an employment agreement with its CEO (the "CEO Employment Agreement") for a five-year term, with a current base salary of $295,000 per year. On April 28, 2016, upon consummation of the IPO, the CEO was granted a stock option to purchase 278,726 shares of the Company's common stock with an exercise price equal to $5.00 per share. Effective on January 1, 2016, the CEO Employment Agreement provides for a guaranteed bonus equal to 50% of base salary, beginning on January 1 of each year. Additionally, the CEO will also be eligible to earn discretionary annual performance bonuses upon meeting certain objectives as determined by the Board of Directors. Effective as of December 31, 2016, the CEO agreed to waive his right to the guaranteed bonus for the year ended December 31, 2016. Under the terms of the Note and Security Purchase Agreement between the Company and Scopia Holdings LLC, effective with the first bi-monthly payroll in July 2017, the CEO agreed to the payment of a reduced salary of $4,200 per month, with the payment of the earned but not paid amount to be deferred until the earlier to occur of: (i) the date FDA 510(k) clearance is obtained for the for the Company's implantable intraosseous vascular access device (the "PortIO Product"); or, (ii) the date the borrowings due Scopia Holdings LLC are repaid-in-full. The CEO Employment Agreement contains provisions for the protection of the Company's intellectual property and contains non-compete restrictions in the event of his termination other than without "cause" or by the board of directors with "good reason."

Effective March 20, 2017, the Company entered into a two-year employment agreement with its current Chief Financial Officer with a base salary of $285,000 per year. The Chief Financial Officer will be eligible to earn discretionary annual performance bonuses upon meeting certain objectives as determined by the Board of Directors.

Effective July 1, 2016, the Company entered into a five-year employment agreement with its Chief Medical Officer with a base salary of $285,000 per year, plus an initial payment of $50,000. The Chief Medical Officer will be eligible to earn discretionary annual performance bonuses upon meeting certain objectives as determined by the Board of Directors.

On March 20, 2017, Richard F. Fitzgerald resigned as our (former) Chief Financial Officer and the Company and Mr. Fitzgerald entered into a separation agreement, under which Mr. Fitzgerald executed a general release and waiver in favor of the Company. Mr. Fitzgerald remained a full-time employee through March 31, 2017. In connection with his employment termination, on March 31, 2017, the Company entered into a consulting agreement with Mr. Fitzgerald, providing for his engagement as an advisor at a fee of $10,000 per month for April, May, and June 2017, and the continuation of health insurance benefits from April 1, 2017 to June 30, 2017, as well as a single $2,200 payment on April 30, 2017 for temporary housing and travel expenses. The Company recognized an expense of $41,240 at March 31, 2017 as an accrued liability related to the termination benefits, with such obligation fully settled as of June 30, 2017.

Effective June 30, 2017, the Company and Michael J. Glennon, Vice Chairman and a member of the Company's Board of Directors, mutually agreed to terminate the consulting agreement between the Company and Mr. Glennon (the "Glennon Consulting Agreement"). Previously, effective October 1, 2016, the Company and Mr. Glennon entered into the Glennon Consulting Agreement, under which Mr. Glennon provided the Company with services and advice relating to the successful development and commercialization of medical device products. Effective as of December 31, 2016, Mr. Glennon and the Company entered into an agreement whereby Mr. Glennon waived his right to compensation under the Glennon Consulting Agreement for the year ended December 31, 2016, and, effective as of March 31, 2017, Mr. Glennon and the Company entered into a second agreement whereby Mr. Glennon further waived his right to compensation under the Glennon Consulting Agreement for the period January 1, 2017 through June 30, 2017. As of June 30, 2017, there were no amounts payable under the Glennon Consulting Agreement.

**JOBS Act**

We are an EGC, as defined in the JOBS Act and are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy or information statements, and not being required to adopt certain new and revised accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to avail ourselves of the extended time for the adoption of new or revised f accounting standards, and, therefore, will not be subject to the same new or revised accounting standards as public companies that are not emerging growth companies.

**Off-Balance sheet arrangements**

We do not have any off-balance sheet arrangements, as defined by applicable SEC regulations.

**Effect of Inflation and Changes in Prices**

We do not expect inflation and changes in prices will have a material effect on our operations.

## Item 3. Quantitative and qualitative disclosures about market risk

Not applicable to smaller reporting companies.

## Item 4. Controls and procedures

**Evaluation of disclosure controls and procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2017, the end of the period covered by this Quarterly Report on Form 10-Q.

Based on our evaluation, we believe our disclosure controls and procedures as of September 30, 2017 have been designed and are functioning effectively to provide reasonable assurance the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. We believe a controls system, no matter how well designed and operated, cannot provide absolute assurance the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance all control issues and instances of fraud, if any, within a company have been detected.

Our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. As a result, it is possible, had our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, material weaknesses and significant control deficiencies may have been identified. However, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

**Changes in internal control over financial reporting**

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 2. Unregistered Sales of Equity Securities

None, except as previously reported in the Company's Current Reports on Form 8-K.

### Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

## EXHIBIT INDEX

| Exhibit No. | Description |
|---|---|
| 31.1 | Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification of Principal Financial and Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema |
| 101.CAL | Taxonomy Extension Calculation Linkbase |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase |

**SIGNATURE**

Pursuant to the requirements of Section 13 or 15(d) 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.

PAVmed Inc.

Date: November 14, 2017

By: */s/ Dennis M. McGrath*
Dennis M. McGrath, Chief Financial Officer
(Principal Financial and Accounting Officer)

**Exhibit 31.1**

**CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER**

I, Lishan Aklog, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PAVmed Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2017

By: */s/ Lishan Aklog, M.D.*

Lishan Aklog, M.D., Chief Executive Officer

*(Principal Executive Officer)*

**Exhibit 31.2**

**CERTIFICATION BY PRINCIPAL FINANCIAL OFFICER**

I, Dennis M. McGrath, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PAVmed Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2017

By: */s/ Dennis M. McGrath*

Dennis M. McGrath, Chief Financial Officer

*(Principal Financial and Accounting Officer)*

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of PAVmed Inc. (the "Company") for the quarter ended September 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lishan Aklog, M.D., Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2017

By: */s/ Lishan Aklog, M.D.*
Lishan Aklog, M.D., Chief Executive Officer
*(Principal Executive Officer)*

**Exhibit 32.2**

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of PAVmed Inc. (the “Company”) for the quarter ended September 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Dennis M. McGrath, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2017

By: */s/ Dennis M. McGrath*
Dennis M. McGrath, Chief Financial Officer
*(Principal Financial and Accounting Officer)*