UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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 **(State or Other Jurisdiction of Incorporation or Organization)**	**47-1214177** **(IRS Employer Identification No.)**
One Grand Central Place **60 E. 42nd Street** **Suite 4600** **New York, NY 10165** **(Address of Principal Executive Offices)**	**10165** **(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
Series W 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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the ExchangeAct. Yes [ ] No [X]

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 if disclosure of delinquent files pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[ ] ()	Smaller reporting company	[X]
Do not check if a smaller reporting company		Emerging Growth Company (EGC)	[X]

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 June 30, 2017, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's voting stock held by non-affiliates was approximately $21.3 million, based on the last reported sales price per share of the registrant's common stock on such date.

As of March 12, 2018 there were 17,235,397 shares of the registrant's Common Stock, par value $0.001 per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2018 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K where indicated. Such definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the year ended December 31, 2017.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K of PAVmed Inc. ("we", "us", "our" or "PAVmed" or "the Company") contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, 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. Forward-looking statements are not guarantees of future performance and the Company's actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in Item 1A of Part I of this Form 10-K under the heading "Risk Factors," which are incorporated herein by reference.

Important factors that may affect our actual results include:

- 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;
- potential ability to obtain additional financing when and if needed;
- 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
- the time during which we will be an Emerging Growth Company ("EGC") under the Jumpstart Our Business Startups Act of 2012, or JOBS Act.

We may not actually achieve the plans, intentions, and /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. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future financings, acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report on Form 10-K and the documents we have filed as exhibits to this Annual Report on Form 10-K 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.

PART I

Item 1. Business

Background and Overview

PAVmed is a highly-differentiated multi-product medical device company organized to advance a broad pipeline of innovative medical technologies we believe address unmet clinical needs and possess attractive market opportunities to commercialization. Our goal is to enhance and accelerate value creation by employing 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. As resources permit, we will continue to explore internal and external innovations that fulfill our project selection criteria without limiting ourselves to any target specialty or condition.

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. 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, ("Scopia" or the "Lender") 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 summarized in "—Recent Events" below. In January 2018, the Company raised $4,3 million of net cash proceeds in an underwritten public offering of shares of common stock of the Company, pursuant to its previously filed effective shelf registration statement on SEC Form S-3 (File No. 333-220549), each as summarized in "—Recent Events" below.

The following is a brief overview of the products currently in our pipeline, including our lead products of CarpX™, PortIO™, and DisappEAR™. These products are all in various phases of development and have not yet received regulatory approval. Among other things:

- We have filed final nonprovisional patent applications for PortIO™ and CarpX™, 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 our DisappEAR™ product.

- We have 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. On November 27, 2017 we filed a 510(k) premarket notification submission with the Federal Food and Drug Administration ("FDA") for CarpX™ using a commercially available carpel tunnel release device as a predicate. We have received promising initial feedback from the FDA and are working to provide additional non-clinical support for our application. In addition, we are preparing to submit for CE Mark clearance in Europe and a first-in-man clinical series outside of the United States. We are exploring commercialization strategies in the United States and commercialization partnerships worldwide.

- We have 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 a *de novo* pre-submission package with the FDA, which was followed by an in-person meeting on January 9, 2018 to discuss the risk assessment and proposed mitigation for the *de novo* application. Based on FDA recommendations, we will initiate a seven-day animal study, having successfully completed a pilot animal study which showed excellent function of the device over the seven-day implant period and on explant. In anticipation of having to follow-up the animal study with a human clinical safe trial, we have accelerated our strategic partnership efforts to include the pre-clearance phase.

- We have advanced, in partnership with our design and contract manufacturing partners and our academic partners at Tufts University and Harvard Medical School, our DisappEAR™. Our efforts have focused on sourcing commercially ready aqueous silk and optimizing manufacturing processes consistent with the necessary cost of good for the commercial product.

- Although we have focused the majority of our resources on our lead products, we have additional products in our pipeline which are currently in different stages of development. We have completed initial design work on the first product in the NextCath™ product line, 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.

Background and Overview (continued)

- We have 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. We have completed benchtop testing of a working prototype demonstrating constant flows across the range of pressures encountered in clinical situations. We will be able to quickly move NextCath™ and NextFlo™ into the commercial and regulatory pathway when resources become available.

- 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.

- 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.

- 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.

- 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.

We have proprietary rights to the trademarks used herein, including, among others, PAVmed™, PortIO™, Caldus™, CarpX™, DisappEAR™, NextCath™, NextFlo™, and "Innovating at the Speed of Life"™, among others. Solely as a matter of convenience, trademarks and trade names referred to herein may or may not be accompanied with the requisite marks of "™" and /or "®", however, the absence of such marks is not intended to indicate, in any way, we will not assert, to the fullest extent possible under applicable law, our rights or the rights to such trademarks and trade names.

Corporate History

The Company was incorporated on June 26, 2014 in the State of Delaware. On April 19, 2015, our name was changed to PAVmed Inc. from PAXmed Inc., which was the Company's initial name.

Our business address is One Grand Central Place, 60 East 42nd Street, Suite 4600, New York, New York 10165, and our telephone number is (212) 949-4319. Our corporate website is www.PAVmed.com.

Our founders are three accomplished medical device entrepreneurs, including: Dr. Lishan Aklog M.D., Michael J. Glennon, and Dr. Brian J. deGuzman, M.D. Together, they founded: in 2007, Pavilion Holdings Group ("PHG"), a medical device holding company, and in 2009, Pavilion Medical Innovations ("PMI"), a venture-backed medical device incubator. Between 2008 and 2013, PHG and PMI founded the following four distinct, single-product medical device companies:

- Vortex Medical Inc. was founded in 2008 with $3.5 million in capital. It created the AngioVac system, designed to remove large volume clots and other undesirable intravascular material. It received its initial U.S. Food and Drug Administration ("FDA") clearance in 16 months after the company was founded. AngioVac was first commercialized at Brigham and Women's Hospital in December 2009. Vortex Medical marketed the AngioVac system across the United States until it was acquired in October 2012 by AngioDynamics Inc. (NASDAQ: ANGO) for $55.0 million in guaranteed consideration. At the time of its acquisition the company was cash-flow positive, carried no debt and its sole funding source was $3.5 million of capital raised.

- Saphena Medical Inc. was founded in 2013 with $3.0 million in capital. It created the VenaPax next-generation endoscopic vessel harvest device for use during coronary artery bypass surgery, which received FDA clearance in 18 months after the company was founded. VenaPax was first commercialized at Massachusetts General Hospital in October 2014. VenaPax is currently being marketed across the United States.

- Cruzar Medsystems Inc. was founded in 2013 with $2.5 million in capital. It has created a novel peripheral chronic total occlusion (CTO) device for use in peripheral arterial disease, which received its initial FDA 510(k) clearance in December 2015. It was first commercialized in May 2016 and is currently being marketed across the United States.

- Kaleidoscope Medical LLC was founded in 2013 with $1.5 million in capital. It has created a novel, reversible inferior vena caval filter which was submitted to the FDA for 510(k) clearance in 16 months. It is currently seeking additional capital to complete a clinical safety study.

PAVmed was created to adapt this model to a multi-product company with access to public capital markets. We believe this model allows us to conceive, develop and commercialize our pipeline of medical device products using significantly less capital and time than a typical medical device company, and provide a streamlined pathway to incorporate outside innovations.

Corporate History (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. On April 28, 2016, upon the issuance of the IPO Units, the 9,560,295 remaining unexercised warrants previously issued in private placements before the IPO, were converted into warrants identical to those issued in the Company's IPO. We refer to all such warrants collectively as "Series W Warrants", inclusive of those issued in private placements prior to those issued in our IPO. 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, are currently exercisable, and expire on January 29, 2022 or earlier upon redemption by the Company, under certain conditions.

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.

As of December 31, 2017 and 2016, there were 14,551,234 and 13,330,811 shares of common stock and 10,567,845 and 10,580,095 Series W Warrants issued and outstanding, respectively. Subsequently, in January 2018, the Company issued to-date, a total of 2,649,818 shares of common stock in an underwritten public offering under a previously filed and effective shelf registration statement, and in February 2018, issued 34,345 shares of common stock upon the exercise of a corresponding number of Series W Warrants, each as discussed herein below in "— Recent Events - Financing Transactions", under the captions "*Issue of Common Stock - Underwritten Public Offering - January 2018*" and "*Series W Warrants Offer-to-Exercise*", respectively. Accordingly, as of the date hereof, there were 17,235,397 shares of common stock and 10,533,500 Series W Warrants issued and outstanding.

Recent Events

Regulatory Events

On November 27, 2017 we filed a 510(k) premarket notification submission with the FDA for our CarpX™ minimally invasive device designed to treat carpal tunnel syndrome, using a commercially available carpal tunnel release device as a predicate. We have received promising initial feedback from the FDA and are working to provide additional non-clinical support for our application.

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 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. After further discussion with the FDA, we 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 filed a *de novo* pre-submission package with the FDA which was followed by an in-person meeting on January 9, 2018 to discuss the risk assessment and proposed mitigation testing for the *de novo* application. Based on their recommendations we will initiate a seven-day animal study, having successfully completed a pilot animal study which showed excellent function of the device over the seven-day implant period and on explant. In anticipation of having to follow up the animal study with a human clinical safety trial, we have accelerated our strategic partnership efforts to include the pre-clearance phase.

Financing Transactions

Shareholders' Rights Offering

On January 17, 2018, we filed an initial registration statement on Form S-1 (File No. 333-222581), currently under SEC review, related to a proposed offering wherein, as currently proposed, we will distribute one transferable equity subscription right for each issued and outstanding share of common stock of the Company as of a record date to be determined by our Board of Directors ("Equity Subscription Rights Offering" or "Rights Offering"). As currently proposed, the Rights Offering is to commence upon an effective registration statement. Further, as currently proposed, for a period of 30 days from their distribution date, the transferable equity subscription right may be exercised for $2.25 per unit to purchase a common stock unit comprised of one share of common stock of the Company and one Series Z Warrant. As currently proposed, the common stock unit will trade for up to 90 days, after which it will separate into its underlying components of one share of common stock of the Company and one Series Z Warrant. The Series Z Warrant may be exercised for one share of common stock of the Company at an exercise price of $3.00 per share, with such exercise price and the number of underlying shares not subject to further adjustment, except for the effect of stock dividends, stock splits or similar events affecting the common stock. The Series Z Warrants will expire after the close of business on April 30, 2024, and are redeemable by the Company under certain conditions.

Recent Events (continued)

Financing Transactions (Continued)

Issue of Common Stock - Underwritten Public Offering

In January 2018, we conducted an underwritten public offering pursuant to a previously filed and effective shelf registration statement on SEC Form S-3 (File No. 333-220549), declared effective October 6, 2017, along with a corresponding prospectus supplement dated January 19, 2018. On January 19, 2018, we entered into an underwriting agreement with Dawson James Securities, Inc., as sole underwriter, under which we agreed to issue to the underwriter at $1.80 per share, 2,415,278 shares of common stock on a firm commitment basis and up to an additional 362,292 shares solely to cover underwriter over-allotments, if any, at the option of the underwriter, exercisable within 45 calendar days from January 19, 2018. The Company issued the 2,415,278 shares on January 23, 2018, and on January 25, 2018, issued 234,540 shares of common stock, under the underwriter's over-allotment, resulting in net cash proceeds of $4,263,099, after deduction of both underwriting discounts of $381,574 and estimated offering costs.

Series A and Series A-1 Exchange Offer - Series B Convertible Preferred Stock and Series Z Warrants

On February 14, 2018, we initiated an exchange offer to the holders of both the Series A Convertible Preferred Stock and Series A Warrants, and the Series A-1 Convertible Preferred Stock and Series A-1 Warrants ("Series A and Series A-1 Exchange Offer"), as follows: (i) one share of Series A Convertible Preferred Stock exchanged for two shares of Series B Convertible Preferred Stock, and one Series A Warrant exchanged for five Series Z Warrants; and (ii) one share of Series A-1 Convertible Preferred Stock exchanged for 1.33 shares of Series B Convertible Preferred Stock, and one Series A-1 Warrant exchanged for five one Series Z Warrants. A condition of the Series A and Series A-1 Exchange Offer is for all outstanding shares of Series A Convertible Preferred Stock and all Series A Warrants, and all shares of Series A-1 Convertible Preferred Stock and all Series A-1 Warrants, must be tendered. If not all are tendered, then the Company reserves the right to not accept any tenders. The Series A and Series A-1 Exchange Offer is scheduled to expire on March 15, 2018, unless extended, at our sole discretion.

The Series B Convertible Preferred Stock has a par value of $0.001 per share, no voting rights, a stated value of $3.00 per share, and is immediately convertible upon its issuance. At the holders' election, one share of Series B Convertible Preferred Stock is convertible into one share of common stock of the Company, based on a common stock conversion exchange factor equal to a numerator of $3.00 and a denominator of $3.00, with such denominator 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 B Convertible Preferred Stock shall not be redeemed for cash and under no circumstances shall the Company be required to net cash settle the Series B Convertible Preferred Stock.

The Series B Convertible Preferred Stock provides for dividends at a rate of 8% per annum on the stated value of the Series B Convertible Preferred Stock, with such dividends compounded quarterly, accumulate, and payable in arrears upon being declared by the Company's Board of Directors. The Series B Convertible Preferred Stock dividends from April 1, 2018 through October 1, 2021 are payable-in-kind ("PIK") in additional shares of Series B 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 B Convertible Preferred Stock, shares of common stock, and /or cash payment.

The Series Z Warrants issued in the Series A and Series A-1 Exchange Offer will be immediately exercisable upon issuance and expire after the close of business on April 30, 2024, and each may be exercised for one share of common stock of the Company at an exercise price of $3.00 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. The Series Z Warrants are redeemable by the Company under certain conditions.

Series W Warrants Offer-to-Exercise

On January 11, 2018, we filed with the SEC a Tender Offer Statement on Schedule TO offering Series W Warrants holders a temporary exercise price of $2.00 per share ("Series W Warrants Offer-to-Exercise"). As of the February 8, 2018 expiry of the Series W Warrants Offer-to-Exercise, a total of 34,345 Series W Warrants were exercised at the temporary exercise of $2.00 per share, resulting in $68,690 of cash proceeds, and the issue of a corresponding number of shares of common stock of the Company.

Series W Warrants Offer-to-Exchange

On February 20, 2018, we filed with the SEC a Tender Offer Statement on Schedule TO offering to exchange two Series W Warrants for one Series Z Warrant, with such exchange offer expiring on March 19, 2018 ("Series W Warrants Offer-to-Exchange"). The Series Z Warrants issued upon exchange of the Series W Warrants will be immediately exercisable upon issuance and expire after the close of business on April 30, 2024, and each may be exercised for one share of common stock of the Company at an exercise price of $3.00 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. The Series Z Warrants are redeemable by the Company under certain conditions.

Recent Events (continued)

Financing Transactions (Continued)

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 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 ("Senior Secured Note"), and 2,660,000 Series S Warrants to purchase shares of common stock of the Company.

The Senior Secured 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 payment, with such deferred amount added to and increasing the outstanding interest-bearing principal balance of the Senior Secured Note by such amount. As of December 31, 2017, the Senior Secured Note principal balance is $5,188,542, including $188,542 of deferred interest payment. The aggregate remaining unpaid principal balance of the Senior Secured 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. In each of October 2017 and November 2017, 532,000 (or a total of 1,064,00) Series S Warrants were exercised for total cash proceeds of $10,640, resulting in the issuance of a corresponding number of shares of common stock of the Company, and in November 2017, a total of 122,360 Series S Warrants were exercised on a cashless basis, resulting in the issuance of a total of 122,080 shares of common stock of the Company. Accordingly, at December 31, 2017, there were 1,473,640 Series S Warrants issued and outstanding.

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

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, 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.

On, August 4, 2017, we entered into a Securities Purchase Agreement, as amended, 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), and on such date, issued a total of 125,000 Series A-1 Preferred Stock Units 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.

On November 17, 2017 ("November 17, 2017 Exchange Date"), the Company completed an exchange offer initiated on October 20, 2017 to the 28 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, one Series A Warrant for one Series A-1 Warrant ("Series A Exchange Offer") - resulting in 154,837 shares of Series A Convertible Preferred Stock exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock, and 154,837 Series A Warrants exchanged for 154,837 Series A-1 Warrants, by 13 holders on the November 17, 2017 Exchange Date. Accordingly, as of December 31, 2017, 357,259 shares of Series A-1 Convertible Preferred Stock and 279,837 Series A-1 Warrants were each issued and outstanding.

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 Events (continued)

Financing Transactions (Continued)

Series A Preferred Stock Units Private Placement

Our 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. 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.

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). On the January 26, 2017 initial closing date of the Series A Preferred Stock Units private placement, 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.

In addition to the 154,837 shares of Series A Convertible Preferred Stock exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock, and the 154,837 Series A Warrants exchanged for 154,837 Series A-1 Warrants in the Series A Exchange Offer, a total of 18,334 shares of Series A Convertible Preferred Stock were converted into a total of 22,093 shares of common stock of the Company during the year ended December 31, 2017. Accordingly, as of December 31, 2017, 249,667 shares of Series A Convertible Preferred Stock and 268,001 Series A Warrants were each issued and outstanding.

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.

Other Events

Nasdaq Notice

On March 5, 2018, we received a notice from the Nasdaq Listing Qualifications Department stating that, for the prior 30 consecutive business days through March 2, 2018, the market value of our listed securities ("MVLS") had been below the minimum of $35 million required for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). The notification letter stated we would be afforded 180 calendar days, or until September 4, 2018, to regain compliance. In order to regain compliance, our MVLS must remain at or above $35 million for a minimum of ten consecutive business days. The notification letter also states in the event we do not regain compliance within the 180-day-period, our securities may be subject to delisting. In the event we receive a delisting determination, we may appeal such determination to a Nasdaq Hearings Panel.

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.

Our Business Model

In contrast to pharmaceuticals and other life science technologies, which typically require long and capital-intensive paths to translate cellular or biochemical processes into commercially-viable therapeutics or diagnostics, we believe that medical devices have the potential to move much more rapidly from concept to commercialization with significantly less capital investment. Many commercially successful medical devices are often elegant solutions to important and prevalent clinical problems. Most medical device companies, however, are not structurally or operationally equipped to fulfill this potential. According to a report by Josh Makower, M.D., Consulting Professor of Medicine at Stanford University, the typical medical device company will spend over $31.0 million and take approximately five years to develop and commercialize a product through the FDA's 510(k) pathway and over $100.0 million and seven or more years through the FDA's Premarket Approval ("PMA") pathway.

Prior to forming PAVmed, our leadership team established a model to realize this potential in single-product companies by advancing medical device products from concept to commercialization using significantly less capital and time than a typical medical device company. When previously applied to single-product venture backed companies, the model utilized a virtual business structure. PAVmed's structure enables us to retain the model's tight focus on capital and time efficiency and the core elements which drive that efficiency, including limited infrastructure and low fixed costs, while taking advantages of the economies of scale and flexibility inherent in a multi-product company.

Project Selection

A key element of our model is the project selection process. We choose projects to develop and commercialize based on characteristics which contribute to a strong commercial opportunity. We place a heavy emphasis on medical device products with the potential for high-margins and high-impact in attractive markets without regard to the target specialty or clinical area.

Our project selection process begins with the identification of an unmet clinical need. We seek prevalent medical conditions where we believe an opportunity exists to advance the care of the patient through improvements in existing technologies or the introduction of new platform technologies. In the current healthcare environment, this usually means that our products have to be less invasive and more cost effective. We select projects which we believe have the potential to lessen procedural invasiveness and/or the opportunity to shift care from the surgical operating room to lower-cost venues such as the interventional suite or the ambulatory setting. We expect our products to decrease complications, hospital stays, recovery times and indirect costs associated with a patient's loss of productivity.

For example, at the time of its introduction, Vortex Medical's AngioVac system was a new platform technology which for the first time allowed physicians to remove large blood clots from patients without the need for open surgery or clot-dissolving medications. This allowed AngioVac to command premium pricing using surgical reimbursement codes, achieve high gross margins and enter a large addressable market consisting of hundreds of thousands of patients who previously did not have a non-surgical /-non-thrombolytic treatment option. On the other hand, Saphena Medical's VenaPax system is an improvement to existing endoscopic vessel harvesting tools which promises to shorten procedure times and decrease vessel trauma at a lower overall cost, providing it an opportunity to capture market share based on price and efficacy.

Additional characteristics which impact a project's commercial opportunity are its technology, regulatory and reimbursement profiles. We typically select projects with strong intellectual property position, low to moderate technological complexity, low to moderate manufacturing costs and primarily disposable products that do not require significant capital equipment.

One of the most important features we consider is the project's regulatory pathway, both in the U.S. and internationally. The FDA's less arduous 510(k) pathway requires us to demonstrate that our product is safe and substantially equivalent to FDA-cleared predicates. The FDA's more costly and prolonged PMA pathway requires us to demonstrate that our product is safe and effective through randomized clinical studies. A product which is eligible for the 510(k) pathway will require substantially less capital and time than one that requires full PMA clearance. With all of our products we are very aggressive about identifying what we believe are the quickest paths to regulatory clearance, paying very careful attention to selection of the best predicates and references as well as careful attention to precisely crafting the primary indications for use language. Although we favor products eligible for the FDA's 510(k) pathway, with or without clinical safety studies, we may also pursue PMA pathway products with large addressable markets, or in the case of one of our lead products, PortIO™, pursue classification under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act, also referred to as de novo classification, which could be more rigorous than the 510(k) pathway, but generally require substantially less time and resources than a PMA pathway. We have a variety of options to commercialize such products more efficiently by initially, or even exclusively, targeting European or emerging markets which have shorter, less costly regulatory pathways for such projects. We also attempt to identify narrower applications and indications with lower regulatory hurdles that will allow us to start commercializing our product, while broader applications and indications with higher hurdles move through the regulatory process.

The project's reimbursement profile, both in the U.S. and internationally, is another very important component of the project's commercial opportunity. We prefer projects with existing reimbursement codes, the opportunity to seek reimbursement under higher-value surgical procedure codes or the potential to seek reimbursement under narrow, product-specific codes as opposed to bundled procedure codes.

Development and Commercialization Processes

Once we add a project to our pipeline, we map out development and commercialization processes specifically tailored to the product seeking to optimize capital and time efficiency and maximize value creation. The model emphasizes parallel development processes, such as engineering, quality, regulatory, supply chain, and manufacturing, utilizing outsourced, best-in-class process experts on an as-needed basis. We initially select the shortest, most-efficient path to commercialization of a safe and effective first-generation product. We then proceed with iterative product development based on real-life product performance and user feedback.

We intend to continue to utilize outsourced best-in-class process experts. We have strong relationships with a network of experts in design engineering, regulatory affairs, quality systems, supply chain management and manufacturing, including many with highly specialized skills in areas critical to our current and future pipeline. We will not be reluctant, however, to in-source certain heavily utilized process experts when and if we decide that such a move will enhance our ability to execute on our strategy. As we grow, we expect to maintain a lean management infrastructure while expanding our bandwidth primarily with skilled project managers.

Although the PHG and PMI companies were created with a credible path to self-commercialization, they were fundamentally "built to sell." We believe our structure will enhance our flexibility to commercialize our products compared to these and other single-product, development-stage companies. Each of our products generally follow one of three commercialization pathways. For certain products with one or more natural strategic acquirers such as PortIO, we may seek an early acquisition of the product prior to or soon after regulatory clearance, providing us with a source of non-dilutive capital. For certain groundbreaking high-margin products with large market opportunities such as CarpX, we retain the flexibility to fully commercialize our products for the foreseeable future. For certain other high-volume, lower sale price products such as DisappEAR, we may seek to co-market them with strategic partners through sales and distribution agreements. We may also choose to monetize products through licensing agreements or the sale of the products' underlying technology if consistent with our broader business strategy. For products we choose to commercialize ourselves, we may do through a network of independent U.S. medical distributors. We eventually may, however, choose to build (or obtain through a strategic acquisition) our own sales and marketing team, initially utilizing a hybrid model with national /regional sales management of independent distributors moving towards direct sales as warranted. As our pipeline grows, we may choose to jointly commercialize subsets of related products which target certain medical specialties or healthcare locations

Research and development expenses are recognized in the period they are incurred and consist principally of internal and external expenses incurred for the research and development of our products. We incurred approximately $4.8 million in cumulative research and development expenses from June 26, 2014 (inception) through December 31, 2017, inclusive of approximately $2.6 million and $1.7 million in each of the years ended December 31, 2017 and 2016, respectively. 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 approval and clearance and initializing commercialization of the lead products in our product portfolio pipeline - PortIO™ and CarpX™ - and advancing our DisappEAR™ product through its initial development phase. The research and development activities on the other portfolio products is commensurate with available sufficient capital resources. See *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations - Financial Results of Operations*, herein below, for a further discussion of research and development expenses.

Our Products Pipeline

Since our inception, we have conceived and developed a pipeline of products which fulfill our selection criteria. Our initial five products focused on hand surgery, medical infusion, and tissue ablation. Our sixth product, whose underlying technology we licensed from a group of academic centers, is focused on pediatric ear infections. We will need to receive regulatory clearance in order to commercialize these products. Additional capital will be required for us to commercialize these products and/or pursue additional regulatory clearances. Further, there is no assurance any of our products will ever be commercialized or, if commercialized, will achieve the results we expect. In December 2016, we filed a 510(k) premarket notification submission with the FDA for our first product, PortIO™, and in October 2017 decided instead to pursue classification under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act, also referred to as de novo classification under a broader indication, for up to seven days and consequently filed its de novo pre-submission package with the FDA for PortIO™ on October 30, 2017. Furthermore, on November 27, 2017 we filed a 510(k) premarket notification submission with the FDA for our CarpX™ minimally invasive device designed to treat carpal tunnel syndrome. We anticipate additional submissions in 2018 and beyond for the products in our pipeline.

Our products pipeline is dynamic, and we adjust our development and commercialization plans based on real-time progress, changes in market conditions, commercial opportunity and availability of resources. As such, we have designated CarpX™, PortIO™ and DisappEAR™ as lead products which are moving aggressively towards regulatory clearance and commercialization.

We have proprietary rights to the trademarks used herein, including, among others, PAVmed™, PortIO™, Caldus™, CarpX™, DisappEAR™, NextCath™, NextFlo™, and "Innovating at the Speed of Life"™, among others. Solely as a matter of convenience, trademarks and trade names referred to herein may or may not be accompanied with the requisite marks of "™" and /or "®", however, the absence of such marks is not intended to indicate, in any way, we will not assert, to the fullest extent possible under applicable law, our rights or the rights to such trademarks and trade names.

Our Products Pipeline (Continued)

CarpX™ - Percutaneous Device to Treat Carpal Tunnel Syndrome

The Market. Carpal tunnel syndrome ("CTS") is the most common cumulative trauma disorder and accounts for over half of all occupational injuries. The carpal tunnel is an anatomic compartment in the wrist through which tendons and the median nerve pass. Cumulative trauma leads to inflammation which manifests itself clinically through its compressive effect on the median nerve, resulting in motor and sensory dysfunction in the hand. A survey published in the Journal of the American Medical Association reported that 2.5% of U.S. adults, or approximately five million individuals, have CTS and about 350,000 surgical procedures are performed annually for CTS. According to the CDC, CTS accounts for two million office visits per year. According to the Agency for Health Care Policy and Research CTS costs the U.S. over $20.0 billion in annual workers' compensation costs.

Current Devices and their Limitations. Patients who have failed to improve with physical therapy or other non-invasive treatments are candidates for interventions which seek to relieve the compression of the median nerve by cutting the transverse carpal ligament, which forms the superficial wall of the carpal tunnel. Traditional surgical approaches are effective, but invasive and must be performed in a surgical operating room. Endoscopic approaches are less invasive, but are more technically challenging, more expensive and have been associated with higher complication rates. These approaches still require a surgical incision and some surgical dissection before the endoscope is passed into the carpal tunnel. Two less-invasive devices are currently on the market. One device attempts to use transillumination to guide blind passage of a protected knife and the other passes a saw-like device blindly or by ultrasound guidance. Technical limitations have hindered market acceptance of these devices.

Our Solution. We are developing a completely minimally invasive device to treat CTS. We believe our device will allow the physician to relieve the compression on the median nerve without an open incision or the need for endoscopic or other imaging equipment. To use our device, the operator first advances a guidewire through the carpal tunnel under the ligament. Our device is then advanced over the wire and positioned in the carpal tunnel under ultrasonic and/or fluoroscopic guidance. When the balloon is inflated it creates tension in the ligament positioning the cutting electrodes underneath it and creates space within the tunnel, providing anatomic separation between the target ligament and critical structures such as the median nerve. Radiofrequency energy is briefly delivered to the electrodes, rapidly cutting the ligament and relieving the pressure on the nerve. We believe our device will be significantly less invasive than existing treatments. We also believe it will allow for more extensive lateral dissection within the tunnel and more reliable division of the ligament, resulting in lower recurrence rates than some of the endoscopic approaches. We have filed a nonprovisional patent application and 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. On November 27, 2017 we filed a 510(k) premarket notification submission with the Food and Drug Administration ("FDA"). Once this product is commercialized, we believe it will have the potential to (i) decrease procedural costs by shifting the procedure from the operating room to an office setting while retaining similar reimbursement to traditional surgical approaches, (ii) reduce post-operative pain, (iii) accelerate the patient's return to full activity and (iv) lower the threshold for intervention for patients "suffering in silence" who chose to delay surgery until symptoms become debilitating. Our device may also be applicable to other clinical situations where percutaneous division of a fibrous structure can be used for therapeutic effect such as plantar fasciitis and extremity compartment syndromes resulting from trauma or ischemia.

Our Products Pipeline (Continued)

PortIO™ - Implantable Intraosseous Vascular Access Device

The Market. Vascular access devices, including peripheral intravenous catheters, central venous lines, peripherally inserted central catheters, tunneled catheters or implanted ports, are used to deliver various medications, fluids, blood products, nutrition or other therapeutic agents to patients with a wide variety of clinical conditions over multiple episodes spanning a period of days to weeks to months. A report by iData Research Group estimates the market for such devices to be several billion dollars annually. The market is moderately fragmented and highly commoditized, with slight premium pricing for modest features, including anti-infective coating, anti-thrombotic properties, tip location and power injector compatibility.

Current Devices and their Limitations Many chronically ill patients requiring long-term vascular access devices have poor or no central venous access as a result of repeated instrumentation of the veins or the presence of pacemaker and defibrillator leads, resulting in thrombosis or scarring. In addition, patients with renal failure need preservation of their peripheral and central veins for future dialysis access. The decades-old core technologies underlying currently available long-term vascular access devices have several limitations which relate directly to the intravascular component of the device. Up to 10% of such devices become infected, which can lead to costly and severe complications and even death (van de Wetering, Cochrane Database 2013). Since they are in constant contact with the blood stream, current devices require regular flushes to clear stagnant blood and prevent thrombus formation and occlusion. Despite these maneuvers, up to one-third of long-term vascular access devices become occluded at some point during their implantation period (Baskin, et al., Lancet 2009) and the resulting clot can dislodge as an embolism causing further downstream complications. This complication requires treatment with clot-dissolving agents or removal and implantation of a new device at an alternative site which in turn can lead to additional complications. Finally, most long-term vascular access devices require surgical insertion and removal, radiographic confirmation of tip placement and careful handling by trained clinicians to prevent the introduction of air into the circulation.

Our Solution. The intraosseous route provides a means for infusing fluids, medications and other substances directly into the bone marrow cavity which communicates with the central venous circulation via nutrient and emissary veins. This route is well established, having been used for decades in a variety of settings including trauma, especially military trauma, and pediatric emergencies. It has been shown to be bioequivalent to the intravenous route. Complication rates are low and there are few contraindications. Recently, physicians have expanded the use of the intraosseous route to non-emergent clinical scenarios. Currently available intraosseous devices pass through the skin into the bone and are therefore limited to short term use. We have developed a novel, implantable intraosseous vascular access device which does not require accessing the central venous system and does not have an indwelling intravascular component. It is designed to be highly resistant to occlusion and, we believe, may not require regular flushing. It features simplified, near-percutaneous insertion and removal, without the need for surgical dissection or radiographic confirmation. It provides a near limitless number of potential access sites and can be used in patients with chronic total occlusion of their central veins. We believe the absence of an intravascular component will result in a very low infection rate. We have filed a final nonprovisional patent application and 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 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 filed a *de novo* pre-submission package with the FDA which was followed by an in-person meeting on January 9, 2018 to discuss the risk assessment and proposed mitigation testing for the *de novo* application. Based on their recommendations we will initiate a seven-day animal study, having successfully completed a pilot animal which showed excellent function of the device over the seven-day implant period and on explant. In anticipation of having to follow up the animal study with a human clinical safe trial, we have accelerated our strategic partnership efforts to include the pre-clearance phase. Our long-term regulatory strategy is focused on expanded, longer-term indications and other clinical applications. Once this product is commercialized, we believe it will have lower cost-of-goods than existing implantable vascular access devices and premium pricing based on improved outcomes and reduced costs.

Our Products Pipeline (Continued)

DisappEAR™ - Antimicrobial Resorbable Ear Tubes

The Market. Each year up to one million children, generally between the ages of 2 and 5, with persistent ear infections (otitis media) or middle ear fluid collections (effusions) undergo placement of metal, plastic or latex bilateral ear tubes to ventilate and drain the middle ear. This procedure, formally known as bilateral tympanostomy, is the most common pediatric surgical procedure in the United States. The procedure is performed under general anesthesia. After the procedure, the patients are typically treated with a one-week course of antibiotic ear drops administered twice a day. The tubes are regularly monitored and allowed to remain in place for at least one year until the natural drainage pathway of the middle ear (the Eustachian tube) opens up as the child grows and the surrounding tonsillar tissue regresses. A second procedure, again under general anesthesia, is often needed to remove the tubes once they are no longer needed or if they become dislodged and do not fall out of the ear canal on their own. Although the tubes themselves are marketed as a moderately priced item, the antibiotics course can cost $300 or more. Thus, there is a significant market opportunity of up to $300 million for a system which can replace the post-operative antibiotic drops and reduce the need for future procedures.

Current Devices and their Limitations. As noted, the currently available pediatric ear tubes require general anesthesia for insertion and removal and a course of antibiotic ear drops. The ear drops can be quite difficult for parents to administer in children of younger age which can lead to poor compliance. Furthermore, tube dislodgement is not uncommon. When the tube dislodges into the ear canal it can get embedded in wax and lead to inflammation, obscured visualization of the ear drum, pain and bleeding. When the tube dislodges into the middle ear, where the fragile bones that transduce sound to the inner ear reside, parents and physicians become concerned about long-term damage and hearing loss. As a result, both situations usually require a second procedure, again under general anesthesia. Up to 50% of patients undergoing ear tube placement require a second procedure.

Our Solution. In November 2016, we entered in a licensing agreement with a group of leading academic institutions, including Tufts University and two Harvard Medical School teaching hospitals - Massachusetts Eye and Ear Infirmary and Massachusetts General Hospital. The agreement provides PAVmed with an exclusive worldwide license for the life of the underlying patents to develop and commercialize antimicrobial resorbable ear tubes based on a proprietary aqueous silk technology conceived and developed at these institutions. One of the visionaries behind this technology, Christopher J. Hartnick, M.D., Professor of Otolaryngology at Harvard Medical School and Chief of Pediatric Otolaryngology at Massachusetts Eye and Ear Infirmary and Massachusetts General Hospital, joined our Medical Advisory Board in October 2016. We are working closely with Dr. Hartnick and Dr. David Kaplan, Stern Family Professor of Engineering, Chair of the Department of Biomedical Engineering and Director of Bioengineering and Biotechnology Center at Tufts University. We have committed to a timeline with certain milestones on the path to commercialization. Once commercialized, the institutions will receive royalties based on revenue and a portion of certain additional proceeds from the sale or sublicensing of the technology to a third party. We believe the resorbable ear tubes will eliminate the need for a second procedure to remove retained or dislodged tubes in most patients. Having the device embedded with antimicrobial agents will eliminate the difficult-to administer post-procedure antibiotic ear tube regimen. Our partners previously completed successful animal studies using working prototypes of the device. Our efforts have focused on sourcing commercially ready aqueous silk and optimizing manufacturing processes consistent with the necessary cost of goods for the commercial product. Once this product is commercialized, we believe it will garner premium pricing based on improving compliance and eliminating the significant cost related to the post-procedure antibiotic regimen, the need for second procedure and fewer complications.

Our Products Pipeline (Continued)

NextCath™ - Self-Anchoring Short-Term Catheters

The Market. A wide variety of short-term catheters are used in clinical practice to infuse fluids, medications or other substances into a vein or other structures, to monitor physiologic parameters and to drain visceral organs or cavities. Interventional radiology catheters, in particular, are widely used to drain various structures and cavities including the pleural space, obstructed kidneys and abscess cavities. There is an increasing appreciation, however, of the importance of catheter securement in preventing complications of all indwelling catheters. There has been an explosion of separate propriety devices marketed to facilitate catheter securement. A report by iData Research Group estimates the catheter securement market to be approximately $4.0 billion annually.

Current Devices and their Limitations. Currently marketed short-term catheters are not self-anchoring, they have been traditionally anchored to the skin with simple tape or some other adhesive incorporated into the sterile dressing. According to a report by Dr. Gregory J. Schears, a pediatric anesthesiologist and expert on catheter securement, both microscopic and macroscopic movements from inadequate catheter securement can lead to complications including vascular injury and dislodgment. Catheter dislodgement leads to increased pain, increased costs and potentially more serious complications arising from interruption of critical treatments or bleeding. These of course can also adversely impact quality of care. Monitoring catheter patency and security and reinserting dislodged catheters is labor intensive. Many types of catheters are sutured to the skin, a process which leads to increased pain and exposure to needle sticks. Dislodgement of interventional radiology catheters are a significant concern since they can lead to serious complications and may require another visit to the procedural suite to replace or reposition the catheter. A wide variety of catheter securement devices are currently marketed. Some have been shown to decrease complications relative to traditional techniques but add cost and complexity to the process.

Our Solution. We are developing self-anchoring short-term catheters which do not require suturing, traditional anchoring techniques or costly add-on catheter securement devices. We are initially focusing on interventional radiology catheters which are less commoditized and result in significantly greater risk when dislodged. Our self-anchoring technique, however, is applicable to most, if not all, short-term catheters. The self-anchoring mechanism is integral to the catheter. It allows insertion with standard techniques and the use of simple clear sterile dressings. It allows the hub of the catheter to be flat and the tubing to come out eccentrically, or parallel to the skin, improving patient comfort and catheter management. We have filed a nonprovisional patent application, engaged design and contract manufacturing firms with experience in extrusions which have completed initial design work on the first product in the NextCath™ product line, 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. Further development of NextCath™ is subject to availability of additional financial resources. Once this product is commercialized, we believe it will garner premium pricing based on fewer complications and reduced overall costs.

Our Products Pipeline (Continued)

NextFlo™ - Highly-Accurate Disposable Infusion System

The Market. Each day, over one million patients receive some type of infusion and 90% of hospitalized patients receive an intravenous infusion at some point during their hospital stay. (Husch et al. Quality & Safety in Health Care 2005; 14:80-86). Unlike twenty years ago, nearly all inpatient infusions, including routine ones which do not require flow adjustment, are delivered by expensive electric infusion pumps instead of with simple gravity. An increasing number of these patients are receiving infusions of medications or other substances outside of a hospital, in ambulatory facilities and at home. In addition, disposable infusion pumps ("DIPs") have many attractive features that favor their use in these settings over outpatient electric infusion pumps. Patients tend to favor DIPs because they are small, disposable, simple to operate, easy to conceal, and allow for greater mobility. They are used to deliver medications including antibiotics, local anesthetics and opioids. According to a report by Transparency Market Research, the overall global infusion market is estimated to be over $5.0 billion annually. DIPs account for approximately 10% of this market and inpatient infusion sets for about 20%.

Current Devices and their Limitations. Infusion pump errors are a serious ongoing problem and represent a large share of the overall human and economic burden of medical errors. Electronic infusion pumps have become expensive, high-maintenance devices and have been plagued in recent years with recalls due to serious software and hardware problems. These pumps are designed for fine titration of infusions in complex patients such as those in a critical care setting. Using them for routine administration of medications or fluids is technological overkill. We believe there is a significant market opportunity for a simple, disposable device which can be incorporated into a standard infusion set and eliminate the need for expensive, problem-prone infusion pumps for routine inpatient infusions. In terms of outpatient infusions, currently marketed DIPs are powered by elastomeric membranes, compressed springs, compressed gas or vacuum and controlled by mechanical flow limiters. The primary limitation of DIPs is that they can be highly inaccurate in actual use because they can be susceptible to changes in operating conditions (e.g. temperature, atmospheric pressure, viscosity, back pressure, partial filing and prolonged storage). As a result, their safety profiles make them unsuitable for use with medications, such as chemotherapeutics, where flow accuracy is critical to achieve the desired therapeutic effect and avoid complications. The FDA's MAUDE database includes numerous reports of complications and even deaths as a result of DIPs infusing a particular medication too slowly or too fast. We believe there is a significant market opportunity for highly accurate disposable infusion pumps for outpatient use.

Our Solution. We are developing highly-accurate infusion systems with variable flow resistors. We acquired U.S. Patent 8,622,976 issued January 7, 2014 and associated U.S. and international patent applications, "*System and Methods for Infusion of Fluids Using Stored Potential Energy and a Variable Flow Resistor*". We have built on the principles underlying this patent and developed a new concept whereby the variable resistor does not have to be mechanically-linked to the infusion drive mechanism. This simplifies the design and expands the range of potential follow-on products. We have performed extensive computer simulation testing on various embodiments and have demonstrated highly-accurate flow rates across a wide range of driving pressures. We have 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. Further development of NextFlo™ is subject to availability of additional financial resources which are currently focused on our three lead products. Once this product is commercialized, we believe it will command a premium price over existing inpatient infusion sets and low-accuracy, DIPs. We believe infusion sets incorporating this product will permit hospitals to return to gravity and eliminating expensive infusions pumps for the most inpatient infusions. We also believe the accuracy of our device incorporated into DIPs will allow them to be used with a broader range of drugs, thereby significantly expanding the addressable market.

Our Products Pipeline (Continued)

Caldus™ - Disposable Tissue Ablation Devices

The Market. Tissue ablation involves the targeted destruction of tumors or benign tissues with pathologic impact (e.g. gastrointestinal, endometrial and cardiac) using one of a variety of commercially-available ablation devices based on a specific energy source (e.g. radiofrequency, microwave, laser, ultrasound, cryoablation). With the exception of cryoablation, all of these devices act through a common pathway of cellular hyperthermia. A 2014 report by Transparency Market Research estimates the tissue ablation market generates $4.0 billion to $5.0 billion in annual revenue. One target which has not been successfully treated with ablation is fistula tracts, specifically *fistula-in-ano*. Up to 100,000 patients present with this condition annually. More recently, the renal nerves have been identified as a therapeutic target for ablation in patients with refractory hypertension. Despite a widely publicized clinical trial which failed to meet its endpoint, many believe that renal denervation remains an attractive clinical and commercial opportunity with approximately 10 million U.S. and 100 million worldwide patients with resistant hypertension (Pimenta et al. Circulation 2012; 125-1594-96).

Current Devices and their Limitations. All commercially-available devices or those under development for renal denervation rely on some form of a console to generate the ablation energy. These consoles, whether sold or leased as capital equipment or incorporated into the disposable costs, represent a significant portion of the cost of the technology and the procedure. These costs can significantly impact procedural margins and marketing in emerging countries with limited biomedical staff. Another limitation of current devices is that they depend on maintaining the conductivity of its energy through the tissue during the ablation period. For example, radiofrequency ablation depends on electrical conductivity to generate heat, but creating too much heat near the probe can generate charring which increases impedance and decreases the effective range of the ablation. A wide variety of technologies and techniques have been developed to accommodate the challenges of ablating across large distances using radiofrequency (e.g. multi-electrode probes, cooling, irrigation and complex power algorithms). As a result, these tissue ablation modalities typically require a complex, external console to assure the precise amount of energy is delivered to the tissue. In addition, the consoles require on-going maintenance and monitoring by the manufacturer and local facility technical staff to assure they remain safe for use in patients. This can be particularly burdensome when commercializing such devices in emerging markets where access to qualified technical personnel may be limited.

Our Solution. We are developing completely disposable tissue ablation devices, including for renal denervation, based on direct thermal ablation of the tissue using heated fluid. 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 upon resources becoming available. Once this product is commercialized, we believe that our completely disposable system will have significantly lower procedural costs and higher margins than existing technologies.

Additional Products

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. Furthermore, 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.

Our Implementation Strategy

We intend to advance our lead products towards commercialization as quickly and efficiently as possible and expand our product pipeline by advancing our conceptual phase projects through patent submission and early testing.

Although we will continue to conceive and develop products internally, as we grow and expand our resources, we intend to expand our pipeline with innovative products sourced from third parties. In contrast to pharmaceuticals and other life sciences technologies, medical device innovation often begins with one, or at most a few, clinicians and/or engineers identifying an unmet clinical need and proposing a technological solution to address such need. Many academic medical centers and other large institutions try to aggregate their intellectual property through technology transfer centers and, more recently, through "innovation" centers which do not merely secure and transfer intellectual property, but actually advance projects internally prior to spinning them out for eventual commercialization.

It is our belief, despite these efforts, only a small fraction of the potential pool of intellectual capital (i.e. the universe of individual clinicians with innovative product ideas) is participating in medical device innovation. These clinicians rarely engage in the process for a variety of reasons, including the belief that they are too busy, can't afford to divert time away from their practice or that the upfront out-of-pocket costs are too great. Other clinicians believe that they lack the knowledge or connections to successfully navigate the process. Technology transfer and full-fledged innovation centers have only had modest success in getting their clinicians to bring them innovative product ideas and even less success getting these products commercialized. Even centers with extensive resources are usually limited in their ability to advance products beyond the pre-clinical phase and are dependent on a shrinking pool of early-stage medical device venture capital to bring their products to market. Furthermore, some technology transfer and innovation centers associated with not-for-profit hospitals, universities, endowments and charitable organizations may be precluded from directly engaging in commercial sales of medical devices, creating opportunities for us to commercialize and market their intellectual property.

Our capital and time efficient model puts us in strong position to partner with innovative clinicians and academic medical centers focusing on medical device innovation. We have developed a collaboration model focused on licensing technologies for development and commercialization. Since our founding, we have been contacted by clinicians and centers inquiring about opportunities to work with us on developing and commercializing their ideas and technologies. In November 2016, we signed a definitive licensing agreement with a group of leading academic institutions, including Tufts University and two Harvard Medical School teaching hospitals - Massachusetts Eye and Ear Infirmary and Massachusetts General Hospital. The agreement provides us with an exclusive worldwide license to develop and commercialize antibiotic-eluting resorbable ear tubes based on a proprietary aqueous silk technology conceived and developed at these institutions, a product we have dubbed DisappEAR™. Once commercialized, the institutions will receive royalties based on revenue and a portion of certain additional proceeds from the sale or sublicensing of the technology to a third party.

Whether internally or externally sourced, we seek to maintain balance within our pipeline with shorter-term, lower-risk products which offer the opportunity for more rapid commercialization, generating revenue to support development of longer-term products. As each product moves through our pipeline from concept to commercialization, we continuously reassess the product's long-term commercial potential, balance it against other products in the pipeline and re-allocate resources accordingly. As such, we expect to have much greater flexibility to move products through our pipeline based on the actual developments and the overall interests of our company. We may accelerate, decelerate, pause or abandon a product and increase or decrease resources applied to a product based on a variety of factors including available capital, shifts in the regulatory, clinical, market and/or intellectual property landscape for a particular product, the emergence of one or more products with significantly greater commercial potential, or any other factor which may impact its long-term commercial potential.

Sales and Marketing

We currently expect to commercialize our products through a network of independent U.S. medical distributors. We focus on high-margin products which are particularly suitable to this mode of distribution. A high gross margin allows us to properly incentivize our distributors, which in turn allows us to attract the top distributors with the most robust networks in our targeted specialties. Independent distributors play an even larger role in many parts of Europe, most of Asia and emerging markets worldwide.

We eventually may, however, choose to build (or obtain through a strategic acquisition) our own sales and marketing team to commercialize some or all of our products if it is in our long-term interests. We may also choose to enter into distribution agreements with larger strategic partners whereby we take full responsibility for the manufacturing of our products but outsource some or all of its distribution to a partner with its own robust distribution channels. Such agreements may include regional carve outs, minimum sales volumes, margin splitting and/or an option or right of first offer to purchase the technology at a future date. As our pipeline grows, we may choose to jointly commercialize subsets of related products which target certain medical specialties or healthcare locations.

Manufacturing

We currently have no plans to manufacture our own products because the fixed overhead costs and limited flexibility that come with owning manufacturing facilities are not consistent with our capital efficient model. The entire medical device industry, including many of its largest players, depends heavily on contract manufacturers operating in the United States and abroad. Medical device manufacturers are subject to extensive regulation by the FDA and other authorities. Compliance with these regulations is costly and particularly onerous on small, development-phase companies. Contract manufacturers can also take advantage of significant economies of scale in terms of purchasing, machining, tooling, specialized personnel, sub-contracting or even off-shoring certain processes to lower-cost operators. These economies are simply not available to us.

We have relationships with many contract manufacturers, including those with specialized skills in several processes important to our devices. We expect them to have sufficient capacity to handle our manufacturing needs and anticipate that our growth will be better served by deploying our resources to expand our pipeline and commercialization efforts.

We intend to work closely with our contract manufacturing partners to establish and manage our products' supply chain, dual sourcing whenever possible. We expect to help them design and build our products' manufacturing lines including subassembly, assembly, sterilization and packaging and to work closely with them to manage our quality system, to assure compliance with all regulations and to handle inspections or other queries with regulatory bodies. Our contract manufacturers have the ability to add lines and shifts to increase the manufacturing capacity of our products as our demand dictates. We may ship our products directly from our contract manufacturers, but we may also choose to utilize third-party regional warehousing and distribution services.

Intellectual Property

Our business will depend on our ability to create or acquire proprietary medical device technologies to commercialize. We intend to vigorously protect our proprietary technologies' intellectual property rights in patents, trademarks and copyrights, as available through registration in the United States and internationally. Patent protection and other proprietary rights are thus essential to our business. Our policy is to aggressively file patent applications to protect our proprietary technologies including inventions and improvements to inventions. We seek patent protection, as appropriate, on:

- the product itself including all embodiments with future commercial potential;
- the methods of using the product; and
- the methods of manufacturing the product.

In addition to filing and prosecuting patent applications in the United States, we intend to file counterpart patent applications in Europe, Canada, Japan, Australia, China and other countries worldwide. Foreign filings can be cumbersome and expensive, and we will pursue such filings when we believe they are warranted as we try to balance our international commercialization plans with our desire to protect the global value of the technology.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be shortened if a patent is terminally disclaimed over another patent or as a result of delays in patent prosecution by the patentee, and a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent.

We intend to continuously reassess and fine-tune our intellectual property strategy in order to fortify our position in the United States and internationally. Prior to acquiring or licensing a technology from a third party, we will evaluate the existing proprietary rights, our ability to adequately obtain and protect these rights and the likelihood or possibility of infringement upon competing rights of others.

We will also rely upon trade secrets, know-how, continuing technological innovation, and may rely upon licensing opportunities in the future, to develop and maintain our competitive position. We intend to protect our proprietary rights through a variety of methods, including confidentiality agreements and/or proprietary information agreements with suppliers, employees, consultants, independent contractors and other entities who may have access to proprietary information. We will generally require employees to assign patents and other intellectual property to us as a condition of employment with us. All of our consulting agreements will pre-emptively assign to us all new and improved intellectual property that arise during the term of the agreement.

Coverage and Reimbursement

Our ability to successfully commercialize our products will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for the procedures during which our products are used.

In the United States, third-party payors continue to implement initiatives that restrict the use of certain technologies to those that meet certain clinical evidentiary requirements. In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our products are used. An example of payment updates is the Medicare program's updates to hospital and physician payments, which are done on an annual basis using a prescribed statutory formula. In the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions.

Competition

Developing and commercializing new products is highly competitive. The market is characterized by extensive research and clinical efforts and rapid technological change. We face intense competition worldwide from medical device, biomedical technology and medical products and combination products companies, including major medical products companies. We may be unable to respond to technological advances through the development and introduction of new products. Most of our existing and potential competitors have substantially greater financial, marketing, sales, distribution, manufacturing and technological resources. These competitors may also be in the process of seeking FDA or other regulatory approvals, or patent protection, for new products. Our competitors may commercialize new products in advance of our products. Our products also face competition from numerous existing products and procedures, some of which currently are considered part of the standard of care. We believe that the principal competitive factors in our markets are:

- the quality of outcomes for medical conditions;
- acceptance by surgeons and the medical device market generally;
- ease of use and reliability;
- technical leadership and superiority;
- effective marketing and distribution;
- speed to market; and
- product price and qualification for coverage and reimbursement.

We will also compete in the marketplace to recruit and retain qualified scientific, management and sales personnel, as well as in acquiring technologies and licenses complementary to our products or advantageous to our business. We are aware of several companies that compete or are developing technologies in our current and future products areas. In order to compete effectively, our products will have to achieve market acceptance, receive adequate insurance coverage and reimbursement, be cost effective and be simultaneously safe and effective.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. The following is a summary of the government regulations applicable to our business.

Healthcare Reform

Current and future legislative proposals to further reform healthcare or reduce healthcare costs may result in lower reimbursement for our products, or for the procedures associated with the use of our products, or limit coverage of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could significantly reduce our revenues from the sale of our products. Alternatively, the shift away from fee-for-service agreements to capitated payment models may support the value of our products which can be shown to decrease resource utilization and lead to cost saving - for both payors and providers.

The implementation of the Affordable Care Act is an example that has the potential to substantially change healthcare financing and delivery by both governmental and private insurers, and significantly impact the pharmaceutical and medical device industries.

The Affordable Care Act imposed, among other things, a new federal excise tax on the sale of certain medical devices. The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law on Dec. 18, 2015, included a two-year moratorium on the medical device excise tax imposed by Internal Revenue Code section 4191. Because of the moratorium, the medical device excise tax did not apply to sales of taxable medical devices during the period beginning on Jan. 1, 2016, and ending on Dec. 31, 2017. The moratorium expired on Dec. 31, 2017. On January 22, 2018 as part of a stop gap spending bill, President Trump signed into law a moratorium for an additional two years retroactive to January 1, 2018. The tax will not go into effect until January 1, 2020.

In addition, the ACA implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. In addition, other legislative changes have been proposed and adopted since the Patient Protection and Affordable Care Act, ("PPACA") was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2.0% per fiscal year, which went into effect on April 1, 2013, and will stay in effect through 2024 unless congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 took effect, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure. Additionally, there is no assurance the PPACA, in whole or in part, will not be repealed in the future. Any impact such a repeal would have on the medical device industry remains unclear.

FDA Regulation

Any product we may develop must be cleared by the FDA before it is marketed in the United States. Before and after approval or clearance in the United States, our products are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act, as well as by other regulatory bodies. FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, recordkeeping, market clearance or approval, advertising and promotion, import and export, marketing and sales, and distribution of medical devices and products.

In the United States, medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the extent of controls the FDA determines are necessary to reasonably ensure their safety and efficacy:

- *Class I:* general controls, such as labeling and adherence to quality system regulations;
- *Class II:* special controls, pre-market notification (often referred to as a 510(k) application), specific controls such as performance standards, patient registries, post-market surveillance, additional controls such as labeling and adherence to quality system regulations; and
- *Class III:* special controls and approval of a PMA application.

In general, the higher the classification, the greater the time and cost to obtain approval to market. There are no "standardized" requirements for approval, even within each class. For example, the FDA could grant 510(k) status, but require a human clinical trial, a typical requirement of a PMA. They could also initially assign a device Class III status, but end up approving a device as a 510(k) device if certain requirements are met. The range of the number and expense of the various requirements is significant. The quickest and least expensive pathway would be 510(k) approval with just a review of existing data. The longest and most expensive path would be a PMA with extensive randomized human clinical trials. We cannot predict how the FDA will classify our products, nor predict what requirements will be placed upon us to obtain market approval, or even if they will approve our products at all.

To request marketing authorization by means of a 510(k) clearance, we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to another currently legally marketed medical device, has the same intended use, and is as safe and effective as a currently legally marketed device and does not raise different questions of safety and effectiveness than does a currently legally marketed device. 510(k) submissions generally include, among other things, a description of the device and its manufacturing, device labeling, medical devices to which the device is substantially equivalent, safety and biocompatibility information, and the results of performance testing. In some cases, a 510(k) submission must include data from human clinical studies. Marketing may commence only when the FDA issues a clearance letter finding substantial equivalence. After a device receives 510(k) clearance, any product modification that could significantly affect the safety or effectiveness of the product, or that would constitute a significant change in intended use, requires a new 510(k) clearance or, if the device would no longer be substantially equivalent, would require PMA, or possibly, a de novo pathway under section 513(f)2 of the Federal Food, Drug and Cosmetic Act .. In addition, any additional claims the Company wished to make at a later date may require a PMA. If the FDA determines that the product does not qualify for 510(k) clearance, they will issue a Not Substantially Equivalent letter, at which point the Company must submit and the FDA must approve a PMA or issue premarket clearance using the de novo before marketing can begin.

In 1997, the Food and Drug Administration Modernization Act (FDAMA) added the de novo classification pathway under section 513(f)(2) of the FD&C Act, establishing an alternate pathway to classify new devices into Class I or II that had automatically been placed in Class III after receiving a Not Substantially Equivalent (NSE) determination in response to a 510(k) submission. In this process, a sponsor who receives an NSE determination may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act.

In 2012, section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA), to provide a second option for de novo classification. In this second pathway, a sponsor who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k).

During the review of a 510(k) submission, the FDA may request more information or additional studies and may decide that the indications for which we seek approval or clearance should be limited. In addition, laws and regulations and the interpretation of those laws and regulations by the FDA may change in the future. We cannot foresee what effect, if any, such changes may have on us.

Clinical Trials of Medical Devices

One or more clinical trials may be necessary to support an FDA submission. Clinical studies of unapproved or uncleared medical devices or devices being studied for uses for which they are not approved or cleared (investigational devices) must be conducted in compliance with FDA requirements. If an investigational device could pose a significant risk to patients, the sponsor company must submit an Investigational Device Exemption, or IDE application to the FDA prior to initiation of the clinical study. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device on humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. Clinical studies of investigational devices may not begin until an institutional review board ("IRB") has approved the study.

During any study, the sponsor must comply with the FDA's IDE requirements. These requirements include investigator selection, trial monitoring, adverse event reporting, and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. We, the FDA, or the IRB at each institution at which a clinical trial is being conducted may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable risk. During the approval or clearance process, the FDA typically inspects the records relating to the conduct of one or more investigational sites participating in the study supporting the application.

Post-Approval Regulation of Medical Devices

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- the FDA Quality Systems Regulation (QSR), which governs, among other things, how manufacturers design, test manufacture, exercise quality control over, and document manufacturing of their products;
- labeling and claims regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and
- the Medical Device Reporting regulation, which requires reporting to the FDA of certain adverse experience associated with use of the product.

We will continue to be subject to inspection by the FDA to determine our compliance with regulatory requirements.

Manufacturing cGMP Requirements

Manufacturers of medical devices are required to comply with FDA manufacturing requirements contained in the FDA's current Good Manufacturing Practices (cGMP) set forth in the quality system regulations promulgated under section 520 of the Food, Drug and Cosmetic Act. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or in product withdrawal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following the approval. We expect to use contract manufacturers to manufacture our products for the foreseeable future we will therefore be dependent on their compliance with these requirements to market our products. We work closely with our contract manufacturers to assure that our products are in strict compliance with these regulations.

Other U.S. Regulation

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal and state laws restrict our business practices. These laws include, without limitation, anti-kickback and false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including certain sales and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal and civil and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Physician Payment Sunshine Act

There has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. On February 8, 2013, the Centers for Medicare & Medicaid Services, or CMS, released its final rule implementing section 6002 of the Affordable Care Act known as the Physician Payment Sunshine Act that imposes new annual reporting requirements on device manufacturers for payments and other transfers of value provided by them, directly or indirectly, to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year, and up to an aggregate of $1 million per year for "knowing failures." Manufacturers that produces at least one product reimbursed by Medicare, Medicaid, or Children's Health Insurance Program and i.) If the product is a drug or biological, and it requires a prescription (or physician's authorization) to administer; or ii.) If the product is a device or medical supply, and it requires premarket approval or premarket notification by the FDA are required to comply with the Open Payments (commonly referred to as the Sunshine Act) filing requirements under CMS. We currently do not have any products covered by Medicare, Medicaid, or Children's Health Insurance Program as none of our products have premarket approval or clearance notification. We expect that once our products receive regulatory clearance, we will be required to comply with the Sunshine Act provisions.

Certain states, such as California and Connecticut, also mandate implementation of commercial compliance programs, and other states, such as Massachusetts and Vermont, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements.

Federal Anti-Kickback Statute

The Federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Federal False Claims Act

The False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the False Claims Act. Several pharmaceutical, device and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus noncovered uses.

The government may further prosecute, as a crime, conduct constituting a false claim under the False Claims Act. The False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike civil claims under the False Claims Act, requires proof of intent to submit a false claim.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

International Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. We may be subject to regulations and product registration requirements in the areas of product standards, packaging requirements, labeling requirements, import and export restrictions and tariff regulations, duties and tax requirements. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

European Union

The European Union or EU will require a CE mark certification or approval in order to market our products in the various countries of the European Union or other countries outside the United States. To obtain CE mark certification of our products, we will be required to work with an accredited European notified body organization to determine the appropriate documents required to support certification in accordance with existing medical device directive. The predictability of the length of time and cost associated with such a CE mark may vary, or may include lengthy clinical trials to support such a marking. Once the CE mark is obtained, we may market our product in the countries of the EU.

European Good Manufacturing Practices

In the European Union, the manufacture of medical devices is subject to good manufacturing practice (GMP), as set forth in the relevant laws and guidelines of the European Union and its member states. Compliance with GMP is generally assessed by the competent regulatory authorities. Typically, quality system evaluation is performed by a Notified Body, which also recommends to the relevant competent authority for the European Community CE Marking of a device. The Competent Authority may conduct inspections of relevant facilities, and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each device manufacturing facility must be audited on a periodic basis by the Notified Body. Further inspections may occur over the life of the product.

Employees

Currently, we have five compensated employees, including our Chairman of the board of directors and Chief Executive Officer ("CEO"), our Executive Vice President and Chief Financial Officer ("CFO"), and our Chief Medical Officer ("CMO"), each of whom are named executive officers, along with our Vice Chairman, who is currently not a compensated employee of the Company, but is a member of our board of directors. No employees are covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Available Information

We make available free of charge through our website our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to the SEC. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. The public also may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE., Washington, DC 20549, on official business days during the hours of 10 a.m. to 3 p.m. The public may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330. The SEC also maintains an Internet site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding us that we file electronically with the SEC.

Our website address is http://www.pavmed.com. The content of our website is not incorporated by reference into this Annual Report on Form 10-K, nor in any other report or document we file with the SEC, and any reference to our website are intended to be inactive textual references only.

Item 1A Risk Factors

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Financial Position and Capital Resources

We have incurred operating losses since our inception and may not be able to achieve profitability.

We have incurred net losses since our inception. We incurred a net loss attributable to common stockholders of $10,398,134 and $5,650,851, and had net cash flows used in operating activities of $6,608,208 and $4,454,857, for the years ended December 31, 2017 and 2016, respectively. As of December 31, 2017, we had an accumulated deficit of $17,907,611 To date, since our inception in June 2014, we have financed our operations principally through issuances of common stock, preferred stock, warrants, and debt, in both private placements, our IPO in April 2016, and in an underwritten public offering of shares of our common stock pursuant to a previously filed effective shelf registration statement. Our ability to generate sufficient revenue from any of our products in development, and to transition to profitability and generate consistent positive cash flows is dependent upon factors that may be outside of our control. We expect our operating expenses will continue to increase as we continue to build our commercial infrastructure, develop, enhance and commercialize new products and incur additional operational and reporting costs associated with being a public company. As a result, we expect to continue to incur operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern.

We have concluded there is substantial doubt of our ability to continue as a going concern and our independent registered public accounting firm's report on our financial statements contains an explanatory paragraph describing our ability to continue as a going concern.

In our December 31, 2017 consolidated financial statements, we have concluded and stated our recurring losses from operations, recurring cash flows used in operations, accumulated deficit, and the requirement to raise additional capital to support our operating and capital expenditures, raise substantial doubt regarding our ability to continue as a going concern. Correspondingly, our independent registered public accounting firm's report on our consolidated financial statements also includes an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. Our plans to address this going concern risk include pursuing additional offerings of debt and /or equity securities. The consolidated financial statements do not include any adjustments that might result from our inability to consummate such offerings or our ability to continue as a going concern. Moreover, there is no assurance if we consummate additional offerings, we will raise sufficient proceeds in such offerings to pay our financial obligations as they become due. These factors raise substantial doubt about our ability to continue as a going concern.

We may need substantial additional funding and may be unable to raise capital when needed, which could force us to delay, reduce, eliminate or abandon growth initiatives or product development programs.

We intend to continue to make investments to support our business growth. Because we have not generated any revenue or cash flow to date, we will require additional funds to:

- continue our research and development;
- protect our intellectual property rights or defend, in litigation or otherwise, any claims that we infringe third-party patents or other intellectual property rights;
- fund our operations;
- deliver our new products, if any such products receive regulatory clearance or approval for commercial sale;
- market acceptance of our products;
- the cost and timing of expanding our sales, marketing and distribution capabilities;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

If we do not have, or are not able to obtain, sufficient funds, we may have to delay product development initiatives or license to third parties the rights to commercialize products or technologies that we would otherwise seek to market. We also may have to reduce marketing, customer support or other resources devoted to our products.

Risks Associated with Our Business

Since we have a limited operating history, and have not generated any revenues, you will have little basis upon which to evaluate our ability to achieve our business objective.

Since we have a limited operating history, and have not generated any revenues, you will have little basis upon which to evaluate our ability to achieve our business objective. We are subject to all of the problems, expenses, delays and other risks inherent in any new business, as well as problems inherent in establishing a name and business reputation.

The markets in which we operate are highly competitive, and we may not be able to effectively compete against other providers of medical devices, particularly those with greater resources.

We face intense competition from companies with dominant market positions in the medical device industry. These competitors have significantly greater financial, technical, marketing and other resources than we have and may be better able to:

- respond to new technologies or technical standards;
- react to changing customer requirements and expectations;
- acquire other companies to gain new technologies or products that may displace our products;
- manufacture, market and sell products;
- acquire, prosecute, enforce and defend patents and other intellectual property;
- devote resources to the development, production, promotion, support and sale of products; and
- deliver a broad range of competitive products at lower prices.

We expect competition in the markets in which we participate to continue to increase as existing competitors improve or expand their product offerings.

Our future performance will depend largely on the success of products we have not yet developed.

Technology is an important component of our business and growth strategy, and our success depends on the development, implementation and acceptance of our products. Commitments to develop new products must be made well in advance of any resulting sales, and technologies and standards may change during development, potentially rendering our products outdated or uncompetitive before their introduction. Our ability to develop products to meet evolving industry requirements and at prices acceptable to our customers will be significant factors in determining our competitiveness. We may expend considerable funds and other resources on the development of our products without any guarantee that these products will be successful. If we are not successful in bringing one or more products to market, whether because we fail to address marketplace demand, fail to develop viable technologies or otherwise, we may not generate any revenues and our results of operations could be seriously harmed.

Our products may never achieve market acceptance.

To date, we have not generated any revenues. Our ability to generate revenues from product sales and to achieve profitability will depend upon our ability to successfully commercialize our products. Because we have not yet begun to offer any of our products for sale, we have no basis to predict whether any of our products will achieve market acceptance. A number of factors may limit the market acceptance of any of our products, including:

- the timing of regulatory approvals of our products and market entry compared to competitive products;
- the effectiveness of our products, including any potential side effects, as compared to alternative treatments;
- the rate of adoption of our products by hospitals, doctors and nurses and acceptance by the health care community;
- the product labeling or product inserts required by regulatory authorities for each of our products;
- the competitive features of our products, including price, as compared to other similar products;
- the availability of insurance or other third-party reimbursement, such as Medicare, for patients using our products;
- the extent and success of our marketing efforts and those of our collaborators; and
- unfavorable publicity concerning our products or similar products.

Any products we may develop may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming our business.

The regulations that govern marketing approvals, pricing and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more other products we may develop, even if our other products we may develop obtain regulatory approval.

Our ability to commercialize any products we may develop successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which treatments they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular treatments. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product that we successfully develop.

Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U.S. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. Our business could be materially harmed if reimbursement of any products we may develop, if any, is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Any products we may develop may cause serious adverse side effects or even death or have other properties that could delay or prevent their regulatory approval, limit the commercial desirability of an approved label or result in significant negative consequences following any marketing approval.

The risk of failure of clinical development is high. It is impossible to predict when or if any products we may develop will prove safe enough to receive regulatory approval. Undesirable side effects caused by any products we may develop could cause us or regulatory authorities to interrupt, delay or halt clinical trials. They could also result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority.

Additionally, after receipt of marketing approval of any products we may develop, if we or others later identify undesirable side effects or even deaths caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to recall such product and suspend the marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of Risk Evaluation Mitigation Strategies or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the sale of any products we may develop. The marketing, sale and use of any products we may develop could lead to the filing of product liability claims against us if someone alleges product failures, product malfunctions, manufacturing flaws, or design defects, resulted in injury to patients. We may also be subject to liability for a misunderstanding of, or inappropriate reliance upon, the information we provide. If we cannot successfully defend ourselves against claims that any product we may develop caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of studies;
- significant costs to defend the related litigation and distraction to our management team;
- substantial monetary awards to patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

In addition, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our business may suffer if we are unable to manage our growth.

If we fail to effectively manage our growth, our ability to execute our business strategy could be impaired. The anticipated rapid growth of our business may place a strain on our management, operations and financial systems. We need to improve existing systems and controls or implement new systems and controls in response to anticipated growth.

We may not be able to protect or enforce our intellectual property rights, which could impair our competitive position.

Our success depends significantly on our ability to protect our rights to the patents, trademarks, trade secrets, copyrights and all the other intellectual property rights used, or expected to be used, in our products. Protecting intellectual property rights is costly and time consuming. We rely primarily on patent protection and trade secrets, as well as a combination of copyright and trademark laws and nondisclosure and confidentiality agreements to protect our technology and intellectual property rights. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or maintain any competitive advantage. Despite our intellectual property rights practices, it may be possible for a third party to copy or otherwise obtain and use our technology without authorization, develop similar technology independently or design around our patents.

We cannot be assured that any of our pending patent applications will result in the issuance of a patent to us. The U.S. Patent and Trademark Office ("PTO") may deny or require significant narrowing of claims in our pending patent applications, and patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. We could also incur substantial costs in proceedings before the PTO. Patents that may be issued to or licensed by us in the future may expire or may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related technologies. Upon expiration of our issued or licensed patents, we may lose some of our rights to exclude others from making, using, selling or importing products using the technology based on the expired patents. There is no assurance that competitors will not be able to design around our patents.

Further, we may not be able to obtain patent protection or secure other intellectual property rights in all the countries in which we operate, and under the laws of such countries, patents and other intellectual property rights may be unavailable or limited in scope. If any of our patents fails to protect our technology, it would make it easier for our competitors to offer similar products. Our trade secrets may be vulnerable to disclosure or misappropriation by employees, contractors and other persons. Any inability on our part to adequately protect our intellectual property may have a material adverse effect on our business, financial condition and results of operations.

We also rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology. We seek to protect our know-how and other unpatented proprietary technology, as trade secrets or otherwise, with confidentiality agreements and/or intellectual property assignment agreements with our team members, independent distributors and consultants. However, such agreements may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that our competitors discover or independently develop similar or identical designs or other proprietary information. Our trade secrets may be vulnerable to disclosure or misappropriation by employees, contractors and other persons.

In addition, we intend to rely on the use of registered and common law trademarks with respect to the brand names of some of our products. Common law trademarks provide less protection than registered trademarks. Loss of rights in our trademarks could adversely affect our business, financial condition and results of operations.

We may be subject to intellectual property infringement claims by third parties which could be costly to defend, divert management's attention and resources, and may result in liability.

The medical device industry is characterized by vigorous protection and pursuit of intellectual property rights. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage in the marketplace. From time to time, third parties may assert against us their patent, copyright, trademark and other intellectual property rights relating to technologies that are important to our business. Searching for existing intellectual property rights may not reveal important intellectual property and our competitors may also have filed for patent protection, which is not publicly-available information, or claimed trademark rights that have not been revealed through our availability searches. We may be subject to claims that our team members have disclosed, or that we have used, trade secrets or other proprietary information of our team members' former employers. Our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Any claims that our products or processes infringe these rights, regardless of their merit or resolution, could be costly, time consuming and may divert the efforts and attention of our management and technical personnel. In addition, we may not prevail in such proceedings given the complex technical issues and inherent uncertainties in intellectual property litigation.

Any claims of patent or other intellectual property infringement against us, even those without merit, could:

- increase the cost of our products;
- be expensive and/or time consuming to defend;
- result in our being required to pay significant damages to third parties;
- force us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products and technologies;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third party's intellectual property on terms that may not be favorable or acceptable to us;
- require us to develop alternative non-infringing technology, which could require significant effort and expense;
- require us to indemnify third parties pursuant to contracts in which we have agreed to provide indemnification for intellectual property infringement claims; and,
- result in our customers or potential customers deferring or limiting their purchase or use of the affected products impacted by the claims until the claims are resolved.

Any of the foregoing could affect our ability to compete or have a material adverse effect on our business, financial condition and results of operations.

Competitors may violate our intellectual property rights, and we may bring litigation to protect and enforce our intellectual property rights, which may result in substantial expense and may divert our attention from implementing our business strategy.

We believe that the success of our business depends, in significant part, on obtaining patent protection for our products and technologies, defending our patents and preserving our trade secrets. Our failure to pursue any potential claim could result in the loss of our proprietary rights and harm our position in the marketplace. Therefore, we may be forced to pursue litigation to enforce our rights. Future litigation could result in significant costs and divert the attention of our management and key personnel from our business operations and the implementation of our business strategy.

We or our third-party manufacturers may not have the manufacturing and processing capacity to meet the production requirements of clinical testing or consumer demand in a timely manner.

Our capacity to conduct clinical trials and commercialize our products will depend in part on our ability to manufacture or provide our products on a large scale, at a competitive cost and in accordance with regulatory requirements. We must establish and maintain a commercial scale manufacturing process for all of our products to complete clinical trials. We or our third-party manufacturers may encounter difficulties with these processes at any time that could result in delays in clinical trials, regulatory submissions or the commercialization of products.

For some of our products, we or our third-party manufacturers will need to have sufficient production and processing capacity in order to conduct human clinical trials, to produce products for commercial sale at an acceptable cost. We have no experience in large-scale product manufacturing, nor do we have the resources or facilities to manufacture most of our products on a commercial scale. We cannot guarantee that we or our third-party manufacturers will be able to increase capacity in a timely or cost-effective manner, or at all. Delays in providing or increasing production or processing capacity could result in additional expense or delays in our clinical trials, regulatory submissions and commercialization of our products.

The manufacturing processes for our products have not yet been tested at commercial levels, and it may not be possible to manufacture or process these materials in a cost-effective manner.

We will be dependent on third-party manufacturers since we will not initially directly manufacture our products.

Initially, we will not directly manufacture our products and will rely on third parties to do so for us. If our manufacturing and distribution agreements are not satisfactory, we may not be able to develop or commercialize products as planned. In addition, we may not be able to contract with third parties to manufacture our products in an economical manner. Furthermore, third-party manufacturers may not adequately perform their obligations, may delay clinical development or submission of products for regulatory approval or otherwise may impair our competitive position. We may not be able to enter into or maintain relationships with manufacturers that comply with good manufacturing practices. If a product manufacturer fails to comply with good manufacturing practices, we could experience significant time delays or we may be unable to commercialize or continue to market the products. Changes in our manufacturers could require costly new product testing and facility compliance inspections. In the United States, failure to comply with good manufacturing practices or other applicable legal requirements can lead to federal seizure of violative products, injunctive actions brought by the federal government, and potential criminal and civil liability on the part of a company and its officers and employees. Because of these and other factors, we may not be able to replace our manufacturing capacity quickly or efficiently in the event that our manufacturers are unable to manufacture our products at one or more of their facilities. As a result, the sale and marketing of our products could be delayed or we could be forced to develop our own manufacturing capacity, which could require substantial additional funds and personnel and compliance with extensive regulations.

We may be dependent on the sales and marketing efforts of third parties if we choose not to develop an extensive sales and marketing staff.

Initially, we will depend on the efforts of third parties (including sales agents and distributors) to carry out the sales and marketing of our products. We anticipate that each third party will control the amount and timing of resources generally devoted to these activities. However, these third parties may not be able to generate demand for our products. In addition, there is a risk that these third parties will develop products competitive to ours, which would likely decrease their incentive to vigorously promote and sell our products. If we are unable to enter into co-promotion agreements or to arrange for third-party distribution of our products, we will be required to expend time and resources to develop an effective internal sales force. However, it may not be economical for us to market our own products or we may be unable to effectively market our products. Therefore, our business could be harmed if we fail to enter into arrangements with third parties for the sales and marketing of our products or otherwise fail to establish sufficient marketing capabilities.

Our officers will allocate their time to other businesses thereby potentially limiting the amount of time they devote to our affairs. This conflict of interest could have a negative impact on our operations.

Our officers are not required to commit their full time to our affairs, which could create a conflict of interest when allocating their time between our operations and their other commitments. We presently expect each of our employees to devote such amount of time as they reasonably believe is necessary to our business. All of our officers are engaged in several other business endeavors and are not obligated to devote any specific number of hours to our affairs. If our officers' other business affairs require them to devote more substantial amounts of time to such affairs, it could limit their ability to devote time to our affairs and could have a negative impact on our operations. We cannot assure you these conflicts will be resolved in our favor.

Our ability to be successful will be totally dependent upon the efforts of our key personnel.

Our ability to successfully carry out our business plan is dependent upon the efforts of our key personnel. We cannot assure you that any of our key personnel will remain with us for the immediate or foreseeable future. The unexpected loss of the services of our key personnel could have a detrimental effect on us. We may also be unable to attract and retain additional key personnel in the future. An inability to do so may impact our ability to continue and grow our operations.

Our officers have fiduciary obligations to other companies and, accordingly, may have conflicts of interest in determining to which entity a particular business opportunity should be presented.

Certain of our officers have fiduciary obligations to other companies engaged in medical device business activities, namely Saphena Medical, Kaleidoscope Medical and Cruzar Medsystems. Accordingly, they may participate in transactions and have obligations that may be in conflict or competition with our business. As a result, a potential business opportunity may be presented by certain members of our management team to another entity prior to its presentation to us and we may not be afforded the opportunity to engage in such a transaction.

Our business, financial condition and results of operations could be adversely affected by the political and economic conditions of the countries in which we conduct business.

Our business, financial condition and results of operations could be adversely affected by the political and economic conditions of the countries in which we conduct business. These factors include:

- challenges associated with cultural differences, languages and distance;
- differences in clinical practices, needs, products, modalities and preferences;
- longer payment cycles in some countries;
- credit risks of many kinds;
- legal and regulatory differences and restrictions;
- currency exchange fluctuations;
- foreign exchange controls that might prevent us from repatriating cash earned in certain countries;
- political and economic instability and export restrictions;
- variability in sterilization requirements for multi-usage surgical devices;
- potential adverse tax consequences;
- higher cost associated with doing business internationally;
- challenges in implementing educational programs required by our approach to doing business;
- negative economic developments in economies around the world and the instability of governments, including the threat of war, terrorist attacks, epidemic or civil unrest;
- adverse changes in laws and governmental policies, especially those affecting trade and investment;
- pandemics, such as the Ebola virus, the enterovirus and the avian flu, which may adversely affect our workforce as well as our local suppliers and customers;
- import or export licensing requirements imposed by governments;
- differing labor standards;
- differing levels of protection of intellectual property;
- the threat that our operations or property could be subject to nationalization and expropriation;
- varying practices of the regulatory, tax, judicial and administrative bodies in the jurisdictions where we operate; and
- potentially burdensome taxation and changes in foreign tax.

Risks Related to Government Regulation

Any products we may develop may not be approved for sale in the U.S. or in any other country.

Neither we nor any future collaboration partner can commercialize any products we may develop in the U.S. or in any foreign country without first obtaining regulatory approval for the product from the FDA or comparable foreign regulatory authorities. The approval route in the U.S. for any products we may develop may be either via the PMA process, a *de novo* 510(k) pathway, or traditional 510(k). The PMA approval process is more complex, costly and time consuming than the 510(k) process. Additional randomized, controlled clinical trials may be necessary to obtain approval. The approval process may take several years to complete, and may never be obtained. Before obtaining regulatory approvals for the commercial sale of any product we may develop in the U.S., we must demonstrate with substantial evidence, gathered in preclinical and well-controlled clinical studies, that the planned products are safe and effective for use for that target indication. We may not conduct such a trial or may not successfully enroll or complete any such trial. Any products we may develop may not achieve the required primary endpoint in the clinical trial, and may not receive regulatory approval. We must also demonstrate that the manufacturing facilities, processes and controls for any products we may develop are adequate. Moreover, obtaining regulatory approval in one country for marketing of any products we may develop does not ensure we will be able to obtain regulatory approval in other countries, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

Even if we or any future collaboration partner were to successfully obtain a regulatory approval for any product we may develop, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for any products we may develop in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient revenue to justify commercial launch. Also, any regulatory approval of a product, once obtained, may be withdrawn. If we are unable to successfully obtain regulatory approval to sell any products we may develop in the U.S. or other countries, our business, financial condition, results of operations and growth prospects could be adversely affected.

The regulatory approval process is expensive, time consuming and uncertain, and may prevent us or our partners from obtaining approval for the commercialization of any products we may develop. Approval of products in the U.S. or other territories may require that we, or a partner, conduct randomized, controlled clinical trials.

The regulatory pathway in the U.S. for approval of the products we are currently developing has not been determined. However, it is possible the FDA will require us to file for approval via the PMA pathway for one or more of our planned products. In this case, the FDA is likely to require that randomized, controlled clinical trials be conducted before an application for approval can be filed. These are typically expensive and time consuming, and require substantial commitment of financial and personnel resources from the sponsoring company. These clinical trials also entail significant risk, and the resulting data may not be sufficient to support approval by the FDA or other regulatory bodies.

Furthermore, regulatory approval of a PMA or a 510(k) pathway is not guaranteed, and the filing and approval process itself is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense exerted, failure may occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical studies. The FDA can delay, limit, or deny approval of a future product for many reasons, including but not limited to:

- a future product may not be deemed to be safe and effective;
- FDA officials may not find the data from clinical and preclinical studies sufficient;
- the FDA may not approve our or our third-party manufacturer's processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

If any products we may develop fail to demonstrate safety and efficacy in further clinical studies may be required, or do not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

Even if we receive regulatory approval for any product we may develop, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

Once regulatory approval has been obtained, the approved product and its manufacturer are subject to continual review by the FDA or non-U.S. regulatory authorities. Our regulatory approval for any products we may develop may be subject to limitations on the indicated uses for which the product may be marketed. Future approvals may contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the approved product. In addition, we are subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. In addition, we are required to comply with cGMP regulations regarding the manufacture of any products we may develop, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing.

Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.

We intend to seek distribution and marketing partners for one or more of the products we may develop in foreign countries. The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Moreover, clinical studies or manufacturing processes conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file we may not receive necessary approvals to commercialize our products in any market.

Healthcare reform measures could hinder or prevent our products' commercial success.

In the U.S., there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that could result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the PPACA, was enacted in 2010. The PPACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The PPACA, among other things:

- imposes a tax of 2.3% on the retail sales price of medical devices sold after December 31, 2012 (On January 22, 2018, the implementation of the medical device tax was deferred until January 1, 2020); and

- could result in the imposition of injunctions.

While the U.S. Supreme Court upheld the constitutionality of most elements of the PPACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. At this time, it remains unclear whether there will be any changes made to the PPACA, whether to certain provisions or its entirety. The 2.3% tax on sales of medical devices may be applicable to sales of one or more products we may develop. We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, which triggered the legislation's automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to 2.0% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by the sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In March 2013, President Obama signed an executive order implementing sequestration, and in April 2013, the 2.0% Medicare reductions went into effect. We cannot predict whether any additional legislative changes will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

- our ability to set a price that we believe is fair for our products;

- our ability to generate revenue and achieve or maintain profitability; and

- the availability of capital.

Further, changes in regulatory requirements and guidance may occur, both in the United States and in foreign countries, and we may need to amend clinical study protocols to reflect these changes. Amendments may require us to resubmit our clinical study protocols to IRB's for reexamination, which may impact the costs, timing or successful completion of a clinical study. In light of widely publicized events concerning the safety risk of certain drug and medical device products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential safety issues. These events have resulted in the recall and withdrawal of medical device products, revisions to product labeling that further limit use of products and establishment of risk management programs that may, for instance, restrict distribution of certain products or require safety surveillance or patient education. The increased attention to safety issues may result in a more cautious approach by the FDA or other regulatory authorities to clinical studies and the drug approval process. Data from clinical studies may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical studies before completion, or require longer or additional clinical studies that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Given the serious public health risks of high profile adverse safety events with certain products, the FDA or other regulatory authorities may require, as a condition of approval, costly risk evaluation and mitigation strategies, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;

- the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits payments or the provision of anything of value to foreign officials for the purpose of obtaining or keeping business;

- the federal False Claims Act, or FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The PPACA, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If required, clinical trials necessary to support a 510(k) notice or PMA application will be expensive and will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support a 510(k) notice or a PMA application will be time-consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product the Company advances into clinical trials may not have favorable results in early or later clinical trials.

Conducting successful clinical studies will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by patients enrolled as subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy may be required and the Company may not adequately develop such protocols to support clearance and approval. Further, the FDA may require the Company to submit data on a greater number of patients than it originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis for any clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. The FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

The results of the Company's clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

Even if any of the Company's clinical trials are completed as planned, it cannot be certain that study results will support product candidate claims or that the FDA or foreign regulatory authorities will agree with our conclusions regarding them. Success in pre-clinical evaluation and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

The Company's medical products may in the future be subject to product recalls that could harm its reputation, business and financial results.

The FDA has the authority to require the recall of commercialized medical device products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by the Company or one of its distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of the Company's products would divert managerial and financial resources and have an adverse effect on its financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within ten (10) working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. The Company may initiate voluntary recalls involving its products in the future that the Company determines do not require notification of the FDA. If the FDA disagrees with the Company's determinations, they could require the Company to report those actions as recalls. A future recall announcement could harm the Company's reputation with customers and negatively affect its sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted. No recalls of the Company's medical products have been reported to the FDA.

If the Company's medical products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If the Company fails to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against the Company. Any such adverse event involving its products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of the Company's time and capital, distract management from operating our business, and may harm its reputation and financial results.

If the effectiveness and safety of the Company's devices are not supported by long-term data, the Company's future revenues could decline.

The Company's products may not be accepted in the market if the Company does not produce clinical data supported by the independent efforts of clinicians, and if that data indicates that treatment with the Company's products does not provide patients with sustained benefits or that treatment with the Company's products is less effective or less safe than the Company's current data suggests, the Company's future revenues could decline. In addition, the FDA could then bring legal or regulatory enforcement actions against the Company and/or its products including, but not limited to, recalls or requirements for pre-market 510(k) authorizations. The Company can give no assurance that its data will be substantiated in studies involving more patients. In such a case, the Company may never achieve significant revenues or profitability.

If the Company is found to be promoting the use of its devices for unapproved or "off-label" uses or engaging in other noncompliant activities, the Company may be subject to recalls, seizures, fines, penalties, injunctions, adverse publicity, prosecution, or other adverse actions, resulting in damage to its reputation and business.

The Company's labeling, advertising, promotional materials and user training materials must comply with the FDA and other applicable laws and regulations, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. Obtaining 510(k) clearance or PMA approval only permits the Company to promote its products for the uses specifically cleared by the FDA. Use of a device outside its cleared or approved indications is known as "off-label" use. Physicians and consumers may use the Company's products off-label because the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine nor is there oversight on patient use of over-the-counter devices. Although the Company may request additional cleared indications for our current products, the FDA may deny those requests, require additional expensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of clearance. Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product.

If the FDA determines that the Company's labeling, advertising, promotional materials, or user training materials, or representations made by Company personnel, include the promotion of an off-label use for the device, or that the Company has made false or misleading or inadequately substantiated promotional claims, or claims that could potentially change the regulatory status of the product, the agency could take the position that these materials have misbranded the Company's devices and request that the Company modifies its labeling, advertising, or user training or promotional materials and/or subject the Company to regulatory or legal enforcement actions, including the issuance of an Untitled Letter or a Warning Letter, injunction, seizure, recall, adverse publicity, civil penalties, criminal penalties, or other adverse actions. It is also possible that other federal, state, or foreign enforcement authorities might take action if they consider the Company's labeling, advertising, promotional, or user training materials to constitute promotion of an unapproved use, which could result in significant fines, penalties, or other adverse actions under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, we would be subject to extensive fines and penalties and the Company's reputation could be damaged and adoption of the products would be impaired. Although the Company intends to refrain from statements that could be considered off-label promotion of its products, the FDA or another regulatory agency could disagree and conclude that the Company has engaged in off-label promotion. For example, the Company has made statements regarding some of its devices that the FDA may view as off-label promotion. In addition, any such off-label use of the Company's products may increase the risk of injury to patients, and, in turn, the risk of product liability claims, and such claims are expensive to defend and could divert the Company's management's attention and result in substantial damage awards against the Company.

The Company may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if the Company is unable to fully comply with such laws.

While the Company does not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, many healthcare laws and regulations apply to the Company's business. For example, the Company could be subject to healthcare fraud and abuse and patient privacy regulation and enforcement by both the federal government and the states in which the Company intends to conduct its business. The healthcare laws and regulations that may affect the Company's ability to operate include:

- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase order or recommendation of, any item or service for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services not provided as claimed and which may apply to entities like the Company to the extent that the Company's interactions with customers may affect their billing or coding practices;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established new federal crimes for knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services, as well as leading to regulations imposing certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Recently, the medical device industry has been under heightened scrutiny as the subject of government investigations and regulatory or legal enforcement actions involving manufacturers who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business, including arrangements with physician consultants. If the Company's operations or arrangements are found to be in violation of any of the laws described above or any other governmental regulations that apply to the Company, the Company may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of its operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of the Company's operations could adversely affect its ability to operate its business and its financial results. The risk of the Company being found in violation of these laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against the Company for violation of these laws, even if the Company successfully defends against that action and the underlying alleged violations, could cause the Company to incur significant legal expenses and divert its management's attention from the operation of its business. If the physicians or other providers or entities with whom the Company does business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on the Company's business.

The Company or its subsidiaries' failure to obtain or maintain necessary FDA clearances or approvals, or equivalents thereof in the U.S. and relevant foreign markets, could hurt our ability to distribute and market our products.

In both the United States and foreign markets, the Company and its subsidiaries are affected by extensive laws, governmental regulations, administrative determinations, court decisions and similar constraints. Such laws, regulations and other constraints may exist at the federal, state or local levels in the United States and at analogous levels of government in foreign jurisdictions.

For example, certain of the Company's planned product candidates may fall under the regulatory purview of various centers at the FDA and in other countries by similar health and regulatory authorities.

In addition, the formulation, manufacturing, packaging, labeling, distribution, importation, sale and storage of the Company's and its subsidiaries' products are subject to extensive regulation by various federal agencies, including, but not limited to, the FDA, the FTC, State Attorneys General in the United States, the Ministry of Health, Labor and Welfare in Japan, as well as by various other federal, state, local and international regulatory authorities in the countries in which its products are manufactured, distributed or sold. If the Company or its manufacturers fail to comply with those regulations, the Company and its subsidiaries could become subject to significant penalties or claims, which could harm its results of operations or its ability to conduct its business. In addition, the adoption of new regulations or changes in the interpretations of existing regulations may result in significant compliance costs or discontinuation of product sales and may impair the marketing of its products, resulting in significant loss of net sales. The Company's failure to comply with federal or state regulations, or with regulations in foreign markets that cover its product claims and advertising, including direct claims and advertising by the Company or its subsidiaries, may result in enforcement actions and imposition of penalties or otherwise harm the distribution and sale of its products. Further, the Company and its subsidiaries' businesses are subject to laws governing our accounting, tax and import and export activities. Failure to comply with these requirements could result in legal and/or financial consequences that might adversely affect its sales and profitability. Each medical device that the Company wishes to market in the U.S. must first receive either 510(k) clearance or premarket approval from the FDA unless an exemption applies. Either process can be lengthy and expensive. The FDA's 510(k) clearance process may take from three to twelve months, or longer, and may or may not require human clinical data. The premarket approval process is much more costly and lengthy. It may take from eleven months to three years, or even longer, and will likely require significant supporting human clinical data. Delays in obtaining regulatory clearance or approval could adversely affect the Company's revenues and profitability. Although the Company has obtained 510(k) clearances for its LHE devices as these clearances may be subject to revocation if post-marketing data demonstrates safety issues or lack of effectiveness. Similar clearance processes may apply in foreign countries. Further, more stringent regulatory requirements or safety and quality standards may be issued in the future with an adverse effect on the Company's business.

Risks Associated with Ownership of Our Common Stock

We may issue shares of our common and /or preferred stock in the future which could reduce the equity interest of our stockholders and might cause a change in control of our ownership.

Our certificate of incorporation authorizes the issuance of up to 50,000,000 shares of common stock, par value $.001 per share, and 20,000,000 shares of preferred stock, par value $.001 per share. We may issue a substantial number of additional shares of our common stock or preferred stock, or a combination of common and preferred stock, to raise additional funds or in connection with any strategic acquisition. The issuance of additional shares of our common stock or any number of shares of our preferred stock:

- may significantly reduce the equity interest of investors;
- may subordinate the rights of holders of common stock if preferred stock is issued with rights senior to those afforded to our common stockholders;
- may cause a change in control if a substantial number of our shares of common stock are issued, which may affect, among other things, our ability to use our net operating loss carryforwards, if any, and most likely also result in the resignation or removal of some or all of our present officers and directors; and
- may adversely affect prevailing market prices for our common stock.

We have incurred substantial indebtedness, and may incur additional indebtedness in the future, which could adversely affect our liquidity, financial condition, and results of operations.

On July 3, 2017, we issued to Scopia Holdings LLC ("Scopia or the Lender") a Senior Secured Note with an initial principal amount of $5.0 million pursuant to a Note and Security Purchase Agreement. The aggregate remaining unpaid principal balance of the note is due on June 30, 2019. The 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, with the unpaid interest added to the outstanding interest-bearing principal balance of the Senior Secured Note. The obligations under the Senior Secured Note are secured by all of our assets and those of our subsidiaries. The Note and Security Purchase Agreement and the Senior Secured Note also contain various affirmative and negative covenants, including restrictions on our 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, while any amount under the Senior Secured Note remains outstanding.

Our indebtedness could have important consequences on our business. To the extent new debt and/or new credit sources are added to our existing debt under the Senior Secured Note issued to Scopia, the related risks for us could intensify. In particular, it could:

- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow to fund operating expenditures, capital expenditures, and for other general corporate purposes;
- limit, among other things, our ability to borrow additional funds and otherwise raise additional capital, and our ability to conduct acquisitions, joint, ventures or similar arrangements, as a result of our obligations to repay such indebtedness and as a result of restrictive covenants contained in the agreements governing our indebtedness;
- limit our flexibility in planning for, or reacting to, changes in our businesses and the industries in which we operate;
- increase our vulnerability to general adverse economic and industry conditions; and
- place us at a competitive disadvantage compared to our competitors that have less debt.

In addition, while the Note and Security Purchase Agreement and the Senior Secured Note do not contain any financial covenants, the agreements governing any future indebtedness we incur, may potentially include such covenants. Our ability to comply with the financial covenants may be subject to factors beyond our control.

Despite our right to increase the principal balance of the Senior Secured Note by a portion of the interest expense, as noted above, we may not be able to generate sufficient cash to service the Senior Secured Note, or any future indebtedness incurred by us, as cash payments become due. If we are unable to make payments as they come due or comply with the restrictions and covenants in the Note and Security Purchase Agreement and the Senior Secured Note with Scopia, or any other agreements governing our future indebtedness, there could be a default under the terms of such agreements. In such event, or if we are otherwise in default under the Note and Security Purchase Agreement and the Senior Secured Note with Scopia, or such other agreements, including pursuant to any cross-default provisions of such agreements, the lenders could terminate their commitments to lend and/or accelerate the loans and declare all amounts borrowed due and payable. Furthermore, Scopia and any future lenders to whom we grant a security interest could foreclose on their security interests in our assets, including our intellectual property. If any of those events occur, our assets might not be sufficient to repay in full all of our outstanding indebtedness and we may be unable to find alternative financing. Even if we could obtain alternative financing, it might not be on terms we deem favorable or acceptable to us. Additionally, we may not be able to amend the Note and Security Purchase Agreement and the Senior Secured Note with Scopia, or such other agreements, or obtain needed waivers, on satisfactory terms or without incurring substantial costs. Failure to maintain existing or secure new financing could have a material adverse effect on our liquidity, financial position, and/or results of operations.

Our management and their affiliates control a substantial interest in us and thus may influence certain actions requiring a stockholder vote.

As of December 31, 2017, our management and their affiliates collectively own approximately 52% of our issued and outstanding shares of common stock. Accordingly, these individuals would have considerable influence regarding the outcome of any transaction that requires stockholder approval. Furthermore, our Board of Directors is and will be divided into three classes, each of which will generally serve for a term of three years with only one class of directors being elected in each year. As a consequence of our "staggered" Board of Directors, only a minority of the Board of Directors will be considered for election in any given year and our initial stockholders, because of their ownership position, will have considerable influence regarding the outcome.

There can be no assurance that our common stock will continue to trade on the Nasdaq Capital Market or another national securities exchange.

As of March 5, 2018, we are not in compliance with the MVLS standard of the continued listing standards for Nasdaq Capital Market companies. We have been afforded until September 4, 2018 to regain compliance. There can be no assurance that we will be able to meet the MVLS or any of the other Nasdaq Capital Market listing standards. If we are unable to regain compliance with the MVLS standard or another listing standard within the time frame set by Nasdaq, and maintain compliance with such standards, our common stock may no longer be listed on the Nasdaq Capital Market or another national securities exchange and the liquidity and market price of our common stock may be adversely affected.

If Nasdaq delists our securities from trading on its exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination our shares of common stock are "penny stock" which will require brokers trading in our shares of common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares of common stock;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

A robust public market for our common stock may not develop or be sustained, which could affect your ability to sell our common stock or depress the market price of our common stock.

We are unable to predict whether an active trading market for our common stock will develop or will be sustained. A substantial number of our securities are "restricted securities" as defined in Rule 144 under the Securities Act of 1933, as amended, or the "Securities Act," and/or are held by affiliates of ours. Securities held by affiliates of an issuer are sometimes referred to as "control securities." Restricted securities and control securities may only be sold publicly pursuant to a registration statement or an exemption from registration. Rule 144, which provides such an exemption, requires that public sales meet certain conditions, including, in the case of restricted securities, that certain holding period requirements are met and, in the case of control securities (including restricted securities that are control securities), that certain information be publicly available and that sales be made in compliance with certain manner of sale and volume limitations. The public information requirement also applies to sales of restricted securities (even if they are not control securities), if such securities have been held for less than one year. There can be no assurance that we will continue to fulfill the public information requirement or that the other conditions to the availability of Rule 144 will be satisfied, and even if satisfied, the volume limitations of Rule 144 will restrict the number of control securities that may be sold. Accordingly, certain amounts of our securities may not be eligible for public sale. If an active market does not develop or is not sustained for the foregoing reasons or for any other reason, it may be difficult for you to sell your securities at the time you wish to sell them, at a price that is attractive to you, or at all.

Our stock price may be volatile, and purchasers of our securities could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general, and the market for life science companies, and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including the following:

- our ability to successfully commercialize, and realize revenues from sales of, any products we may develop;
- the performance, safety and side effects of any products we may develop;
- the success of competitive products or technologies;
- results of clinical studies of any products we may develop or those of our competitors;
- regulatory or legal developments in the U.S. and other countries, especially changes in laws or regulations applicable to any products we may develop;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or other products we may develop;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a cost-effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the medical device, pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- the other risks described in this "*Risk Factors*" section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Our outstanding warrants and other convertible securities may have an adverse effect on the market price of our common stock.

We currently have outstanding warrants and other convertible securities to purchase an aggregate of 16,421,793 shares of our Common Stock, including (i) 301,416 shares of issuable upon conversion of our Series A Preferred Stock, (ii) 268,001 shares of issuable upon exercise of our Series A Warrants, (iii) 357,259 shares issuable upon conversion of our Series A-1 Preferred Stock, (iv) 279,837 shares issuable upon exercise of our Series A-1 Warrants, (v) 1,473,640 shares issuable upon exercise of our Series S Warrants, (vi) 106,000 shares issuable upon exercise of the unit purchase option granted to the selling agents in our IPO, (vii) 3,102,140 shares issuable upon exercise of our employee stock options, and (viii) 10,533,500 Series W warrants issued in our initial public offering in April 2016 (the "*IPO*") and in private placements prior to our IPO (the latter of which automatically converted into Series W Warrants upon completion of the IPO). In addition, each Series A Warrant is exchangeable for four Series X Warrants, each to purchase one share of Common Stock, and each Series A-1 Warrant is exchangeable for either five Series W Warrants or four Series X-1 Warrants, each to purchase one share of Common Stock. Furthermore, dividends on the Series A Preferred Stock may be paid in additional shares of Series A Preferred Stock or in shares of our Common Stock. We have an effective registration statement under the Securities Act registering the issuance of the shares underlying the employee stock options and the resale to the public of the shares of our Common Stock underlying the Series A Preferred Stock, the Series A Warrants, the Series X Warrants issuable in exchange for the Series A Warrants, and certain of the Series W Warrants that previously were issued in private placements. Additionally, we have filed a registration statement under the Securities Act registering the resale to the public of the shares of our Common Stock underlying the Series A-1 Preferred Stock, the Series A-1 Warrants, the Series X-1 Warrants and Series W Warrants issuable in exchange for the Series A-1 Warrants, and the Series S Warrants. The sale, or even the possibility of sale, of such shares could have an adverse effect on the market price for our securities or on our ability to obtain future public financing. If and to the extent our warrants or other convertible securities, or any additional warrants or other convertible securities, we issue, are exercised or converted, you may experience dilution to your holdings.

If our initial stockholders exercise their registration rights, it may have an adverse effect on the market price of our common stock.

Our initial stockholders are entitled to demand that we register the resale of their securities acquired in connection with our organization and private placements. The presence of additional number of shares of common stock and warrants eligible for trading in the public market may have an adverse effect on the market price of our common stock.

If the Company's proposed Rights Offering is completed, it could result in additional dilution of our stockholders and could cause the price of our Common Stock to fall.

The Company intends to conduct the Rights Offering. Pursuant to the Rights Offering, the Company expects to distribute to the holders of outstanding shares of its Common Stock, for no consideration, one transferable right to purchase a new unit of the Company's securities for each share of Common Stock outstanding. Each unit is expected to be comprised of one share of Common Stock and one Series Z Warrant. The rights are expected to be exercisable at a price of $2.25 per unit. If the Company completes the rights offering, such offering may result in material dilution to the holders of the warrants, including Series W Warrants and Series Z Warrants.

There can be no assurance that we will complete the Rights Offering.

Although the Company intends to conduct the Rights Offering, there can be no assurance that the Company will complete such Rights Offering on the terms described above, or at all.

We do not intend to pay any dividends on our common stock at this time.

We have not paid any cash dividends on our shares of common stock to date. The payment of cash dividends on our common stock in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition and will be within the discretion of our Board of Directors. It is the present intention of our Board of Directors to retain all earnings, if any, for use in our business operations and, accordingly, our Board of Directors does not anticipate declaring any dividends on our common stock in the foreseeable future. As a result, any gain you will realize on our common stock (including common stock obtained upon exercise of our warrants) will result solely from the appreciation of such shares.

We are an "emerging growth company" ("EGC"), and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

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. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period under the JOBS Act.

We incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, the other rules and regulations of the Securities and Exchange Commission, or SEC, and the rules and regulations of Nasdaq or any other national securities exchange on which our securities are then trading. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and Nasdaq have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel devote a substantial amount of time to these compliance initiatives. These rules and regulations result in significant legal and financial compliance costs and make some activities more time-consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are no longer an emerging growth company. Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and as our business expands we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. If any analyst who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following.

- our Board of Directors is divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;
- our Board of Directors has the right to elect directors to fill a vacancy created by the expansion of our Board of Directors or the resignation, death or removal of a director, which will prevent stockholders from being able to fill vacancies on our Board of Directors;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- our stockholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to our Board of Directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company; and
- our Board of Directors is able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15.0% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15.0% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Item 1B. Unresolved Staff Comments

None

Item 2. Property

We occupy approximately 610 square feet of office space plus common area facilities at One Grand Central Place, 60 East 42nd Street, New York, NY 10165, under a lease agreement which initially provided for two consecutive six month terms beginning on February 1, 2016, and was subsequently amended to 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. 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.

Previously we rented access to a research and development facility, located at 375 West Street, West Bridgewater, MA 02379, 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, we ceased use of the research and development facility and canceled the rental arrangement.

At this time, we consider the leased facilities to be adequate for our current operations. Notwithstanding, we may obtain additional space as warranted by our business operations.

Item 3. Legal Proceedings

In the normal course of business, from time-to-time, we may become subject to claims in legal proceedings, however, we do not believe we are 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 our business, financial position, results of operations, and /or cash flows.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrants Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

The Company consummated its IPO on April 28, 2016 under a registration statement on Form S-1 (File No. 333-203569) declared effective January 29, 2016. The IPO resulted in $4.2 million of net cash proceeds, after deducting cash selling agent discounts and commissions and cash offering expenses, from the issuance of 1,060,000 IPO Units, at an offering price of $5.00 per unit, with each such IPO Unit comprised of one share of common stock of the Company and one Series W Warrant to purchase a share of common stock of the Company.

The IPO Units were initially listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "PAVMU" from the consummation of the IPO until July 27, 2016 when the IPO Units ceased to be quoted and traded on Nasdaq, whereupon, the IPO Units separated into their constituent securities, 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. Prior to our initial public offering, there was no public market for our securities.

The following table shows the high and low closing sale prices per share of our securities as reported on the Nasdaq for the periods indicated:

	Common Stock		Series W Warrants	
	High	Low	High	Low
2018:				
First Quarter*	$ 3.98	$ 1.35	$ 1.56	$ 0.21
2017:				
Fourth Quarter	$ 5.70	$ 2.18	$ 1.91	$ 0.38
Third Quarter	$ 8.59	$ 2.86	$ 2.65	$ 0.98
Second Quarter	$ 5.43	$ 3.57	$ 4.53	$ 1.51
First Quarter	$ 8.00	$ 4.64	$ 5.84	$ 2.24
2016:				
Fourth Quarter	$ 14.00	$ 6.80	$ 8.00	$ 5.51
Third Quarter**	$ 15.24	$ 5.00	$ 4.85	$ 4.00

* Through March 12, 2018.
** Commencing July 27, 2016

Holders

As of March 12, 2018, there were 17,235,397 shares of common stock outstanding. We believe our shares of common stock are held by more than 1,200 beneficial owners of our common stock.

Dividends

We have not paid any cash dividends on our common stock to date. Any future decisions regarding dividends will be made by our board of directors. We do not anticipate paying dividends in the foreseeable future, but expect to retain earnings to finance the growth of our business. Our board of directors has complete discretion on whether to pay dividends. Even if our board of directors decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that the board of directors may deem relevant.

Information about our equity compensation plans

Information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

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. The shares issued upon exercise of the warrants were issued pursuant to the exemption from registration contained in Section 3(a)(9) of the Securities Act, as the warrants were exchanged for shares exclusively, and no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange.

Item 6. Selected Financial Data

Not applicable.

Item 7. 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 consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, 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 this Annual Report on Form 10-K 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 Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, as well as "Risk Factors" section of this Annual Report on Form 10-K, 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 Annual Report on Form 10-K 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
- the time during which we will be an ECG under the JOBS Act.

We may not actually achieve the plans, intentions, and /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. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future financings, acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report on Form 10-K and the documents we have filed as exhibits to this Annual Report on Form 10-K 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, each as summarized herein below in "— Recent Developments - Financing Transactions". Additionally, subsequent to December 31, 2017, in January 2018, the Company raised $4.3 million of net cash proceeds to-date in an underwritten public offering of shares of common stock of the Company pursuant to its previously filed effective shelf registration statement on SEC Form S-3 (File No. 333-220549), each as further discussed herein below in "— Recent Developments - Financing Transactions".

The following is a brief overview of the lead products currently in our pipeline, including: CarpX™, PortIO™, and DisappEAR™. These products are all in various phases of development and have not yet received regulatory approval. Among other things:

- We have filed final nonprovisional patent applications for PortIO™ and CarpX™ 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 our DisappEAR™ product.

- We have 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. On November 27, 2017 we filed a 510(k) premarket notification submission with the Federal Food and Drug Administration ("FDA") for CarpX™ using a commercially available carpal tunnel release device as a predicate. We have received promising initial feedback from the FDA and we are working to provide additional non-clinical support for our application. In addition, we are preparing to submit for CE Mark clearance in Europe and a first-in-man clinical series outside of the United States. We are exploring commercialization strategies in the United States and commercialization partnerships worldwide.

- We have 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 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 filed with a *de novo* pre-submission package with the FDA which was followed by an in-person meeting on January 9, 2018 to discuss the risk assessment and proposed mitigation testing for the *de novo* application. Based on their recommendations are about to initiate a seven-day animal study, having successfully completed a pilot animal study which showed excellent function of the device over the seven-day implant period and on explant. In anticipation of having to follow up the animal study with a human clinical safety trial, we have accelerated our strategic partnership efforts to include the pre-clearance phase.

- We have advanced, in partnership with our design and contract manufacturing partners and our academic partners at Tufts University and Harvard Medical School, our DisappEAR™. Our efforts have focused on sourcing commercially ready aqueous silk and optimizing manufacturing processes consistent with the necessary cost of good for the commercial product.

- Although we have focused the majority of our resources on our lead products, we have additional products in our pipeline which are currently in different stages of development. We have completed initial design work on the first product in the NextCath™ product line, 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. We have 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. We have, completed benchtop testing of a working prototype demonstrating constant flows across the range of pressures encountered in clinical situations. We will be able to quickly move NextCath™ and NextFlo™ into the commercial and regulatory pathway when resources become available. Finally, 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.

Overview (continued)

- 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.

- 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.

- 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.

We have proprietary rights to the trademarks used herein, including, among others, PAVmed™, PortIO™, Caldus™, CarpX™, DisappEAR™, NextCath™, NextFlo™, and "Innovating at the Speed of Life™, among others. Solely as a matter of convenience, trademarks and trade names referred to herein may or may not be accompanied with the requisite marks of "™" and /or "®", however, the absence of such marks is not intended to indicate, in any way, we will not assert, to the fullest extent possible under applicable law, our rights or the rights to such trademarks and trade names.

Recent Developments

Regulatory Events

On November 27, 2017 we filed a 510(k) premarket notification submission with the FDA for our CarpX™ minimally invasive device designed to treat carpal tunnel syndrome. using a commercially available carpal tunnel release device as a predicate. We have received promising initial feedback from the FDA and are working to provide additional non-clinical support for our application.

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 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. After further discussion with the FDA, we 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 filed a *de novo* pre-submission package with the FDA which was followed by an in-person meeting on January 9, 2018 to discuss the risk assessment and proposed mitigation testing for the *de novo* application. Based on their recommendations we are about to initiate a seven-day animal study, having successfully completed a pilot animal study which showed excellent function of the device over the seven-day implant period and on explant. In anticipation of having to follow up the animal study with a human clinical safety trial, we have accelerated our strategic partnership efforts to include the pre-clearance phase.

Financing Transactions

Shareholders' Rights Offering

Subsequently, on January 17, 2018, the Company filed an initial registration statement on Form S-1 (File No. 333-222581), currently under SEC review, related to a proposed offering wherein, as currently proposed, the Company will distribute one transferable equity subscription right for each issued and outstanding share of common stock of the Company as of a record date to be determined by the Company's Board of Directors ("Equity Subscription Rights Offering" or "Rights Offering"). As currently proposed, the Equity Subscription Rights Offering is to commence upon an effective registration statement. Further, as currently proposed, for a period of 30 days from their distribution date, the transferable equity subscription right may be exercised for $2.25 per unit to purchase a common stock unit comprised of one share of common stock of the Company and one Series Z Warrant. As currently proposed, the common stock unit will trade for up to 90 days, after which it will separate into its underlying components of one share of common stock of the Company and one Series Z Warrant. The Series Z Warrant may be exercised for one share of common stock of the Company at an exercise price of $3.00 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 will expire after the close of business on April 30, 2024. The Series Z Warrants are redeemable by the Company under certain conditions. See our consolidated financial statements Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a further discussion of the Series Z Warrants.

Recent Developments (continued)

Financing (continued)

Issue of Common Stock - Underwritten Public Offering - January 2018

Subsequently, in January 2018, we conducted an underwritten public offering pursuant to a previously filed and effective shelf registration statement on SEC Form S-3 (File No. 333-220549), declared effective October 6, 2017, along with a corresponding prospectus supplement dated January 19, 2018. On January 19, 2018, we entered into an underwriting agreement with Dawson James Securities, Inc., as sole underwriter, under which we agreed to issue to the underwriter at $1.80 per share, 2,415,278 shares of common stock of the Company on a firm commitment basis and up to an additional 362,292 shares solely to cover underwriter over-allotments, if any, at the option of the underwriter, exercisable within 45 calendar days from January 19, 2018. The Company issued the 2,415,278 of such shares on January 23, 2018, and on January 25, 2018, issued 234,540 of such shares, under the underwriter's over-allotment, resulting in net cash proceeds of $4,263,099, after deduction of both underwriting discounts of $381,574 and estimated offering costs.

Series A and Series A-1 Exchange Offer - Series B Convertible Preferred Stock and Series Z Warrants

Subsequently, on February 14, 2018 the Company initiated an exchange offer to the holders of both the Series A Convertible Preferred Stock and Series A Warrants, and the Series A-1 Convertible Preferred Stock and Series A-1 Warrants ("Series A and Series A-1 Exchange Offer"), as follows: (i) one share of Series A Convertible Preferred Stock exchanged for two shares of Series B Convertible Preferred Stock, and one Series A Warrant exchanged for five Series Z Warrants; and (ii) one share of Series A-1 Convertible Preferred Stock exchanged for 1.33 shares of Series B Convertible Preferred Stock, and one Series A-1 Warrant exchanged for five Series Z Warrants. A condition of the Series A and Series A-1 Exchange Offer is for all outstanding shares of Series A Convertible Preferred Stock and all Series A Warrants, and all shares of Series A-1 Convertible Preferred Stock and all Series A-1 Warrants, must be tendered. If not all are tendered, then the Company reserves the right to not accept any tenders. The Series A and Series A-1 Exchange Offer is scheduled to expire on March 15, 2018, unless extended by the Company, at its sole discretion.

The Series B Convertible Preferred Stock has a par value of $0.001 per share, no voting rights, a stated value of $3.00 per share, and is immediately convertible upon its issuance. At the holders' election, one share of Series B Convertible Preferred Stock is convertible into one share of common stock of the Company, based on a common stock conversion exchange factor equal to a numerator of $3.00 and a denominator of $3.00, with such denominator 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 B Convertible Preferred Stock shall not be redeemed for cash and under no circumstances shall the Company be required to net cash settle the Series B Convertible Preferred Stock.

The Series B Convertible Preferred Stock provides for dividends at a rate of 8% per annum on the stated value of the Series B Convertible Preferred Stock, with such dividends compounded quarterly, accumulate, and payable in arrears upon being declared by the Company's Board of Directors. The Series B Convertible Preferred Stock dividends from April 1, 2018 through October 1, 2021 are payable-in-kind ("PIK") in additional shares of Series B 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 B Convertible Preferred Stock, shares of common stock, and /or cash payment.

The Series Z Warrants issued in the Series A and Series A-1 Exchange Offer will be immediately exercisable upon issuance and expire after the close of business on April 30, 2024, and each may be exercised for one share of common stock of the Company at an exercise price of $3.00 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. The Series Z Warrants are redeemable by the Company under certain conditions. See our consolidated financial statements Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a further discussion of the Series B Convertible Preferred Stock and the Series Z Warrants.

Recent Developments *(continued)*

Financing (continued)

Series W Warrants Offer-to-Exercise

Subsequently, on January 11, 2018, the Company filed with the SEC a Tender Offer Statement on Schedule TO offering Series W Warrants holders a temporary exercise price of $2.00 per share ("Series W Warrants Offer-to-Exercise"). As of the February 8, 2018 expiry of the Series W Warrants Offer-to-Exercise, a total of 34,345 Series W Warrants were exercised at the temporary exercise of $2.00 per share, resulting in $68,690 of cash proceeds, and the issue of a corresponding number of shares of common stock of the Company.

Series W Warrants Offer-to-Exchange

Subsequently, on February 20, 2018, the Company filed with the SEC a Tender Offer Statement on Schedule TO offering to exchange two Series W Warrants for one Series Z Warrant, with such exchange offer expiring on March 19, 2018 ("Series W Warrants Offer-to-Exchange"). The Series Z Warrants issued upon exchange of the Series W Warrants will be immediately exercisable upon issuance and expire after the close of business on April 30, 2024, and each may be exercised for one share of common stock of the Company at an exercise price of $3.00 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. The Series Z Warrants are redeemable by the Company under certain conditions. See our consolidated financial statements Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a further discussion of the Series W Warrants and the Series Z 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 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 ("Senior Secured Note"), and 2,660,000 Series S Warrants to purchase shares of common stock of the Company.

The Senior Secured 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 payment, with such deferred amount added to and increasing the outstanding interest-bearing principal balance of the Senior Secured Note by such amount. As of December 31, 2017, the Senior Secured Note principal balance is $5,188,542, including $188,542 of deferred interest payment. The aggregate remaining unpaid principal balance of the Senior Secured 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. In each of October 2017 and November 2017, 532,000 (or a total of 1,064,00) Series S Warrants were exercised for total cash proceeds of $10,640, resulting in the issuance of a corresponding number of shares of common stock of the Company, and in November 2017, a total of 122,360 Series S Warrants were exercised on a cashless basis, resulting in the issuance of a total of 122,080 shares of common stock of the Company. Accordingly, at December 31, 2017, there were 1,473,640 Series S Warrants issued and outstanding.

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, 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.

On, August 4, 2017, the Company entered into a Securities Purchase Agreement, as amended, 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), and on such date, issued a total of 125,000 Series A-1 Preferred Stock Units 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.

On November 17, 2017 ("November 17, 2017 Exchange Date"), the Company completed an exchange offer initiated on October 20, 2017 to the 28 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, one Series A Warrant for one Series A-1 Warrant ("Series A Exchange Offer") - resulting in 154,837 shares of Series A Convertible Preferred Stock exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock, and 154,837 Series A Warrants exchanged for 154,837 Series A-1 Warrants, by 13 holders on the November 17, 2017 Exchange Date. Accordingly, as of December 31, 2017, 357,259 shares of Series A-1 Convertible Preferred Stock and 279,837 Series A-1 Warrants were each issued and outstanding.

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.

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. 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.

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). On the January 26, 2017 initial closing date of the Series A Preferred Stock Units private placement, 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.

In addition to the 154,837 shares of Series A Convertible Preferred Stock exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock, and the 154,837 Series A Warrants exchanged for 154,837 Series A-1 Warrants in the Series A Exchange Offer, a total of 18,334 shares of Series A Convertible Preferred Stock were converted into a total of 22,093 shares of common stock of the Company during the year ended December 31, 2017. Accordingly, as of December 31, 2017, 249,667 shares of Series A Convertible Preferred Stock and 268,001 Series A Warrants were each issued and outstanding.

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)*

Other Events

Nasdaq Notice

On March 5, 2018, we received a notice from the Nasdaq Listing Qualifications Department stating that, for the prior 30 consecutive business days through March 2, 2018, the market value of our listed securities ("MVLS") had been below the minimum of $35 million required for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). The notification letter stated we would be afforded 180 calendar days, or until September 4, 2018, to regain compliance. In order to regain compliance, our MVLS must remain at or above $35 million for a minimum of ten consecutive business days. The notification letter also states in the event we do not regain compliance within the 180 day period, our securities may be subject to delisting. In the event we receive a delisting determination, we may appeal such determination to a Nasdaq Hearings Panel.

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.

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, referred to as an "IPO Unit", at an offering price of $5.00 per unit. The IPO Unit was 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.

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 Series W Warrants are exercised prior to the date specified in the notice of redemption. On and after the redemption date, a record holder of a Series W Warrant will have no further rights except to receive the redemption price for such holder's Series W Warrant upon surrender of such warrant.

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 complete the development and initiate the commercialization of 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 the number of personnel to support the expected 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 are recognized in the period they are incurred and consist principally of internal and external expenses incurred for the research and 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 $4.8 million in research and development costs from June 26, 2014 (inception) through December 31, 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

Comparison of the years ended December 31, 2017 and 2016.

	Years Ended December 31,	
	2017	**2016**
Revenue	$ —	$ —
Operating expense		
General and administrative expenses	5,415,324	3,931,264
Research and development expenses	2,618,795	1,719,587
Total operating expenses	8,034,119	5,650,851
Loss from operations	(8,034,119)	(5,650,851)
Other income (expense)		
Interest expense	(724,684)	—
Loss on Series A Preferred Stock Units issued in a private placement	(3,124,285)	—
Change in fair value of Series A Warrants derivative liability	1,942,501	—
Change in fair value of Series A Convertible Preferred Stock conversion option derivative liability	643,318	—
Modification of Series A-1 Warrant agreement	(222,000)	—
Other income (expense), net	(1,485,150)	—
Loss before income tax	(9,519,269)	(5,650,851)
Income tax	—	—
Net loss	(9,519,269)	(5,650,851)
Series A Convertible Preferred Stock dividends	(112,570)	—
Series A-1 Convertible Preferred Stock dividends	(79,788)	—
Deemed dividend Series A-1 Convertible Preferred Stock issued in a private placement	(182,500)	—
Deemed dividend Series A-1 Convertible Preferred Stock issued in the Series A Exchange Offer	(504,007)	—
Net loss attributable to common stockholders	$ (10,398,134)	$ (5,650,851)

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 complete the development and initiate the commercialization of our products.

Financial Results of Operations (continued)

General and administrative expense

The following table summarizes our general and administrative expense incurred during the years ended December 31, 2017 and 2016:

	Year Ended December 31, 2017	Year Ended December 31, 2016	$ Change	%Change
Compensation and related personnel costs	$ 1,167,714	$ 728,125	$ 439,589	60%
Stock-based compensation	925,534	664,068	261,466	39%
Outside professional services	2,580,344	1,846,497	733,847	40%
Facility related costs	169,145	164,189	4,956	3%
Board related costs	306,667	193,333	113,334	59%
Other operating costs	265,920	335,052	(69,132)	-21%
Total general and administrative expenses	$ 5,415,324	$ 3,931,264	$ 1,484,060	38%

General and administrative expenses incurred for the year ended December 31, 2017 were $5,415,324, an increase of $1,484,060 as compared to $3,931,264 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 $439,589, stock-based compensation expense of $261,466, outside professional services of $733,847, facility related costs of $4,956, and, board of directors related costs of 113,334; offset by a decrease of $69,132 in other operating costs.

The increased compensation and related personnel costs expense of $439,589 in the year ended December 31, 2017 as compared to the prior year period, resulted from higher salary expense related to additional personnel, and, principally, the recognition of an accrued bonus expense for the year ended December 31, 2017, for which there was no corresponding expense in the prior year. Such accrued bonus payable as of December 31, 2017, represents both the guaranteed bonus under the Chief Executive Officer ("CEO") employment agreement and discretionary bonus payments to other employees.

The stock-based compensation expense, which includes stock-based compensation expense classified as general and administrative expense related to stock options granted to both employees and non-employees, increased $261,466 in the year ended December 31, 2017 as compared to the prior year period, principally resulting from a full twelve months of stock-based compensation expense recognized in the year ended December 31, 2017 as compared to a partial period expense recognized in the prior year period, as the stock options granted in the prior year 2016 were principally granted effective with the April 28, 2016 IPO, along with other stock option grants in the fourth quarter of 2016. Additionally, stock-based compensation expense in the year ended December 31, 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. The increase in total employee stock-based compensation expense for the current year 2017, was offset by lower stock-based compensation expense related to non-employees, principally associated with lower stock option vesting date fair value corresponding to lower share price of the underlying common stock of the Company 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 /or former directors, including: $300,000 incurred for each of the years ended December 31, and 2016 under the HCP/Advisors consulting agreement; $80,000 and $100,000 incurred in the years ended December 31, 2017 and 2016, respectively, related to the previous (expired) HCFP/Strategy Advisors consulting agreement; and, $0 and $15,000 incurred in the year ended December 31, 2017 and 2016, respectively, related to the previous (expired) Swartwood Hesse consulting agreement - 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: $662,136 associated with professional fees for information technology, legal, accounting, tax, valuations, auditing, SEC reporting, and public company requirements; $75,432 of increased expenses related to regulatory matters, $78,310 of increased expenses related to intellectual property matters; offset by $47,031 of decreased expenses related to investor and public relations.

The increase in facility related costs of $4,995 in the year ended December 31, 2017 as compared to the prior year period, principally resulted from higher rent expense associated with our corporate offices, as a result of twelve months rent expense in the year ended December 31, 2017 as compared to eleven months in the prior year. Notwithstanding, effective August 1, 2017, the Company reduced the quantity of leased office space, resulting in a decrease in the monthly rent expense.

The board of director related costs includes the expense of member compensation expense incurred for the services of non-executive members of $306,667 for the year ended December 31, 2017, as compared to $193,333 in 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 was less than a full year, as such compensation commenced on the IPO closing date of April 28, 2016.

The decrease in other operating expenses of $69,132 in the year ended December 31, 2017 as compared to the prior year period, principally resulted from lower travel and related costs offset by higher director and officers insurance premiums.

Financial Results of Operations (continued)

Research and development expenses

The following table summarizes our research and development expenses incurred during the year ended December 31, 2017 and 2016:

	Year Ended December 31, 2017	Year Ended December 31, 2016	$ Change	%Change
Compensation and related personnel costs	$ 423,231	$ 215,790	$ 207,441	96%
Stock-based compensation	122,593	83,297	39,296	47%
Patent license fees	—	50,000	(50,000)	-100%
Regulatory filing fees	10,566	4,690	5,876	125%
Outside professional services	2,062,405	1,365,810	696,595	51%
Total research and development expenses	$ 2,618,795	$ 1,719,587	$ 899,208	52%

Research and development expenses incurred for the year ended December 31, 2017 totaled $2,618,795, an increase of $899,208 as compared to $1,719, 587 incurred for the prior year. The increase in research and development expenses for the current year period is principally due to increased outside professional services of $696,595, along with compensation and related personnel costs of $207,441, and stock-based compensation of 39,296, offset by $50,000 of patent license fees.

Compensation and related personnel cost classified as research and development expense is related to our Chief Medical Officer (“CMO”), with such expense incurred for twelve 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 payment 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 also resulted from the recognition of an accrued discretionary bonus expense for the year ended December 31, 2017, for which there was no corresponding expense in the prior year.

The stock-based compensation expense classified as research and development expense relates to stock options granted to the CMO, with such amount resulting in an increase of $39,296 in the year ended December 31, 2017, as compared to the prior year period, as twelve months of stock-based compensation expense was recognized in the current year 2017 as compared to a partial period expense recognized in the prior year 2016, as the CMO stock options were granted on the IPO date of April 28, 2016.

In the prior year ended December 31, 2016, we incurred $50,000 of patent license fees upon the execution of the Tufts Patent License Agreement. There was no such expense incurred in the current year ended December 31, 2017.

We incurred expenses related to FDA regulatory filing fees for 510(k) premarket notification submissions of $10,566 for our CarpX™ product in the year ended December 31, 2017, and $4,690 for our PortIO™ product in the year ended December 31, 2016.

The increased research and development expenses related to outside professional services of $646,596 in the year ended December 31, 2017 as compared to the prior year period, resulted from increased research and development activities in support of advancing our products toward FDA submittals and corresponding approval and clearance, as compared with limited research and development activities on certain of the products during the prior year period, with such expenses principally related to our CarpX™ product, offset by decreased research and development expenses related to our PortIO™ product.

Financial Results of Operations (continued)

Other Income and Expense

Other income (expense), net for the periods indicated, is as follows:

	Years Ended December 31,	
	2017	**2016**
Other income (expense)		
Interest expense	$ (724,684)	$ —
Loss on Series A Preferred Stock Units issued in a private placement	(3,124,285)	—
Change in fair value of Series A Warrants derivative liability	1,942,501	—
Change in fair value of Series A Convertible Preferred Stock conversion option derivative liability	643,318	—
Modification of Series A-1 Warrant agreement	(222,000)	—
Other income (expense), net	$ (1,485,150)	$ —

Interest Expense

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, the Company issued to Scopia and its designees, a Senior Secured Note with an initial principal amount of $5.0 million ("Senior Secured Note"), and 2,660,000 Series S Warrants to purchase shares of common stock of the Company. The aggregate remaining unpaid principal balance of the Senior Secured Note is due on June 30, 2019.

The $4,842,577 of cash proceeds, which are 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 Senior Secured 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 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 unpaid semi-annual interest payment added to the outstanding interest-bearing principal balance of the Senior Secured Note. As of December 31, 2017, the Senior Secured Note principal balance is $5,188,542, including $188,542 of deferred interest payment.

During the year ended December 31, 2017, interest expense recognized totaled $724,684, including $377,083 with respect to the semi-annual interest payment, which as discussed above, 50% of such amount or $188,542, has been added to the outstanding interest-bearing principal balance of the Senior Secured Note, and $347,601 with respect to the amortization of debt discount. The Senior Secured Note remaining unamortized debt discount is $3,244,274 at December 31, 2017.

Financial Results of Operations (continued)

Other Income and Expense (continued)

Loss on Series A Preferred Stock Units Issued in a Private Placement

The Series A Preferred Stock Units were issued in a private placement with closings in the three months ended March 31, 2017, including an initial closing on January 26, 2017, and subsequent closings on January 31, 2017 and March 8, 2017, resulting in a total of 422,838 Series A Preferred Stock Units 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.

The Series A Preferred Stock Unit was comprised of one share of Series A Convertible Preferred Stock and one Series A Warrant, with each 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 common stock exchange factor, 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.

On November 17, 2017 ("November 17, 2017 Exchange Date"), the Company completed an exchange offer initiated on October 20, 2017 to the 28 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, one Series A Warrant for one Series A-1 Warrant ("Series A Exchange Offer") - resulting in 154,837 shares of Series A Convertible Preferred Stock exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock, and 154,837 Series A Warrants exchanged for 154,837 Series A-1 Warrants, by 13 holders on the November 17, 2017 Exchange Date. Further, at the election of their respective holders, a total of 18,334 shares of Series A Convertible Preferred Stock were converted into 22,093 shares of common stock of the Company. Accordingly, as of December 31, 2017, 249,667 shares of Series A Convertible Preferred Stock and 268,001 Series A Warrants were each issued and outstanding.

The Series A Warrant and the Series A Convertible Preferred Stock conversion option were each determined to be a derivative liability under FASB ASC 815. The issuance of the Series A Preferred Stock Units resulted in the recognition of a loss of $3,124,285, resulting from the aggregate initial fair value of each of the Series A Warrant and the Series A Convertible Preferred Stock conversion option derivative liability, being in excess of the gross proceeds of the Series A Preferred Stock Units private placement, 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 derivative liability initial fair value	(4,050,706)
Less: Series A Convertible Preferred Stock conversion option derivative liability initial fair value	(1,221,963)
Excess of initial fair value of derivative liabilities 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)

See our consolidated financial statements Note 13,*Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for further information regarding the Series A Preferred Stock Units private placement, the Series A Convertible Preferred Stock, and the Series A Warrants.

Financial Results of Operations (continued)

Other Income and Expense (continued)

Change in Fair Value of Series A Warrants and Series A Convertible Preferred Stock Conversion Option Derivative Liabilities

The Series A Warrant and the Series A Convertible Preferred Stock conversion option were each determined to be a derivative liability under FASB ASC 815. The respective Series A Warrants and the Series A Convertible Preferred Stock conversion option derivative liability are classified as a current liability on the consolidated balance sheet, and each were initially measured at fair value at the time of issuance and are subsequently remeasured at fair value on a recurring basis at each reporting period date, with changes in fair value recognized as other income or expense in the consolidated statement of operations. The reconciliation of each of the Series A Warrants and the Series A Convertible Preferred Stock conversion option derivative liability for the year ended December 31, 2017 are as follows:

Derivative Liability	Series A Warrants	Series A Convertible Preferred Stock Conversion Option
Balance at December 31, 2016	$ —	$ —
Initial fair value on dates of issuance	4,050,706	1,221,963
Change in fair value	(1,942,501)	(643,318)
Conversion of Series A Convertible Preferred Stock	—	(27,335)
Series A Exchange Offer	(1,347,082)	(339,093)
Balance at December 31, 2017	$ 761,123	$ 212,217

Change in Fair Value

The change in estimated fair value, including fair value adjustments on the dates of the Series A Exchange Offer, the conversion of Series A Convertible Preferred Stock, and the recurring fair value adjustment as of December 31, 2017, resulted in the recognition of other income of $1,942,501 and $643,318, with corresponding decreases in both the Series A Warrants derivative liability and the Series A Convertible Preferred Stock conversion option derivative liability, respectively, during the year ended December 31, 2017.

The initial issue date and subsequent reporting period date recurring estimated fair value of each of the Series A Warrants and the Series A Convertible Preferred Stock conversion option derivative liability were each estimated using a Monte Carlo simulation valuation model using the Company's common stock price, the Company's dividend yield, the risk-free rates based on U.S. Treasury security yields, and certain other Level-3 inputs including, assumptions regarding the estimated volatility in the value of the Company's common stock price and probabilities associated with the likelihood and timing of future dilutive transactions. See our consolidated financial statements Note 11, *Financial Instruments Fair Value Measurements*, for further information with respect to the initial issue date and subsequent recurring reporting period date estimated fair values of each of the Series A Warrants and the Series A Convertible Preferred Stock conversion option derivative liability.

Conversion of Series A Convertible Preferred Stock

At the election of their respective holders, a total of 18,334 shares of Series A Convertible Preferred Stock were converted into a total of 22,093 shares of common stock of the Company. The Series A Convertible Preferred Stock conversion option derivative liability fair value was adjusted as of each conversion date, with the resulting change in fair value recognized as other income or expense in the consolidated statement of operations, upon which the corresponding Series A Convertible Preferred Stock conversion option derivative liability was derecognized, with a corresponding recognition of common stock par value and additional paid-in capital with respect to the shares of common stock of the Company issued, summarized as follows:

Series A Convertible Preferred Stock Converted to shares of Common Stock of the Company Year ended December 31, 2017		Conversion Dates Aggregated
Shares of Series A Convertible Preferred Stock converted to common stock		18,334
Shares of common stock issued upon conversion of Series A Convertible Preferred Stock		22,093
Fair Value - Series A Convertible Preferred Stock conversion option derivative liability derecognized	$	27,335
Shares of common stock issued - par value	$	22
Shares of common stock issued - additional paid-in capital	$	27,313

The fair value of the Series A Convertible Preferred Stock conversion option derivative liability was estimated on each of the respective conversion dates using a Monte Carlo simulation valuation model using the Company's common stock price the Company's dividend yield, the risk-free rates based on U.S. Treasury security yields, and certain other Level-3 inputs to take into account the probabilities of certain events occurring over their respective life, including, assumptions regarding the estimated volatility in the value of the Company's common stock price and the likelihood and timing of future dilutive transactions, as applicable, as of each conversion date.

Financial Results of Operations (continued)

Other Income and Expense (continued)

Change in Fair Value of Series A Warrants and Series A Convertible Preferred Stock Conversion Option Derivative Liabilities (continued)

Series A Exchange Offer - November 17, 2017 Exchange Date

As noted above, a total of 422,838 shares of Series A Convertible Preferred Stock and 422,838 Series A Warrants were issued in the Series A Preferred Stock private placement. On the November 17, 2017 Exchange Date, the Company completed the Series A Exchange Offer, resulting in 154,837 shares of Series A Convertible Preferred Stock being exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock, and 154,837 Series A Warrants being exchanged for 154,837 Series A-1 Warrants, by 13 holders on the November 17, 2017 Exchange Date.

The Series A Exchange Offer resulted in the extinguishment of: 154,837 shares of Series A Convertible Preferred Stock, the corresponding (bifurcated) conversion option derivative liability, and, 154,837 Series A Warrants, resulting from the issuance-upon-exchange of: 232,259 shares of Series A-1 Convertible Preferred Stock and 154,837 Series A-1 Warrants, each as discussed herein below.

Series A Exchange Offer - Series A Convertible Preferred Stock Exchanged for Series A-1 Convertible Preferred Stock

The fair value of the consideration given in the form of the issue of 232,259 shares of Series A-1 Convertible Preferred Stock, with such fair value recognized as the carrying value of such issued shares of Series A-1 Convertible Preferred Stock, as compared to the extinguishment of both: the carrying value of the Series A Convertible Preferred Stock and the fair value of the corresponding conversion option derivative liability, resulted in an excess of fair value of $504,007 recognized as a deemed dividend charged to accumulated deficit in the consolidated balance sheet on the November 17, 2017 Exchange Date, with such deemed dividend included as a component of net loss attributable to attributable to common stockholders, summarized as follows:

Series A-1 Convertible Preferred Stock Issued Series A Convertible Preferred Stock and Conversion Option Derivative Liability Extinguished Deemed Dividend Charged to Accumulated Deficit	Series A Exchange Offer November 17, 2017 Exchange Date
Fair value - 232,259 shares of Series A-1 Convertible Preferred Stock issued	$ 843,100
Less: Fair value - Series A Convertible Preferred Stock conversion option derivative liability extinguished	339,093
Less: Carrying value - 154,837 shares of Series A Convertible Preferred Stock exchanged	—
Deemed dividend charged to accumulated deficit	$ 504,007

- The November 17, 2017 Exchange Date fair value of $843,100 for the 232,259 shares of Series A-1 Convertible Preferred Stock issued in the Series A Exchange Offer, was estimated using a combination of the present value of its cash flows using a synthetic credit rating analysis required rate of return and the Black-Scholes option pricing model, using the Company's common stock price, the Company's dividend yield, the risk-free rates based on U.S. Treasury security yields, estimated volatility in the value of the Company's common stock, and certain other Level-3 inputs.

- The November 17, 2017 Exchange Date fair value of $339,093 for the 154,837 shares of Series A Convertible Preferred Stock conversion option derivative liability extinguished, was estimated using a Monte Carlo simulation valuation model using the Company's common stock price, the Company's dividend yield, the risk-free rates based on U.S. Treasury security yields, and certain other Level-3 inputs including, assumptions regarding the estimated volatility in the value of the Company's common stock price and probabilities associated with the likelihood and timing of future dilutive transactions.

- The Series A Convertible Preferred Stock is classified in temporary equity in the consolidated balance sheet and 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 derivative liability being in excess of the Preferred Stock Units private placement issuance gross proceeds, with such excess recognized as a current period loss in the consolidated statement of operations. 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 and the Series A Convertible Preferred Stock.

Financial Results of Operations (continued)

Other Income and Expense (continued)

Change in Fair Value of Series A Warrants and Series A Convertible Preferred Stock Conversion Option Derivative Liabilities (continued)

Series A Exchange Offer - November 17, 2017 Exchange Date (continued)

Series A Exchange Offer - Series A Warrants Exchanged for Series A-1 Warrants

The 154,837 Series A Warrants derivative liability fair value was adjusted to the November 17, 2017 Exchange Date fair value of the consideration given in the form the 154,837 Series A-1 Warrants issued, with the resulting change in fair value recognized as other income or expense in the consolidated statement of operations, immediately followed by the derecognition of the 154,837 Series A Warrants derivative liability and the recognition of additional paid-in capital of such amount in the consolidated balance sheet, as the Series A-1 Warrants are equity classified. The November 17, 2017 Exchange Date fair value of the Series A-1 Warrants of $1,347,082 was estimated assuming the exchange of one Series A-1 Warrant for five Series W Warrants, using a Black-Scholes valuation model, using the Company's common stock price, the Company's dividend yield, the risk-free rates based on U.S. Treasury security yields, the estimated volatility in the value of the Company's common stock price, and the Series W Warrant exercise price.

Modification of Series A-1 Warrant Agreement

The Series A-1 Preferred Stock Units were issued in a private placement on August 4, 2017, and were comprised of one share of Series A-1 Convertible Preferred Stock and one Series A-1 Warrant, each, at their issuance, were immediately separable, and immediately convertible and exercisable, respectively. At the election of their respective holder, a share of Series A-1 Convertible Preferred Stock is convertible into one shares of common stock of the Company, and a Series A-1 Warrant may be exercised for one share of common stock of the Company at an exercise of $6.67 per share, or may be exchanged into either five Series W Warrants with an exercise price of $5.00 per share for one share of common stock of the Company, or four Series X-1 Warrants with an exercise of $6.00 per share for one share of common stock of the Company, with each such warrant exercise price not subject to further adjustment, except for the effect of stock dividends, stock splits or similar events affecting the common stock. As of December 31, 2017, no Series A-1 Warrants had been exchanged for Series W Warrants nor Series X-1 Warrants.

On October 18, 2017, the Series A-1 Convertible Preferred Stock holders unanimously approved Amendment No. 1 to Series A-1 Preferred Stock Units private placement transaction documents ("Series A-1 Amendment No. 1), wherein: a Series A-1 Warrant may be exchanged for four Series X-1 Warrants, or additionally, exchanged for five Series W Warrants. The Series X-1 Warrants replaced the previous election to exchange one Series A-1 Warrant for four Series X Warrants, which had an exercise price of $6.00 per share for one share of common stock of the Company.

The Series A-1 Amendment No. 1 modification to the Series A-1 Warrants' exchange elections was accounted for under the analogous guidance of FASB ASC 718, wherein, the incremental fair value is measured as the difference between the fair value immediately after the modification as compared to the fair value immediately before the modification, with such incremental fair value, to the extent an increase, recognized as a modification expense. On the October 18, 2017 date of the Series A-1 Amendment No.1, the Company recognized a current period expense related to the Series A-1 Warrants' modification of $222,000, with such expense included in other income (expense) on the consolidated statement of operations, with a corresponding increase in additional paid-in capital in the consolidated balance sheet, as the Series A-1 Warrants are equity classified. Such incremental fair value was estimated assuming the exchange of one Series A-1 Warrant for five Series W Warrants after the modification of the Series A-1 Warrant, as compared to an exchange of one Series A-1 Warrant for four Series X Warrants before such modification, using a Black-Scholes valuation model, using the Company's common stock price, the Company's dividend yield, the risk-free rates based on U.S. Treasury security yields, the estimated volatility in the value of the Company's common stock price, and the respective warrants' exercise price.

See our consolidated financial statements 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, the Series A-1 Warrant modification resulting from the Series A-1 Amendment No.1, and the Series W Warrants or Series X-1 Warrants which may be issued upon the exchange of Series A-1 Warrants.

The estimated fair values presented herein are subjective and are affected by changes in inputs to the valuation models, including the Company's common stock price, the Company's dividend yield, the risk-free rates based on U.S. Treasury security yields, and certain other Level-3 inputs to take into account the probabilities of certain events occurring over their respective life, including, assumptions regarding the estimated volatility in the value of the Company's common stock price and the likelihood and timing of future dilutive transactions, as applicable. Changes in these assumptions can materially affect the estimated fair values. See our consolidated financial statements Note 11, *Financial Instruments Fair Value Measurements*, for further information with respect to recurring reporting period date and non-recurring issue-date and /or date -of-occurrence estimated fair values.

Financial Results of Operations (continued)

Non-GAAP Financial Measures

The factors described above resulted in net loss attributable to common stockholders of $10,398,134 and $5,650,851 for the years ended December 31, 2017 and 2016, respectively.

To supplement our consolidated financial statements presented in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") within this Annual Report on Form 10-K, management provides certain non-GAAP financial measures ("NGFM") of the Company's financial results, including such amounts captioned: "net loss before interest, taxes, depreciation, and amortization" or "EBITDA", and "non-GAAP Adjusted Loss", as presented herein below.

Such NGFM are presented with the intent of providing greater transparency of information used by us in our financial performance analysis and operational decision-making. Additionally, we believe these NGFM provide meaningful information to assist investors, shareholders, and other readers of our consolidated financial statements, in making comparisons to our historical financial results, and analyzing the underlying financial results of our operations. The NGFM are provided to enhance readers' overall understanding of our current financial results and to provide further information to enhance the comparability of results between the current year period and the prior year period.

We believe the NGFM provide useful information by isolating certain expenses, gains, and losses, which are not necessarily indicative of our operating financial results and business outlook. In this regard, the presentation of the NGFM herein below, is to help the reader of our consolidated financial statements to understand the effects of the non-cash impact on our (U.S. GAAP) consolidated statement of operations of: the loss recognized with respect to the issuance of the Series A Preferred Stock Units; the change in fair value of each of the respective Series A Warrant and Series A Convertible Preferred Stock conversion option derivative liability; and, the expense recognized resulting from the modification of the Series A-1 Warrant agreement, each as discussed herein above.

Importantly, we note the NGFM measures captioned "EBITDA" and "non-GAAP Adjusted Loss" are not recognized terms under U.S. GAAP, and as such, they are not: a substitute for, considered superior to, considered separately from, nor as an alternative to, U.S. GAAP and /or the most directly comparable U.S. GAAP financial measures.

Financial Results of Operations (continued)

Non-GAAP Financial Measures (continued)

A reconciliation to the most directly comparable U.S. GAAP measure to NGFM, as discussed above, is as follows:

	Year Ended December 31,		
	2017	2016	$ Change
Net loss attributable to common stockholders	$ (10,398,134)	$ (5,650,851)	$ (4,747,283)
Series A Convertible Preferred Stock dividends	112,570	—	112,570
Series A-1 Convertible Preferred Stock dividends	79,788	—	79788
Deemed dividend Series A-1 Convertible Stock issued in a private placement on August 4, 2017	182,500	—	182,500
Deemed dividend Series A-1 Convertible Stock issued in the Series A Exchange Offer on November 17, 2017	504,007	—	504,007
Net loss - as reported	(9,519,269)	(5,650,851)	(3,868,418)
Adjustments			
Depreciation expense[1]	7,110	3,793	3,317
Interest expense	724,684	—	728,684
Income tax provision	—	—	—
EBITDA	(8,787,475)	(5,647,058)	(3,140,417)
Stock-based compensation expense[2]	1,048,127	747,365	300,762
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 derivative liability[4]	(1,942,501)	—	(1,942,501)
Change in fair value of Series A Convertible Preferred Stock conversion option derivative liability[4]	(643,318)	—	(643,318)
Modification of Series A-1 Warrant agreement[5]	222,000	—	222,000
Non-GAAP adjusted loss $	(6,978,882)	$ (4,899,693)	$ (2,079,189)

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

(2) Stock-based compensation expense of $925,534 (which includes $51,389 of stock-based compensation expense related to the March 31, 2017 modifications of the stock options previously granted to the Company's former Chief Financial Officer) and $664,068, is included in general administrative expenses; and, $122,593 and $83,297, is included in research and development expenses, in the consolidated statement of operations, for the years ended December 31, 2017 and 2016, respectively.

(3) As discussed herein above, the issuance of the Series A Preferred Stock Units resulted in the recognition of a loss of $3,124,285, resulting from the aggregate initial fair value of each of the Series A Warrant and the Series A Convertible Preferred Stock conversion option derivative liability, being in excess of the gross proceeds of the Series A Preferred Stock Units private placement, 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. There was no comparable amount in the prior year.

(4) As discussed herein above, the Series A Warrant and the Series A Convertible Preferred Stock conversion option were each determined to be a derivative liability, and each were initially measured at fair value at the time of issuance and are subsequently remeasured at fair value on a recurring basis at each reporting period, with changes in fair value recognized as other income or expense in the consolidated statement of operations. The change in estimated fair value, including fair value adjustments on the dates of the Series A Exchange Offer, the conversion of Series A Convertible Preferred Stock, and the recurring fair value adjustment as of December 31, 2017, resulted in the recognition of other income of $1,942,501 and $643,318, with corresponding decreases in each of the Series A Warrants derivative liability and the Series A Convertible Preferred Stock conversion option derivative liability, respectively, during the year ended December 31, 2017. There were no comparable amounts in the prior year.

(5) As discussed herein above, the Series A-1 Amendment No. 1 resulted in a modification to the Series A-1 Warrant agreement, with such modification resulting in the recognition of a $222,000 current period expense the October 18, 2017 date of the Series A-1 Amendment No.1, with such modification expense included in other income (expense) on the consolidated statement of operations, with a corresponding increase in additional paid-in capital in the consolidated balance sheet, as the Series A-1 Warrants are equity classified. There was no comparable amount in the prior year.

Financial Results of Operations (continued)

Income Taxes

We account for income taxes using the asset and liability method, wherein, current tax liabilities or receivables are recognized for the amount of taxes estimated to be payable or refundable for the current year, and deferred tax assets and deferred tax 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 used for income tax purposes, along with net operating loss ("NOL") and tax credit carryforwards.

Deferred tax assets and deferred tax 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. 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. See herein below for a discussion of the "Tax Act of 2017", which resulted in a change to future years' statutory corporate tax rate applicable to taxable income. Changes in deferred tax assets and deferred tax liabilities are recorded in the provision for income taxes.

As required by Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 740, *Income* Taxes", ("ASC 740), a "more-likely-than-not" criterion is applied when assessing the estimated realization of deferred tax assets through their utilization to reduce future taxable income, or with respect to a deferred tax asset for tax credit carryforward, to reduce future tax expense. A valuation allowance is established, when necessary, to reduce deferred tax assets, net of deferred tax liabilities, when the assessment indicates it is more-likely-than-not, the full or partial amount of the net deferred tax asset will not be realized. Accordingly, we have evaluated the positive and negative evidence bearing upon the estimated realizability of our net deferred tax assets, and based on our history of operating losses, we have concluded it is more-likely-than-not the deferred tax assets will not be realized, and therefore have recognized a valuation allowance reserve equal to the full amount of the deferred tax assets, net of deferred tax liabilities, as of December 31, 2017 and 2016.

We have total estimated federal and state NOL carryforward of $13,780,719 and $6,432,797 at December 31, 2017 and 2016, respectively, which is available to reduce future taxable income and begin to expire in 2035. We have total estimated research and development ("R&D") tax credit carryforward of $194,345 and $91,535 as of December 31, 2017 and 2016, respectively, including generating such R&D tax credit of $102,810 and $70,861, during the years ended December 31, 2017 and 2016, respectively, with the R&D tax credit carryforward available to reduce future tax expense and begin to expire in 2035.

On December 22, 2017, the president of the United States signed into law what is commonly referred to as the Tax Cuts and Jobs Act of 2017 (Public Law No. 115-97), referred to herein as the Tax Act of 2017. The Tax Act of 2017 is a comprehensive revision to federal tax law which makes broad and complex changes to the U.S. tax code, including, but not limited to, reducing the U.S. federal corporate tax rate from 35% to 21%, eliminating the corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; creating a new limitation on deductible interest expense; changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017; and limitations on the deductibility of certain executive compensation.

In December 2017, the SEC issued Staff Accounting Bulletin No. 118 ("SAB 118"), which addresses situations where the accounting is incomplete for the income tax effects of the Tax Act of 2017. SAB 118 directs taxpayers to consider the impact of the Act as "provisional" when the Company does not have the necessary information available, prepared, or analyzed, including computations, to finalize the accounting for the changes resulting from the Tax Act of 2017. Companies are provided a measurement period of up to one year to obtain, prepare, and analyze information necessary to finalize the accounting for provisional amounts or amounts that cannot be estimated as of December 31, 2017.

With regards to the Tax Act of 2017 impact on our tax provision for year ending December 31, 2017, we have recognized the provisional impact of the revaluation of deferred tax assets and deferred tax liabilities to 21% from 35%, resulting in an estimated $1.6 million tax expense, which was fully offset by a corresponding change in the valuation allowance applied to the net deferred tax assets.

See our consolidated financial statements Note 7, *Income Taxes*, for additional information with respect to our income tax provision, deferred tax assets, and deferred tax liabilities.

Liquidity and Capital Resources

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, as we complete the development process of our products, including regulatory approvals and clearances, 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 incurred a net loss attributable to common stockholders of $10,398,134 and $5,650,851, and had net cash flows used in operating activities of $6,608,208 and $4,454,857, for the years ended December 31, 2017 and 2016, respectively. As of December 31, 2017, we had an accumulated deficit of $17,907,611 and working capital of $53,060, adjusted to exclude the Series A Warrants derivative liability of $761,123 and the Series A Convertible Preferred Stock conversion option derivative liability of $212,217. We anticipate incurring operating losses and do not expect to generate positive cash flows from operating activities, if any, for the next several years as we complete the development of our products, file for and request regulatory approvals and clearances of such products, and begins to commercially market such products. These factors raise substantial doubt about our ability to continue as a going concern within one year after the date our consolidated financial statements are issued.

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 our 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 and clearances of 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 raise substantial doubt regarding our ability to continue as a going concern within one year after the date our consolidated financial statements are issued.

Our 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 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.

Financing

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. During 2017, we raised a total of approximately $7.5 million of net cash proceeds from: a Note and Security Purchase Agreement with Scopia Holdings LLC ("Scopia" or "the Lender"), 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 summarized herein below. Subsequent to December 31, 2017, in January 2018, the Company raised $4.3 million of net cash proceeds in an underwritten public offering of shares of common stock of the Company pursuant to its previously filed effective shelf registration statement on SEC Form S-3 (File No. 333-220549), as summarized below.

Liquidity and Capital Resources (continued)

Note and Security Purchase Agreement with Scopia Holdings LLC

We entered into a Note and Security Purchase Agreement with Scopia, under which, upon Scopia delivering to the Company $4.8 million in net cash proceeds, we issued to Scopia and its designees, a Senior Secured Note with an initial principal amount of $5.0 million ("Senior Secured Note"), and 2,660,000 Series S Warrants to purchase a corresponding number of shares of our common stock. The aggregate remaining unpaid principal balance of the Senior Secured Note is due on June 30, 2019.

The Senior Secured 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 December 30, 2017. The Company may elect, at its sole discretion, to defer payment of up to 50% of the semi-annual interest payment, with such deferred amount added to and increasing the outstanding interest-bearing principal balance of the Senior Secured Note by such amount. As of December 31, 2017, the Senior Secured Note principal balance is $5,188,542, including $188,542 of deferred interest payment. The aggregate remaining unpaid principal balance of the Senior Secured Note is due on June 30, 2019.

During the year ended December 31, 2017, interest expense recognized totaled $724,684, including $377,083 with respect to the semi-annual interest payment, which as discussed above, 50% or $188,542, has been added to the outstanding interest-bearing principal balance of the Senior Secured Note, and $347,601 with respect to the amortization of debt discount. The Senior Secured Note remaining unamortized debt discount is $3,244,274 at December 31, 2017.

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.

In each of October 2017 and November 2017, 532,000 (or a total of 1,064,00) Series S Warrants were exercised for total cash proceeds of $10,640, resulting in the issuance of a corresponding number of shares of common stock of the Company, and in November 2017, a total of 122,360 Series S Warrants were exercised on a cashless basis, resulting in the issuance of a total of 122,080 shares of common stock of the Company. Accordingly, at December 31, 2017, there were 1,473,640 Series S Warrants issued and outstanding.

See our 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 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, 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.

On, August 4, 2017, the Company entered into a Securities Purchase Agreement, as amended, 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), and on such date, issued a total of 125,000 Series A-1 Preferred Stock Units 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.

On November 17, 2017 ("November 17, 2017 Exchange Date"), the Company completed an exchange offer initiated on October 20, 2017 to the 28 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, one Series A Warrant for one Series A-1 Warrant ("Series A Exchange Offer") - resulting in 154,837 shares of Series A Convertible Preferred Stock exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock, and 154,837 Series A Warrants exchanged for 154,837 Series A-1 Warrants, by 13 holders on the November 17, 2017 Exchange Date. Accordingly, as of December 31, 2017, 357,259 shares of Series A-1 Convertible Preferred Stock and 279,837 Series A-1 Warrants were each issued and outstanding.

See our consolidated financial statements Note 11,*Financial Instruments Fair Value Measurements*, for a further discussion of the Series A Exchange Offer, and 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.

Liquidity and Capital Resources (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. 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.

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). On the January 26, 2017 initial closing date of the Series A Preferred Stock Units private placement, 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.

In addition to the 154,837 shares of Series A Convertible Preferred Stock exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock, and the 154,837 Series A Warrants exchanged for 154,837 Series A-1 Warrants in the Series A Exchange Offer, a total of 18,334 shares of Series A Convertible Preferred Stock were converted into a total of 22,093 shares of common stock of the Company during the year ended December 31, 2017. Accordingly, as of December 31, 2017, 249,667 shares of Series A Convertible Preferred Stock and 268,001 Series A Warrants were each issued and outstanding.

See our consolidated financial statements Note 11, *Financial Instruments Fair Value Measurements*, for a further discussion of the Series A Exchange Offer and the shares of Series A Convertible Preferred Stock converted into shares of common stock of the Company, and 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.

Issue of Common Stock - Underwritten Public Offering

Subsequently, in January 2018, the Company conducted an underwritten public offering of shares of common stock of the Company pursuant to its previously filed and effective shelf registration statement on SEC Form S-3 (File No. 333-220549), declared effective October 6, 2017, along with a corresponding prospectus supplement dated January 19, 2018. On January 19, 2018, the Company entered into an underwriting agreement with Dawson James Securities, Inc., as sole underwriter, under which the company agreed to issue to the underwriter at $1.80 per share, 2,415,278 shares of common stock on a firm commitment basis and up to an additional 362,292 shares solely to cover underwriter over-allotments, if any, at the option of the underwriter, exercisable within 45 calendar days from January 19, 2018. The Company issued the 2,415,278 shares on January 23, 2018, and on January 25, 2018, issued 234,540 shares of common stock, under the underwriter's over-allotment, resulting in net cash proceeds of $4,263,099, after deduction of both underwriting discounts of $381,574 and estimated offering costs.

Series W Warrants Offer-to-Exercise

Subsequently, on January 11, 2018, the Company filed with the SEC a Tender Offer Statement on Schedule TO with respect to offered Series W Warrants holders the opportunity to exercise their Series W Warrants at a temporarily reduced exercise price of $2.00 per share ("Series W Warrants Offer-to-Exercise"). As of the February 8, 2018 expiry of the Series W Warrants Offer-to-Exercise, a total of 34,345 Series W Warrants were exercised at the temporary exercise of $2.00 per share, resulting in $68,690 of cash proceeds, and the issue of a corresponding number of shares of common stock of the Company.

Series W Warrants Offer-to-Exchange

Subsequently, on February 20, 2018, the Company filed with the SEC a Tender Offer Statement on Schedule TO with respect to the Company offering Series W Warrant holders the opportunity to exchange two Series W Warrants for one Series Z Warrant, with such exchange offer expiring on March 19, 2018 ("Series W Warrants Offer-to-Exchange"). The Series Z Warrants issued upon exchange of the Series W Warrants will be immediately exercisable upon issuance and expire after the close of business on April 30, 2024, and each may be exercised for one share of common stock of the Company at an exercise price of $3.00 per share, with such exercise price and number of underlying shares not subject to further adjustment, except for the effect of stock dividends, stock splits or similar events affecting the common stock. The Series Z Warrants are redeemable by the Company under certain conditions. See our consolidated financial statements Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a further discussion of the Series W Warrants and the Series Z Warrants.

Liquidity and Capital Resources (continued)

Shareholders' Rights Offering

Subsequently, on January 17, 2018, the Company filed an initial registration statement on Form S-1 (File No. 333-222581), currently under SEC review, related to a proposed rights offering wherein, as currently proposed, the Company will distribute one transferable equity subscription right for each issued and outstanding share of common stock of the Company as of a record date to be determined by the Company's Board of Directors ("Rights Offering"). As currently proposed, the equity subscription Rights Offering is to commence upon an effective registration statement. Further, as currently proposed, for a period of 30 days from their distribution date, the transferable equity subscription right may be exercised for $2.25 per unit to purchase a common stock unit comprised of one share of common stock of the Company and one Series Z Warrant. As currently proposed, the common stock unit will trade for up to 90 days, after which it will separate into its underlying components of one share of common stock of the Company and one Series Z Warrant. The Series Z Warrant may be exercised for one share of common stock of the Company at an exercise price of $3.00 per share, with such exercise price and number of underlying shares not subject to further adjustment, except for the effect of stock dividends, stock splits or similar events affecting the common stock, and will expire after the close of business on April 30, 2024. The Series Z Warrants are redeemable by the Company under certain conditions. See our consolidated financial statements Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a further discussion of the Series Z Warrants.

Series A and Series A-1 Exchange Offer - Series B Convertible Preferred Stock and Series Z Warrants

Subsequently, on February 14, 2018 the Company initiated an exchange offer to the holders of both the Series A Convertible Preferred Stock and Series A Warrants, and the Series A-1 Convertible Preferred Stock and Series A-1 Warrants ("Series A and Series A-1 Exchange Offer"), as follows: one (1) share of Series A Convertible Preferred Stock exchanged for two (2) shares of Series B Convertible Preferred Stock, and one (1) Series A Warrant exchanged for five (5) Series Z Warrants; and one (1) share of Series A-1 Convertible Preferred Stock exchanged for 1.33 shares of Series B Convertible Preferred Stock, and one (1) Series A-1 Warrant exchanged for five (5) one Series Z Warrants. A condition of the Series A and Series A-1 Exchange Offer is for all outstanding shares of Series A Convertible Preferred Stock and all Series A Warrants, and all shares of Series A-1 Convertible Preferred Stock and all Series A-1 Warrants, must be tendered, else, if not all are tendered, then the Company reserves the right to not accept any tenders, if any. The Series A and Series A-1 Exchange Offer is scheduled to expire on March 15, 2018, unless extended by the Company, at its sole discretion.

The Series B Convertible Preferred Stock has a par value of $0.001 per share, no voting rights, a stated value of $3.00 per share, and is immediately convertible upon its issuance. At the holders' election, a share of Series B Convertible Preferred Stock is convertible into a number of shares of common stock of the Company at a common stock conversion exchange factor equal to a numerator of $3.00 and a denominator of $3.00, with such denominator 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 B Convertible Preferred Stock shall not be redeemed for cash and under no circumstances shall the Company be required to net cash settle the Series B Convertible Preferred Stock.

The Series B Convertible Preferred Stock provides for dividends at a rate of 8% per annum on the stated value of the Series B Convertible Preferred Stock, with such dividends compounded quarterly, accumulate, and are payable in arrears upon being declared by the Company's Board of Directors. The Series B Convertible Preferred Stock dividends from April 1, 2018 through October 1, 2021 are payable-in-kind ("PIK") in additional shares of Series B 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 B Convertible Preferred Stock, shares of common stock, and /or cash payment.

The Series Z Warrants issued in the Series A and Series A-1 Exchange Offer will be immediately exercisable upon issuance and expire after the close of business on April 30, 2024, and each may be exercised for one share of common stock of the Company at an exercise price of $3.00 per share and number of underlying shares, 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. The Series Z Warrants are redeemable by the Company under certain conditions. See our consolidated financial statements Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a further discussion of the Series B Convertible Preferred Stock and the Series Z Warrants.

Liquidity and Capital Resources (continued)

Cash flows and liquidity

The primary cash flow sources and uses for each period is as follows:

	Year Ended December 31,	
	2017	2016
Net cash flows (used in) or provided by:		
Operating activities	$ (6,608,208)	$ (4,454,857)
Investing activities	(5,301)	(21,793)
Financing activities	7,562,851	4,295,062
Net increase in cash	949,342	181,588
Cash, beginning of period	585,680	767,268
Cash, end of period	$ 1,535,022	$ 585,680

Net cash flows used in operating activities

Net cash flows used in operating activities was $6,608,2018 and $4,454,857 in the years ending December 31, 2017 and 2016, respectively, consisting of, respectively, a net loss of $9,519,269 and $5,650,851, with adjustments totaling, respectively, $2,911,061 and $1,195,994 to reconcile such net loss to net cash used in operating activities, including, respectively, a total of $2,351,846 and 751,158 of non-cash items, and a total of $559,215 and $444,836 of a net change in operating assets and liabilities, for each of the years ended December 31, 2017 and 2016, as follows:

	Year Ended December 31,	
	2017	2016
Net cash flows (used in) operating activities		
Net loss	$ (9,519,269)	$ (5,650,851)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation expense	7,110	3,793
Stock-based compensation	1,048,127	747,365
Loss on issuance of Preferred Stock Units	3,124,285	—
Change in fair value - Series A Warrants derivative liability	(1,942,501)	—
Change in fair value - Series A Convertible Preferred Stock conversion option derivative liability	(643,318)	—
Modification of Series A-1 Warrant agreement	222,000	—
Amortization of discount - Senior Secured Note	347,601	—
Unpaid interest expense added to principal of Senior Secured Note	188,542	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	67,023	(146,729)
Accounts payable	(85,008)	877,592
Accrued expenses and other current liabilities	577,200	(286,027)
Adjustments to reconcile net loss to net cash used in operating activities	$ 2,911,061	$ 1,195,994
Net cash flows used in operating activities	$ (6,608,208)	$ (4,454,857)

Net cash flows used in investing activities

Net cash flows used in investing activities in the years ended December 31, 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 year ended December 31, 2017, totaled $7,562,851, 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 Preferred Stock Units private placement, $4,842,577 from the Scopia Note and Security Purchase Agreement, each as discussed herein above, along with $71,890 of cash proceeds from the exercise of IPO Warrants.

Net cash flows provided by financing activities in the year ended December 31, 2016, totaled $4,295,062, comprised of $5,300,000 of gross proceeds, offset by $1,004,938 of offering costs, from the issuance of units in our April 28, 2016 IPO, as discussed herein above.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated 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 consolidated financial statements requires us to make estimates and assumptions affecting the reported amounts of assets, liabilities, and equity, along with the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the corresponding periods. 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 our consolidated financial notes, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated 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 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.

Financial Instruments and 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 FASB 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 Company evaluates its financial instruments to determine if those instruments or any embedded components of those instruments potentially qualify as derivatives that need to be separately accounted for in accordance with FASB ASC Topic 815, *Derivatives and Hedging* (ASC 815). 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, and are generally classified as equity, but may be classified as a derivative liability if the warrant agreement provides required or potential full or partial cash settlement. A warrant classified as a derivative liability, or a bifurcated embedded conversion or settlement option classified as a derivative liability, is initially measured at its issue-date fair value, with such fair value subsequently adjusted at each reporting period, with the resulting fair value 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, or the exercise of the warrant or the conversion option, the fair value of the derivative liability will be adjusted on such date-of-occurrence, with such date-of-occurrence fair value adjustment recognized as other income or expense, and then the derivative liability will be derecognized at such date-of-occurrence fair value.

Critical Accounting Policies and Significant Judgments and Estimates (continued)

Financial Instruments and Fair Value Measurements (continued)

The Series A Warrant and the Series A Convertible Preferred Stock conversion option were each determined to be a derivative liability under FASB ASC 815, as the Series A Convertible Preferred Stock common stock exchange factor denominator and the Series A Warrant exercise price are each subject to potential adjustment resulting from future financing transactions, under certain conditions, along with certain other provisions which may result in required or potential full or partial cash settlement. The respective Series A Warrants and the Series A Convertible Preferred Stock conversion option derivative liability are each classified as a current liability on the consolidated balance sheet, and each were initially measured at fair value at the time of issuance and are subsequently remeasured at fair value on a recurring basis at each reporting period, with changes in fair value recognized as other income or expense in the consolidated statement of operations, with each such estimated fair values using a Monte Carlo simulation valuation model, utilizing the Company's common stock price and certain Level 3 inputs to take into account the probabilities of certain events occurring over their respective life.

In addition to the recurring estimated fair value measurements, the issue-date and /or date -of-occurrence non-recurring estimated fair value measurements include: 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; the Series A-1 Convertible Preferred Stock and Series A-1 Warrants issued in the Series A-1 Preferred Stock Units private placement; the Series A-1 Warrants modification resulting from the Series A-1 Amendment No.1, and the Series A Exchange Offer - with each utilizing the Company's common stock price along with certain Level 3 inputs, as discussed below, in the development of discounted cash flow analyses and /or Black-Scholes valuation models.

The recurring and non-recurring estimated fair value measurements are subjective and are affected by changes in inputs to the valuation models, including the Company's common stock price, and certain Level 3 inputs, including, 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 future dilutive transactions, as applicable, along with the risk-free rates based on U.S. Treasury security yields. Changes in these assumptions can materially affect the estimated fair values.

Income Taxes

The Company accounts for income taxes using the asset and liability method, wherein, current tax liabilities or receivables are recognized for the amount of taxes estimated to be payable or refundable for the current year, and deferred tax assets and deferred tax 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 used for income tax purposes, along with net operating loss ("NOL") and tax credit carryforwards.

Deferred tax assets and deferred tax 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. 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. See herein below for a discussion of the "Tax Act of 2017", which resulted in a change to future years' statutory corporate tax rate applicable to taxable income. Changes in deferred tax assets and deferred tax liabilities are recorded in the provision for income taxes.

On December 22, 2017, the president of the United States signed into law what is commonly referred to as the Tax Cuts and Jobs Act of 2017 (Public Law No. 115-97), referred to herein as the Tax Act of 2017. The Tax Act of 2017 is a comprehensive revision to federal tax law which makes broad and complex changes to the U.S. tax code, including, but not limited to, reducing the U.S. federal corporate tax rate from 35% to 21%, eliminating the corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; creating a new limitation on deductible interest expense; changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017; and limitations on the deductibility of certain executive compensation.

In December 2017, the SEC issued Staff Accounting Bulletin No. 118 ("SAB 118"), which addresses situations where the accounting is incomplete for the income tax effects of the Tax Act of 2017. SAB 118 directs taxpayers to consider the impact of the Act as "provisional" when the Company does not have the necessary information available, prepared, or analyzed, including computations, to finalize the accounting for the changes resulting from the Tax Act of 2017. Companies are provided a measurement period of up to one year to obtain, prepare, and analyze information necessary to finalize the accounting for provisional amounts or amounts that cannot be estimated as of December 31, 2017.

As required by FASB ASC Topic 740, *Income* Taxes", ("ASC 740), a "more-likely-than-not" criterion is applied when assessing the estimated realization of deferred tax assets through their utilization to reduce future taxable income, or with respect to a deferred tax asset for tax credit carryforward, to reduce future tax expense. A valuation allowance is established, when necessary, to reduce deferred tax assets, net of deferred tax liabilities, when the assessment indicates it is more-likely-than-not, the full or partial amount of the net deferred tax asset will not be realized. Accordingly, the Company evaluated the positive and negative evidence bearing upon the estimated realizability of the net deferred tax assets, and based on the Company's history of operating losses, concluded it is more-likely-than-not the deferred tax assets will not be realized, and therefore recognized a valuation allowance reserve equal to the full amount of the deferred tax assets, net of deferred tax liabilities, as of December 31, 2017 and 2016.

Critical Accounting Policies and Significant Judgments and Estimates (continued)

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 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, and 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 adoption of this guidance as of January 1, 2018 did not have an effect on the Company's consolidated financial statements.

Recently Issued Accounting Standards (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 adoption of this guidance as of January 1, 2018 did not have an effect on the Company's 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.

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, the Company issued to Scopia and its designees, a Senior Secured Note with an initial principal amount of $5.0 million ("Senior Secured Note"), and 2,660,000 Series S Warrants to purchase a corresponding number of shares of our common stock. The aggregate remaining unpaid principal balance of the Senior Secured Note is due on June 30, 2019.

The Senior Secured 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 December 30, 2017. At our sole discretion, we may elect to defer payment of up to 50% of the semi-annual interest due, with the unpaid semi-annual interest payment added to the outstanding interest-bearing principal balance of the Senior Secured Note. As of December 31, 2017, the Senior Secured Note principal balance is $5,188,542, including $188,542 of deferred interest payment.

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

During the year ended December 31, 2017, interest expense recognized totaled $724,684, including $377,083 with respect to the semi-annual interest payment, which as discussed above, 50% or $188,542, has been added to the outstanding interest-bearing principal balance of the Senior Secured Note, and $347,601 with respect to the amortization of debt discount. The Senior Secured Note remaining unamortized debt discount is $3,244,274 at December 31, 2017.

At our discretion, the aggregate principal balance of the Senior Secured Note and any earned and unpaid interest may be repaid at any time without penalty or premium. Additionally, under the Senior Secured Note, if at the Company's discretion, it sells its implantable intraosseous vascular access device (the "PortIO™ Product"), then the Senior Secured Note holders' may require the Company to repay the then outstanding aggregate principal amount of the Senior Secured 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 Senior Secured Note remains outstanding. Additionally, 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 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 Senior Secured Note holders may request the Company to repay the then aggregate remaining unpaid principal balance of the Senior Secured Note. Notwithstanding, as the FDA has indicated the PortIO™ Product will be reviewed for approval and clearance under a regulatory pathway other than a 510(k) clearance, such Note and Securities Purchase Agreement provision is not operative;

- 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 such earned but unpaid salary to occur on the earlier 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 Senior Secured Note is repaid in full. Subsequently, Scopia irrevocably waived compliance with this provision by the Company and the CEO on a prospective basis commencing February 1, 2018. Notwithstanding, the unpaid CEO salary for the period July 1, 2017 to January 31, 2018, may only be paid upon the Senior Secured Note first being repaid-in-full.

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 Senior Secured 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 Senior Secured Note are guaranteed by the Company, and the obligations under the Senior Secured 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 Senior Secured 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 Senior Secured 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, and was subsequently amended to 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. 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 $147,276 and $134,356 for the years ended December 31, 2017 and 2016, respectively. At December 31, 2017, the Company's future minimum lease payments totaled $125,186 for the period January 1, 2018 to December 31, 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 former 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 first month 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 $300,000 in each of the years ending December 31, 2017 and 2016, with such expense included in "General and administrative expenses" in the accompanying consolidated statements of operations.

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 "emerging growth company" or EGC, as defined in the JOBS Act, and are eligible to take advantage of certain exemptions from various reporting requirements applicable to other public companies who are not an ECG, 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 accounting standards, and, therefore, will not be subject to the same new or revised accounting standards as public companies who are not an ECG.

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 7A. Quantitative and Qualitative Disclosure About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements, together with the report of our independent registered public accounting firm, appear herein commencing on page F-1 of this Annual Report on Form 10-K and are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2017. Based on that evaluation, our principal executive officer and principal financial officer concluded our disclosure controls and procedures (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) are effective as of such date at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting, as such term is defined in Exchange Act Rules 13(a)-15(f). Our system of internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the U.S.

Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that our transactions are recorded as necessary to permit preparation of our financial statements in accordance with accounting principles generally accepted in the U.S., and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and
- provide a reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect all misstatements. Further, because of changes in conditions, effectiveness of internal controls over financial reporting may vary over time. Our system contains self-monitoring mechanisms, so actions will be taken to correct deficiencies as they are identified.

Our management conducted an evaluation of the effectiveness of the system of internal control over financial reporting based on the framework in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our system of internal control over financial reporting was effective as of December 31, 2017.

This Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the rules of the SEC that permit us to provide only management's report in this Form 10-K.

Changes to Internal Controls Over Financial Reporting

There has been no change in internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our fourth quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

Item 11. Executive Compensation

The information required by this Item 11 is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents filed as a part of the report:

(1) The following financial statements:
Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets
Consolidated Statements of Operations
Consolidated Statement of Stockholders' (Deficit) Equity
Consolidated Statements of Cash Flows
Notes to Consolidated Financial Statements

(2) The financial statement schedules:
Schedules other than those listed above are omitted for the reason they are not required or are not applicable, or the required information is shown in the financial statements or notes thereto. Columns omitted from schedules filed have been omitted because the information is not applicable.

(3) The following exhibits:

Exhibit No.	Description
3.1	Certificate of Incorporation(1)
3.2	Certificate of Amendment to Certificate of Incorporation (1)
3.3	Form of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (2)
3.4	Form of Certificate of Designation of Preferences, Rights, and Limitations of Series A-1 Convertible Preferred Stock (6)
3.5	Bylaws (1)
4.1	Specimen Common Stock Certificate (1)
4.2	Specimen Warrant Certificate (1)
4.3	Warrant Agreement, dated April 28, 2016, between Continental Stock Transfer & Trust Company and the Registrant (3)
4.4	Form of Unit Purchase Option (1)
4.5	Form of Series A Warrant (2)
4.6	Form of Series X Warrant (2)
4.7	Form of Series A-1 Warrant (6)
10.1	Patent Option Agreement (1)
10.2.1*	Employment Agreement between PAVmed and Dr. Aklog (1)
10.2.2*	Amendment to Employment Agreement between PAVmed and Dr. Aklog (1)
10.2.3*	Second Amendment to Employment Agreement between PAVmed and Dr. Aklog (1)
10.2.4*	Third Amendment to Employment Agreement between PAVmed and Dr. Aklog (9)
10.3.1	Form of Subscription Agreement (July 2014) (1)
10.3.2	Form of Subscription Agreement (November 2014) (1)
10.4.1	Form of Letter Agreement with HCFP Capital Partners III LLC (1)
10.4.2	Form of Letter Agreement with Pavilion Venture Partners LLC (1)
10.5.1	Letter agreement regarding corporate opportunities executed by Dr. Lishan Aklog (1)
10.5.2	Letter agreement regarding corporate opportunities executed by Michael Glennon (1)
10.5.3	Letter agreement regarding corporate opportunities executed by Dr. Brian deGuzman (1)
10.6	Management services agreement between PAVmed and HCP/Advisors LLC (1)
10.7.1*	Employment Agreement between PAVmed and Richard Fitzgerald (1)
10.7.2*	Separation Agreement between PAVmed and Richard F. Fitzgerald (8)
10.7.3*	Consulting Agreement between PAVmed and Richard F. Fitzgerald (8)
10.8*	Employment Agreement between PAVmed and Dr. Brian deGuzman (4)
10.9.1*	Consulting Agreement between PAVmed and Michael Glennon (5)
10.9.2*	Amendment to Consulting Agreement between PAVmed and Michael J. Glennon (9)
10.9.3*	Amendment to Consulting Agreement between PAVmed and Michael J. Glennon (8)
10.9.4*	Termination of Consulting Agreement between PAVmed and Michael J. Glennon (10)
10.10.1	Securities Purchase Agreement between PAVmed and the purchasers of the Series A Preferred Stock Units (2)
10.10.2	Registration Rights Agreement between PAVmed and the purchasers of the Series A Preferred Stock Units (2)
10.11*	2014 Long-Term Equity Incentive Plan (1)
10.12*	Employment Agreement between PAVmed and Dennis M. McGrath (8)
10.14	Note and Securities Purchase Agreement between PAVmed and Scopia Holdings LLC (7)
10.15.1	Securities Purchase Agreement between PAVmed and the purchasers of the Series A-1 Preferred Stock Units (2)
10.15.2	Registration Rights Agreement between PAVmed and the purchasers of the Series A-1 Preferred Stock Units (2)
14	Form of Code of Ethics (1)

Item 15. Exhibits and Financial Statement Schedules (continued)

(3) The following exhibits (continued):

Exhibit No.	Description
23.1	Consent of Citrin Cooperman & Company, LLP
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	XBRL 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

(1) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-203569)
(2) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on February 1, 2017.
(3) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on May 3, 2016.
(4) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 19, 2016.
(5) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on October 14, 2016.
(6) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on August 8, 2017.
(7) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 6, 2017.
(8) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed on May 22, 2017.
(9) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed on February 16, 2017.
(10) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed on August 11, 2017.

* Management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PAVmed Inc.

March 14, 2018 By: */s/ Lishan Aklog, M.D.*
Lishan Aklog, M.D.
Chairman of Board of Directors
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated. Each person whose signature appears below hereby authorizes both Lishan Aklog, M.D. and Dennis M. McGrath or either of them acting in the absence of the others, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and re-substitution for him or her and in his or her name, place and stead, in any and all capacities to sign any and all amendments to this report, and to file the same, with all exhibits thereto and other documents in connection therewith, with the United States Securities and Exchange Commission.

Signature	Title	Date
/s/ Lishan Aklog, M.D. Lishan Aklog, M.D.	Chairman of the Board of Directors Chief Executive Officer (Principal Executive Officer)	March 14, 2018
/s/ Michael J. Glennon Michael J. Glennon	Vice Chairman Director	March 14, 2018
/s/ Dennis M. McGrath Dennis M. McGrath	Executive Vice President Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2018
/s/ David S. Battleman David S. Battleman	Director	March 14, 2018
/s/ James L. Cox, M.D. James L. Cox, M.D.	Director	March 14, 2018
/s/ Ronald M. Sparks Ronald M. Sparks	Director	March 14, 2018
/s/ David Weild IV David Weild IV	Director	March 14, 2018

PAVMED INC. AND SUBSIDIARY
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of PAVmed Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of PAVmed Inc. and Subsidiary (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of operations, Series A Convertible preferred stock and stockholders' deficit, and cash flows, for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2017 and 2016, and the results of their consolidated operations and their cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's recurring losses from operations, recurring cash used in operating activities, accumulated deficit and absence of revenue generation raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CITRIN COOPERMAN & COMPANY, LLP

We have served as the Company's auditor since 2014.

New York, New York
March 14, 2018

PAVMED INC.
and SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	December 31, 2017	December 31, 2016
Assets		
Current assets		
Cash	$ 1,535,022	$ 585,680
Prepaid expenses and other current assets	88,467	155,490
Total current assets	1,623,489	741,170
Equipment, net	16,191	18,000
Deferred offering costs	—	111,249
Total assets	$ 1,639,680	$ 870,419
Liabilities, Preferred Stock, and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 864,405	$ 949,413
Accrued expenses and other current liabilities	706,024	240,073
Series A Warrants derivative liability	761,123	—
Series A Convertible Preferred Stock conversion option derivative liability	212,217	—
Total current liabilities	2,543,769	1,189,486
Senior Secured Note, net of $3,244,274 unamortized debt discount	1,944,268	—
Total liabilities	$ 4,488,037	$ 1,189,486
COMMITMENTS AND CONTINGENCIES (NOTE 9)		
Series A Convertible Preferred Stock		
Preferred stock, par value $0.001, 20,000,000 shares authorized; Series A Convertible Preferred Stock, par value $0.001, 249,667 and 0 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	—	—
Stockholders' Deficit		
Preferred stock, par value $0.001, 20,000,000 shares authorized; Series A-1 Convertible Preferred Stock, par value $0.001, 357,259 and 0 shares issued and outstanding at December 31, 2017 and December 31, 2016 respectively	1,032,650	—
Common stock, par value $0.001; 50,000,000 shares authorized, 14,551,234 and 13,330,811 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	14,551	13,331
Additional paid-in capital	14,012,053	7,369,437
Accumulated deficit	(17,907,611)	(7,701,835)
Total Stockholders' Deficit	(2,848,357)	(319,067)
Total Liabilities, Series A Convertible Preferred Stock, and Stockholders' Deficit	$ 1,639,680$	870,419

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2017	2016
Revenue	$ —	$ —
General and administrative expenses	5,415,324	3,931,264
Research and development expenses	2,618,795	1,719,587
Total operating expenses	8,034,119	5,650,851
Loss from operations	(8,034,119)	(5,650,851)
Other income (expense)		
Interest expense	(724,684)	—
Loss on issuance of Series A Preferred Stock Units in a private placement	(3,124,285)	—
Change in fair value of Series A Warrants derivative liability	1,942,501	—
Change in fair value of Series A Convertible Preferred Stock conversion option derivative liability	643,318	—
Modification of Series A-1 Warrant agreement	(222,000)	—
Other income (expense), net	(1,485,150)	—
Loss before income tax	(9,519,269)	(5,650,851)
Income tax	—	—
Net loss	(9,519,269)	(5,650,851)
Series A Convertible Preferred Stock dividends	(112,570)	—
Series A-1 Convertible Preferred Stock dividends	(79,788)	—
Deemed dividend Series A-1 Convertible Preferred Stock issued in a private placement	(182,500)	—
Deemed dividend Series A-1 Convertible Preferred Stock issued in the Series A Exchange Offer	(504,007)	—
Net loss attributable to common stockholders	$ (10,398,134)	$ (5,650,851)
Net loss per share - basic and diluted	$ (0.71)	$ (0.44)
Net loss attributable to common stockholders per share - basic and diluted	$ (0.77)	$ (0.44)
Weighted average common shares outstanding - basic and diluted	13,495,951	12,972,153

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARY
CONSOLIDATED STATEMENT OF
SERIES A CONVERTIBLE PREFERRED STOCK
STOCKHOLDERS' DEFICIT

	Series A Convertible Preferred Stock		Stockholders' Deficit						
			Series A-1 Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2015	—	$ —	—	—	12,250,000	$ 12,250	$ 2,672,652	$ (2,050,984)	$ 633,918
Units issued in connection with initial public offering, net of offering costs			—	—	1,060,000	1,060	3,949,441		3,950,501
Common stock issued upon exercise of warrants					20,811	21	(21)		—
Stock-based compensation							747,365		747,365
Net loss								(5,650,851)	(5,650,851)
Balance at December 31, 2016	—	$ —	—	$ —	13,330,811	$ 13,331	$ 7,369,437	$ (7,701,835)	$ (319,067)

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARY
CONSOLIDATED STATEMENT OF
SERIES A CONVERTIBLE PREFERRED STOCK
STOCKHOLDERS' DEFICIT

	Series A Convertible Preferred Stock		Stockholders' Deficit						
			Series A-1 Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders Equity (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)
Series A Convertible Preferred Stock issued in a in a private placement	422,838	---							---
Series A-1 Convertible Preferred Stock and Series A-1 Warrants issued in a private placement			125,000	7,050			492,950		500,000
Series A Exchange Offer	(154,837)	---	232,259	843,100			1,347,082	(504,007)	1,686,175
Series A-1 Convertible Preferred Stock deemed dividend				182,500				(182,500)	---
Modification of Series A-1 Warrant Agreement							222,000		222,000
Series S Warrants issued in connection with Senior Secured Note payable							3.434,452		3,434,452
Common stock issued upon exercise of warrants					1,193,330	1,198	70,692		71,890
Common stock issued upon conversion of Series A Convertible Preferred Stock	(18,334)	---			22,093	22	27,313		27,335
Stock-based compensation							1,048,127		1,048,127
Net loss								(9,519,269)	(9,519,269)
Balance at December 31, 2017	249,667	$ ---	357,259	$ 1,032,650	14,551,234	$ 14,551	$ 14,012,053	$ (17,907,611)	$ (2,848,357)

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2017	2016
Cash flows from operating activities		
Net loss	$ (9,519,269)	$ (5,650,851)
Adjustments to reconcile net loss to net cash used in operating activities Depreciation expense	7,110	3,793
Stock-based compensation	1,048,127	747,365
Loss on issuance of Preferred Stock Units	3,124,285	—
Change in fair value - Series A Warrants derivative liability	(1,942,501)	—
Change in fair value - Series A Convertible Preferred Stock conversion option derivative liability	(643,318)	—
Modification of Series A-1 Warrant agreement	222,000	—
Amortization of discount - Senior Secured Note	347,601	—
Unpaid interest expense added to principal of Senior Secured Note	188,542	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	67,023	(146,729)
Accounts payable	(85,008)	877,592
Accrued expenses and other current liabilities	577,200	(286,027)
Net cash flows used in operating activities	(6,608,208)	(4,454,857)
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	71,890	—
Net cash flows provided by financing activities	7,562,851	4,295,062
Net increase (decrease) in cash	949,342	(181,588)
Cash, beginning of period	585,680	767,268
Cash, end of period	$ 1,535,022	$ 585,680

See accompanying notes to the 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 prior to 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 year ended December 31, 2017, the Company raised approximately $7.5 million of net cash proceeds, including: the Note and Security Purchase Agreement with Scopia Holdings LLC, the Series A-1 Preferred Stock Units private placement; and the Series A Preferred Stock Units private placement, and, subsequent to December 31, 2017, in January 2018, the Company raised $4.3 million of net cash proceeds in an underwritten public offering of shares of common stock of the Company pursuant to its previously filed effective shelf registration statement on United States Securities and Exchange Commission ("SEC") Form S-3 (File No. 333-220549).

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 a further discussion of the Series A-1 Preferred Stock Units private placement, Series A Preferred Stock Units private placement, and the issue of common stock of the Company in an underwritten public offering in January 2018.

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 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, it completes the development process of its products, including regulatory approvals and clearances, and thereafter, begins to commercialize and achieve substantial marketplace acceptance 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.

The Company incurred a net loss attributable to common stockholders of $10,398,134 and had net cash flows used in operating activities of $6,608,208 for the year ended December 31, 2017. As of December 31, 2017, the Company had an accumulated deficit of $17,907,611 and working capital of $53,060, adjusted to exclude the Series A Warrants derivative liability of $761,123 and the Series A Convertible Preferred Stock conversion option derivative liability of $212,217.

The Company anticipates incurring operating losses and does not expect to experience positive cash flows from operating activities, if any, and may continue to incur operating losses for the next several years as it completes the development of its products, seeks regulatory approvals and clearances of such products, and begins to commercially market such products. These factors, which have existed since inception, are expected to continue for the foreseeable future, and raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the accompanying consolidated financial statements are issued.

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 and clearances 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 consolidated financial statements are issued.

The Company's 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 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 consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), and include the accounts of the Company and its wholly-owned subsidiary as of December 31, 2017 and 2016. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make accounting 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 consolidated financial statements include those related to the fair value of warrants, the fair value of derivative liabilities, stock-based compensation, research and development expenses, the provision or benefit for income taxes and the corresponding 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 such accounting estimates and assumptions, the actual financial statement results could differ materially from such accounting estimates and assumptions.

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 the Series A Preferred Stock Units private placement financing transaction, with such private placement financing transaction discussed in Note 13, *Series A Convertible Preferred Stock, Stockholders' 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.

Note 2 — Summary of Significant Accounting Policies (continued)

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.

Financial Instruments Fair Value Measurements

The Company evaluates its financial instruments to determine if those instruments or any embedded components of those instruments potentially qualify as derivatives that need to be separately accounted for in accordance with FASB ASC Topic 815, *Derivatives and Hedging* (ASC 815). 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, and are generally classified as equity, but may be classified as a derivative liability if the warrant agreement provides required or potential full or partial cash settlement. A warrant classified as a derivative liability, or a bifurcated embedded conversion or settlement option classified as a derivative liability, is initially measured at its issue-date fair value, with such fair value subsequently adjusted at each reporting period, with the resulting fair value adjustment recognized as other income or expense. If upon the occurrence of an event resulting in the derivate liability being subsequently classified as equity or otherwise derecognized, the fair value of the derivative liability will be adjusted on such date-of-occurrence, with such date-of-occurrence fair value adjustment recognized as other income or expense, and then the derivative liability will be derecognized at such date-of-occurrence fair value.

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.

As of December 31, 2017 and 2016, 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.

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-based 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 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-based 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. See Note 7, *Income Taxes*, for a discussion of the "Tax Cuts and Jobs Act of 2017", enacted on December 22, 2017, which resulted in a change to future years' statutory federal corporate tax rate applicable to taxable income. 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 December 31, 2017 and December 31, 2016, or recognized during the years ended December 31, 2017 and 2016. As of December 31, 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 and basic net loss attributable to common stockholders per share, are each computed by dividing the net loss and the net loss attributable to common stockholders, respectively, by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share and diluted net loss attributable to common stockholders per share, are each computed by dividing the net loss and the net loss attributable to common stockholders, respectively, 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 and a net loss attributable to common stockholders for all periods presented, basic and diluted net loss per share and net loss attributable to common stockholders per share are the same due to the exclusion of incremental shares resulting from common stock equivalents, as their inclusion would be anti-dilutive.

Note 2 — Summary of Significant Accounting Policies (continued)

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" or "EGC", as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, an EGC 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 who are not an EGC.

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 adoption of this guidance as of January 1, 2018 did not have an effect on the Company's 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 adoption of this guidance as of January 1, 2018 did not have an effect on the Company's 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 — Prepaid Expenses and Other Current Assets

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

	December 31, 2017	December 31, 2016
Security deposits	$ 14,250	$ 48,350
Prepaid insurance	33,175	35,947
Advanced payments to suppliers	41,042	71,193
Total prepaid expenses and other current assets	$ 88,467	$ 155,490

Note 4 — Equipment, Net

Equipment, net consisted of the following as of:

	December 31, 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	(10,903)	(3,793)
Equipment, net	$ 16,191	$ 18,000

Depreciation expense was $7,110 and $3,793 for the year ended December 31, 2017 and 2016, respectively.

Note 5 — Agreement Related to Intellectual Property Right

Tufts Patent License Agreement - Antimicrobial 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 antimicrobial 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 $67,501 in the year ended December 31, 2017. There were no such expenses incurred in the year ended December 31, 2016.

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 6 — Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of:

	December 31, 2017	December 31, 2016
Accrued bonus	$ 459,451	$ —
Accrued payroll	125,088	—
Accrued vacation	28,722	28,324
Accrued board of director fees	82,500	72,500
Accrued professional fees	—	111,249
Accrued operating expenses	10,263	28,000
Total accrued expenses and other current liabilities	$ 706,024	$ 240,073

At December 31, 2017, the accrued bonus represents the guaranteed bonus payment to the Company's Chief Executive Officer ("CEO") under the CEO Employment Agreement and to other employees. 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 waiver of 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 December 31, 2017, the accrued payroll represents earned but unpaid salary for the period July 1, 2017 through December 31, 2017, payable to the Company's CEO. In this regard, under the terms of the Note and Security Purchase Agreement, including the corresponding 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. Subsequently, Scopia irrevocable waived compliance with this provision by the Company and the CEO on a prospective basis commencing February 1, 2018. Notwithstanding, the unpaid CEO salary for the period July 1, 2017 to January 31, 2018, may only be paid upon the Senior Secured Note first being 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 December 31, 2017 and December 31, 2016 represent amounts payable to all non-executive members of the board of directors, including $10,000 payable to a former board member previously deemed to be a related party, at each of December 31, 2017 and 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, as further discussed in Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*.

Included in accrued operating expenses at December 31, 2016, is $10,000 due to HCFP/Strategy Advisors LLC, a former related party, as further discussed in Note 8, *Related Party Transactions*.

Note 7 — Income Taxes

Income tax (benefit) expense consisted of the following for the years ended December 31, 2017 and 2016:

	December 31, 2017	December 31, 2016
Current:		
Federal, state, and local	$ —	$ —
Deferred:		
Federal	(105,093)	(1,945,638)
State and local	(471,522)	(424,840)
	(576,616)	(2,370,478)
Less: Valuation allowance reserve	576,616	2,370,478
	$ —	$ —

At December 31, 2017 and 2016, the reconciliation of the federal statutory income tax rate to the effective income tax rate is as follows:

	December 31, 2017	December 31, 2016
U.S. federal statutory rate	35.0%	35.0%
U.S. state and local income taxes, net of federal tax benefit	5.6%	7.5%
Permanent differences	(2.3)%	(1.8)%
Tax credits	1.2%	1.3%
Change in U.S. federal tax law	(19.4)%	—%
Valuation allowance	(20.1)%	(42.0)%
Effective tax rate	0.0%	0.0%

At December 31, 2017 and 2016, the approximate tax effects of temporary differences which give rise to the net deferred tax assets are as follows:

Deferred tax assets:		
Net operating loss	$ 4,309,231	$ 2,795,050
Stock-based compensation expense	201,950	199,921
Deferred compensation	—	—
Accrued expenses	8,981	12,307
Section 195 deferred start-up costs	26,445	39,746
Patent licenses	17,077	25,466
Research and development tax credit carryforward	194,345	91,535
Deferred tax assets	4,758,029	3,164,025
Deferred tax liabilities:		
Discount on debt	(1,014,484)	—
Depreciation	(2,904)	—
Deferred tax liabilities	(1,017,388)	—
Less: valuation allowance	(3,740,641)	(3,164,025)
Deferred tax assets, net after valuation allowance	$ —	$ —

Deferred tax assets and deferred tax 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. 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. See herein below for a discussion of the “Tax Cuts and Jobs Act of 2017”, which resulted in a change to future years’ statutory federal corporate tax rate applicable to taxable income. Changes in deferred tax assets and deferred tax liabilities are recorded in the provision for income taxes.

On December 22, 2017, the president of the United States signed into law what is commonly referred to as the Tax Cuts and Jobs Act of 2017 (Public Law No. 115-97). , referred to herein as the Tax Cuts and Jobs Act. The Tax Cuts and Jobs Act is a comprehensive revision to federal tax law which makes broad and complex changes to the U.S. tax code, including, but not limited to, reducing the U.S. federal corporate tax rate from 35% to 21%, eliminating the corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; creating a new limitation on deductible interest expense; changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017; and limitations on the deductibility of certain executive compensation.

Note 7 — Income Taxes (continued)

In December 2017, the SEC issued Staff Accounting Bulletin No. 118 ("SAB 118"), which addresses situations where the accounting is incomplete for the income tax effects of the Tax Cuts and Jobs Act. SAB 118 directs taxpayers to consider the impact of the Tax Cuts and Jobs Act as "provisional" when the Company does not have the necessary information available, prepared, or analyzed, including computations, to finalize the accounting for the changes resulting from the Tax Cuts and Jobs Act. Companies are provided a measurement period of up to one year to obtain, prepare, and analyze information necessary to finalize the accounting for provisional amounts or amounts that cannot be estimated as of December 31, 2017.

The Tax Cuts and Jobs Act impact on the tax provision of the Company for year ending December 31, 2017, resulted in the Company recognizing the provisional impact of the revaluation of deferred tax assets and deferred tax liabilities to 21% from 35%, resulting in an estimated $1.6 million tax expense, which was fully offset by a corresponding change in the valuation allowance applied to the net deferred tax assets.

As required by FASB ASC Topic 740, *Income* Taxes", ("ASC 740), a "more-likely-than-not" criterion is applied when assessing the estimated realization of deferred tax assets through their utilization to reduce future taxable income, or with respect to a deferred tax asset for tax credit carryforward, to reduce future tax expense. A valuation allowance is established, when necessary, to reduce deferred tax assets, net of deferred tax liabilities, when the assessment indicates it is more-likely-than-not, the full or partial amount of the net deferred tax asset will not be realized. Accordingly, the Company evaluated the positive and negative evidence bearing upon the estimated realizability of the net deferred tax assets, and based on the Company's history of operating losses, concluded it is more-likely-than-not the deferred tax assets will not be realized, and therefore recognized a valuation allowance reserve equal to the full amount of the deferred tax assets, net of deferred tax liabilities, as of December 31, 2017 and 2016.

The Company has total estimated federal and state net operating loss ("NOL") carryforward of $13,780,719 and $6,432,797 at December 31, 2017 and 2016, respectively, which is available to reduce future taxable income and begin to expire in 2035. The Company has total estimated research and development ("R&D") tax credit carryforward of $194,345 and $91,535 as of December 31, 2017 and 2016, respectively, including generating R&D tax credit of $102,810 and $70,861, during the years ended December 31, 2017 and 2016, respectively, with the R&D tax credit carryforward available to reduce future tax expense, and begin to expire in 2035.

The Company files income tax returns in the United States in federal and applicable state jurisdictions. The Company's tax filings for the years 2016, 2015 and for its initial period of operations from June 26, 2014 (inception) through December 31, 2014, each remain subject to examination by taxing authorities. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. The Company has not recognized any penalties or interest related to its income tax provision.

Note 8 — 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 former director of the Company, wherein HCP/Advisors LLC is 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. Pursuant to such agreement with HCP/Advisors LLC, the Company paid HCP/Advisors LLC an initial first month's fee of $35,000 commencing as of November 1, 2015, and thereafter, a monthly fee of $25,000 through October 31, 2018. Under the agreement with HCP/Advisors LLC, the Company incurred an expense of $300,000 in each of the years ended December 31, 2017 and 2016, included in "General and administrative expenses" in the accompanying consolidated statements of operations.

Effective September 2016, the Company and HCFP/Strategy Advisors LLC, an affiliate of certain former directors and current officers of the Company, entered into a management consulting agreement referred to as the "HCFP Strategic Advisory Agreement", which expired on May 14, 2017, as discussed below. 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, 2017 to May 14, 2017, and obligating the Company to make payments of $20,000 per month in each of 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, the Company incurred an expense of $10,000 related to a HCFP/Strategy Advisors LLC vendor invoice dated June 30, 2017, for a professional services fee 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, which were separate and apart from the previously expired HCFP Strategic Advisory Agreement.

The Company incurred expense of $80,000 and $100,000 in the years ended December 31, 2017 and 2016, respectively, under the HCFP Strategic Advisory Agreement and the HCFP/Strategy Advisors LLC discrete invoice dated June 30, 2017, as noted above, with such expense included in "General and administrative expenses" in the accompanying 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 former directors and current 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 paid and recognized as expense upon execution of the agreement. No such expense was incurred in the year ended December 31, 2017.

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 former directors and current 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 $177,576 of fees paid to HCFP/Capital Markets in connection with the issuances of Series A Preferred Stock Units in the year ended December 31, 2017, with such expense included in "Loss on issuance of Series A Preferred Stock Units" in the accompanying consolidated statements of operations.

Note 8 — Related Party Transactions (continued)

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 9 — 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 for a five-year term, with a current base salary of $295,000 per year ("CEO Employment Agreement"). 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 Company's CEO agreed to the payment of a reduced salary of $4,200 per month, with the payment of such earned but unpaid salary to occur on the earlier 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 Senior Secured Note is repaid-in-full. Subsequently, Scopia irrevocable waived compliance with this provision by the Company and the CEO on a prospective basis commencing February 1, 2018. Notwithstanding, the unpaid CEO salary for the period July 1, 2017 to January 31, 2018, may only be paid upon the Senior Secured Note first being 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.

On April 28, 2016, the CEO was granted a stock option with an exercise price of $5.00 per share to purchase 278,726 shares of common stock of the Company, and on February 14, 2018, the CEO was granted a stock option with an exercise price of $2.01 per share to purchase 195,108 shares of common stock of the Company. 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 ("CFO"), 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 ("CFO Employment Agreement"). Additionally, the Company will reimburse Mr. McGrath up to $2,250 per month for housing and travel expenses for up to 12 months. On March 20, 2017, the CFO was granted a stock option with an exercise price of $5.95 per share to purchase 250,000 shares of common stock of the Company, and a on February 14, 2018, the CFO was granted a stock option with an exercise price of $2.01 per share to purchase 195,108 shares of common stock of the Company. The CFO 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".

Note 9 — Commitments and Contingencies (continued)

Employment Agreements & Compensation (continued)

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 Chief Medical Officer ("CMO") with a base annual salary of $285,000, plus an initial bonus of $50,000 for services provided before the agreement's effective date ("CMO Employment Agreement"). 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, the CMO was granted a stock option with an exercise price of $5.00 per share to purchase 278,726 shares of common stock of the Company, and on February 14, 2018, the CMO was granted a stock option with an exercise price of $2.01 per share to purchase 100,000 shares of common stock of the Company. The CMO 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 CEO with "good reason".

Leases

The Company leases office space for its corporate office, which initially provided for two consecutive six-month terms beginning on February 1, 2016, and was subsequently amended to 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. 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 $147,276 and $134,356 for the years ended December 31, 2017 and 2016, respectively. At December 31, 2017, the Company's future minimum lease payments totaled $125,186 for the period January 1, 2018 to December 31, 2018, with respect to the lease arrangement on a month-to-month basis.

Additionally, 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 $2,000 and $12,000 for the years ended December 31, 2017 and 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, and /or cash flows.

Note 10 — 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 following table summarizes information about stock options outstanding for the periods presented below:

	Number Stock Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2015	—	$	
Granted	1,633,313	$ 5.14	
Exercised	—	$ —	
Forfeited	—	$ —	
Outstanding at December 31, 2016	1,633,313	$ 5.14	$ 3,017,795
Vested and exercisable at December 31, 2016	356,719	$ 5.05	$ 670,621
Unvested at December 31, 2016	1,276,594	$ 5.16	$ 2,347,175
Outstanding at December 31, 2016	1,633,313	$ 5.14	
Granted	380,000	$ 5.35	
Exercised	—	$ —	
Forfeited	(76,389)	$ 5.00	
Outstanding at December 31, 2017	1,936,924	$ 5.19	$ —
Vested and exercisable at December 31, 2017	964,080	$ 5.14	$ —
Unvested at December 31, 2017	972,844	$ 5.23	$ —

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 December 31, 2017, to the extent the exercise price is less than the quoted price.

During the year ended December 31, 2016, the Company granted a total of 1,633,313 stock options, each with a ten year contractual term from date-of-grant, as follows:

- April 2016 - an aggregate of 1,588,313 stock options were granted upon the closing of the closing of the Company's IPO on April 28, 2016, each with an exercise price of $5.00 per share, vesting of 3/36 on July 28, 2016 and 1/36 on each successive month thereafter from Aug 28, 2016 to April 28, 2019, including: a total of 487,770 stock options granted to members of the Company's board of directors, a total 961,178 to employees, and a total of 139,365 to members of the Company's medical advisory board;

- November 2016 - 25,000 stock options with an exercise price of $10.50 per share, vesting ratably on a quarterly basis over a three year period commencing December 31, 2016, granted to a new member of the Company's medical advisory board; and, 20,000 stock options with an exercise price of $9.50 per share, vesting ratably on a quarterly basis over a three year period commencing December 31, 2016, granted to (related party) consultant.

During the year ended December 31, 2017, the Company granted a total of 380,000 stock options, each with a ten year contractual term from date-of-grant, as follows:

- March 2017 - 25,000 stock options with an exercise price of $5.01 per share, vesting ratably on a quarterly basis over a three year period commencing June 30, 2017, granted to a new member of the Company's medical advisory board, and, 250,000 stock options granted outside the 2014 Stock Plan, with an exercise price of $5.95 per share, vesting ratably on a quarterly basis over a three year period commencing June 30, 2017, to the Company's new CFO;

- July 2017 - 50,000 stock options with an exercise price of $4.50 per share, vesting ratably on a quarterly basis over a three year period commencing September 30, 2017, granted to the Company's Corporate Controller;

- August 2017 - 40,000 stock options with an exercise price of $2.98 per share, vesting ratably on a quarterly basis over a three year period commencing September 30, 2017, granted to a new member of the Board of Directors;

- October 2017 - 15,000 stock options with an exercise price of $5.11 per share, vesting ratably on an annual basis over a three year period commencing October 2018, granted to a consultant.

In March 2017, 76,389 stock options were forfeited upon the resignation of the Company's former CFO, as discussed below.

Note 10 — Stock-Based Compensation (continued)

Subsequently, an aggregate of 1,265,216 stock options were granted, each with a ten year contractual term from date-of-grant, and each vesting ratably on a quarterly basis over a three year period commencing March 31, 2018, including: in January 2018, 175,000 stock options with an exercise price of $2.96 granted to the Company's VP Technology and Product Development, and in February 2018, a total of 500,000 stock options granted to non-executive members of the Company's board of directors, and a total of 590,216 stock options granted to employees, each with an exercise price of $2.01 per share. Additionally, in February 2018, a total of 195,108 previously granted stock options were forfeited in connection with the resignation of two members from the Company's board of directors.

A total of 2,951,081 shares of common stock of the Company are reserved for issuance under the 2014 Stock Plan. As of December 31, 2017, 1,515,011 shares of common stock of the Company were available for grant under the 2014 Stock Plan, excluding stock options granted outside the 2014 Stock Plan, including 250,000 in 2017 and 250,854 in 2016.

At December 31, 2017, the weighted average remaining contractual term was 8.4 years for stock options outstanding and 8.1 years for stock options vested and exercisable.

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 recognized for the periods indicated was as follows:

	Year Ended December 31,	
	2017	2016
General and administrative expenses	$ 925,534	$ 664,068
Research and development expenses	122,593	83,297
	$ 1,048,127	$ 747,365

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 to the Company's former CFO. Previously, on April 28, 2016, upon the closing of the Company's IPO, the former CFO was granted 125,000 stock options at an exercise price of $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 December 31, 2017, total unrecognized stock-based compensation expense of $1,573,988 is expected to be recognized over the weighted average remaining requisite service period of 1.5 years. At December 31, 2016, total unrecognized stock-based compensation expense of $ 2,196,566 was expected to be recognized over the weighted average remaining requisite service period of 2.3 years.

Stock-based compensation expense recognized for stock options granted to employees and members of the board of directors was based on a weighted average fair value of $2.62 per share and $1.32 per share during the years ended December 31, 2017 and 2016, respectively, calculated using the following weighted average Black-Scholes valuation model assumptions:

	Year Ended December 31,	
	2017	2016
Risk free interest rate	2.1%	1.4%
Expected term of stock options (in years)	5.8	5.8
Expected stock price volatility	50%	50%
Expected dividend yield	0%	0%

Stock-based compensation expense recognized for stock options granted to non-employees was based on a weighted average fair value of $2.80 per share and $5.60 per share during the years ended December 31, 2017 and 2016, respectively, calculated using the following weighted average Black-Scholes valuation model assumptions

	Year Ended December 31,	
	2017	2016
Risk free interest rate	2.3%	1.9%
Expected term of stock options (in years)	9.0	9.6
Expected stock price volatility	60%	60%
Expected dividend yield	0%	0%

Note 10 — Stock Based Compensation (continued)

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 11 — Financial Instruments Fair Value Measurements

Recurring Fair Value Measurements

The Series A Warrants and the Series A Convertible Preferred Stock conversion option derivative liabilities as of December 31, 2017, are summarized in the fair value hierarchy table, as follows:

	Fair Value Measurement on a Recurring Basis at Reporting Date Using:			
	Level-1 Inputs	Level-2 Inputs	Level-3 Inputs	Total
December 31, 2017				
Series A Warrants derivative liability	$ —	$ —	$ 761,123	$ 761,123
Series A Convertible Preferred Stock conversion option derivative liability	—	—	212,217	212,217
Totals	$ —	$ —	$ 973,340	$ 973,340

As noted above, as presented in the fair value hierarchy table, Level-1 represents quoted prices in active markets for identical items, Level-2 represents significant other observable inputs, and Level-3 represents significant unobservable inputs.

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 FASB ASC 820.

The Series A Preferred Stock Units were issued in a private placement with three closings occurring in the three months ended March 31, 2017, and were each comprised of one share of Series A Convertible Preferred Stock and one Series A Warrant. At the option of their respective holder, the Series A Convertible Preferred Stock may be converted into shares of common stock of the Company and the Series A Warrant may be exercised 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, the Series A Convertible Preferred Stock, and the Series A Warrant.

The Series A Warrant and the Series A Convertible Preferred Stock conversion option were each determined to be a derivative liability under FASB ASC 815, as the Series A Convertible Preferred Stock common stock exchange factor denominator and the Series A Warrant exercise price are each subject to potential adjustment resulting from future financing transactions, under certain conditions, along with certain other provisions which may result in required or potential full or partial cash settlement. The respective Series A Warrants and the Series A Convertible Preferred Stock conversion option derivative liability are classified as a current liability on the consolidated balance sheet, and each were initially measured at fair value at the time of issuance and are subsequently remeasured at fair value on a recurring basis at each reporting period date, with changes in fair value recognized as other income or expense in the consolidated statement of operations. The reconciliation of each of the Series A Warrants and the Series A Convertible Preferred Stock conversion option derivative liability for the year ended December 31, 2017 are as follows:

Derivative Liability	Series A Warrants	Series A Convertible Preferred Stock Conversion Option
Balance at December 31, 2016	$ —	$ —
Initial fair value on dates of issuance	4,050,706	1,221,963
Change in fair value	(1,942,501)	(643,318)
Conversion of Series A Convertible Preferred Stock	—	(27,335)
Series A Exchange Offer	(1,347,082)	(339,093)
Balance at December 31, 2017	$ 761,123	$ 212,217

As of December 31, 2017, 249,667 shares of Series A Convertible Preferred Stock and 268,001 Series A Warrants were each issued and outstanding, summarized as follows:

Issued and Outstanding	Series A Warrants	Series A Convertible Preferred Stock
Issued and outstanding as of December 31, 2016	—	—
Issued in Series A Preferred Stock Units private placement	422,838	422,838
Conversion of Series A Convertible Preferred Stock	—	(18,334)
Series A Exchange Offer	(154,837)	(154,837)
Issued and outstanding as of December 31, 2017	268,001	249,667

Note 11 — Financial Instruments Fair Value Measurements (continued)

Change in Fair Value

The change in estimated fair value, including fair value adjustments on the dates of the Series A Exchange Offer, the conversion of Series A Convertible Preferred Stock, and the recurring fair value adjustment as of December 31, 2017, resulted in the recognition of other income of $1,942,501 and $643,318, with corresponding decreases in each of the Series A Warrants derivative liability and the Series A Convertible Preferred Stock conversion option derivative liability, respectively, during the year ended December 31, 2017.

The initial issue date and subsequent recurring reporting period date estimated fair value of each of the Series A Warrants and the Series A Convertible Preferred Stock conversion option derivative liability were each estimated using a Monte Carlo simulation valuation model using the Company's common stock price, the Company's dividend yield, the risk-free rates based on U.S. Treasury security yields, and certain other Level-3 inputs to take into account the probabilities of certain events occurring over their respective life, including, assumptions regarding the estimated volatility in the value of the Company's common stock price and the likelihood and timing of future dilutive transactions, as applicable, using the following assumptions as of the dates indicated:

Series A Warrants Derivative Liability Fair Value Assumptions	December 31, 2017	Issue Dates' Aggregated Weighted Average
Calculated aggregate fair value	$ 761,123	$ 4,050,706
Series A Warrants outstanding	268,001	422,838
Value of common stock	$ 2.29	$ 5.73
Exercise price per share	$ 6.61	$ 8.00
Expected term (years)	6.33	7.21
Volatility	55%	47%
Risk free rate	2.2%	2.3%
Dividend yield	0%	0%

Series A Convertible Preferred Stock Conversion Option Derivative Liability Fair Value Assumptions	December 31,2017	Issue Dates' Aggregated Weighted Average
Calculated aggregate fair value	$ 212,217	$ 1,221,963
Series A Convertible Preferred Stock shares	249,667	422,838
Value of common stock	$ 2.29	$ 5.73
Common stock exchange factor numerator	$ 6.00	$ 6.00
Common stock exchange factor denominator	$ 4.97	$ 6.00
Expected term (years)	6.33	7.21
Volatility	55%	47%
Risk-free interest rate	2.2%	2.3%
Dividend yield	0%	0%

Conversion of Series A Convertible Preferred Stock

At the election of their respective holders, a total of 18,334 shares of Series A Convertible Preferred Stock were converted into a total of 22,093 shares of common stock of the Company. The Series A Convertible Preferred Stock conversion option derivative liability fair value was adjusted as of each conversion date, with the resulting change in fair value recognized as other income or expense in the consolidated statement of operations, upon which the corresponding Series A Convertible Preferred Stock conversion option derivative liability was derecognized, with a corresponding recognition of common stock par value and additional paid-in capital with respect to the shares of common stock of the Company issued, summarized as follows:

Series A Convertible Preferred Stock Converted to Shares of Common Stock of the Company Year ended December 31, 2017	Conversion Dates Aggregated
Shares of Series A Convertible Preferred Stock converted to common stock	18,334
Shares of common stock issued upon conversion of Series A Convertible Preferred Stock	22,093
Fair Value - Series A Convertible Preferred Stock conversion option derivative liability derecognized	$ 27,335
Common stock issued - par value	$ 22
Common stock issued - additional paid-in capital	$ 27,313

On each of the respective conversion dates, the Series A Convertible Preferred Stock conversion option derivative liability fair value was estimated using a Monte Carlo simulation valuation model using the Company's common stock price, the Company's dividend yield, the risk-free rates based on U.S. Treasury security yields, and certain other Level-3 inputs to take into account the probabilities of certain events occurring over their respective life, including, assumptions regarding the estimated volatility in the value of the Company's common stock price and the likelihood and timing of future dilutive transactions, as applicable.

Note 11 — Financial Instruments Fair Value Measurements (continued)

Series A Exchange Offer - November 17, 2017 Exchange Date

As noted above, a total of 422,838 shares of Series A Convertible Preferred Stock and 422,838 Series A Warrants were issued in the Series A Preferred Stock private placement. On November 17, 2017 ("November 17, 2017 Exchange Date"), the Company completed an exchange offer initiated on October 20, 2017 to all 28 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, one Series A Warrant for one Series A-1 Warrant ("Series A Exchange Offer") - resulting in 154,837 shares of Series A Convertible Preferred Stock exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock, and 154,837 Series A Warrants exchanged for 154,837 Series A-1 Warrants, by 13 holders on the November 17, 2017 Exchange Date.

The Series A Exchange Offer resulted in the extinguishment of: 154,837 shares of Series A Convertible Preferred Stock, the corresponding (bifurcated) conversion option derivative liability, and, 154,837 Series A Warrants, resulting from the issuance-upon-exchange of: 232,259 shares of Series A-1 Convertible Preferred Stock and 154,837 Series A-1 Warrants, each as discussed herein below.

Series A Exchange Offer - Series A Convertible Preferred Stock Exchanged for Series A-1 Convertible Preferred Stock

The fair value of the consideration given in the form of the issue of 232,259 shares of Series A-1 Convertible Preferred Stock, with such fair value recognized as the carrying value of such issued shares of Series A-1 Convertible Preferred Stock, as compared to the extinguishment of both the carrying value of the Series A Convertible Preferred Stock and the fair value of the corresponding conversion option derivative liability, resulted in an excess of fair value of $504,007 recognized as a deemed dividend charged to accumulated deficit in the consolidated balance sheet on the November 17, 2017 Exchange Date, with such deemed dividend included as a component of net loss attributable to attributable to common stockholders, summarized as follows:

Series A-1 Convertible Preferred Stock Issued Series A Convertible Preferred Stock and Conversion Option Derivative Liability Extinguished Deemed Dividend Charged to Accumulated Deficit	Series A Exchange Offer November 17, 2017 Exchange Date
Fair value - 232,259 shares of Series A-1 Convertible Preferred Stock issued	$ 843,100
Less: Fair value - Series A Convertible Preferred Stock conversion option derivative liability extinguished	339,093
Less: Carrying value - 154,837 shares of Series A Convertible Preferred Stock exchanged	—
Deemed dividend charged to accumulated deficit	$ 504,007

The November 17, 2017 Exchange Date estimated fair value of $843,100 of the 232,259 shares of Series A-1 Convertible Preferred Stock issued was estimated using a combination of the present value of its cash flows using a synthetic credit rating analysis required rate of return and the Black-Scholes option pricing model, using the following assumptions:

Series A-1 Convertible Preferred Stock Fair Value Assumptions	November 17, 2017 Exchange Date
Aggregate fair value	$ 843,100
Series A-1 Convertible Preferred Stock shares	232,259
Required rate of return	27.0%
Common stock conversion factor numerator	$ 4.00
Common stock conversion factor denominator	$ 4.00
Value of common stock	$ 4.33
Expected term (years)	6.45
Volatility	53%
Risk free rate	2.2%
Dividend yield	0%

The November 17, 2017 Exchange Date estimated fair value of $339,093 of the extinguished Series A Convertible Preferred Stock conversion option derivative liability was estimated 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 their respective life, using the following assumptions.

Series A Convertible Preferred Stock Conversion Option Derivative Liability Fair Value Assumptions	November 17, 2017 Exchange Date
Aggregate fair value	$ 339,093
Series A Convertible Preferred Stock shares	154,837
Value of common stock	$ 4.33
Common stock exchange factor numerator	$ 6.00
Common stock exchange factor denominator	$ 4.97
Expected term (years)	6.45
Volatility	53%
Risk-free interest rate	2.2%
Dividend yield	0%

Note 11 — Financial Instruments Fair Value Measurements (continued)

Series A Exchange Offer - November 17, 2017 Exchange Date (continued)

Series A Exchange Offer - Series A Convertible Preferred Stock Exchanged for Series A-1 Convertible Preferred Stock (continued)

The Series A Convertible Preferred Stock is classified in temporary equity in the consolidated balance sheet and 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 derivative liability being in excess of the Preferred Stock Units private placement issuance gross proceeds, with such excess recognized as a current period loss in the consolidated statement of operations. 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 and the Series A Convertible Preferred Stock.

Series A Exchange Offer - Series A Warrants Exchanged for Series A-1 Warrants

The 154,837 Series A Warrants derivative liability fair value was adjusted to the November 17, 2017 Exchange Date fair value of the consideration given in the form the 154,837 Series A-1 Warrants issued, with the resulting change in fair value recognized as other income or expense in the consolidated statement of operations, immediately followed by the derecognition of the 154,837 Series A Warrants derivative liability and the recognition of additional paid-in capital of such amount in the consolidated balance sheet, as the Series A-1 Warrants are equity classified. The November 17, 2017 Exchange Date fair value of the Series A-1 Warrants of $1,347,082 was estimated using a Black-Scholes valuation model assuming the exchange of one Series A-1 Warrant for five Series W Warrants, using the following assumptions:

Series A-1 Warrants Fair Value Assumptions		November 17, 2017 Exchange Date
Aggregate fair value	$	1,347,082
Exercise price per share - Series W Warrant	$	5.00
Value of common stock	$	4.33
Expected term (years)		4.2
Volatility		57%
Risk free rate		2.0%
Dividend yield		0%

Non-recurring Fair Value Measurements

In addition to the Series A Exchange Offer discussed above, the other issue-date and /or date -of-occurrence non-recurring estimated fair values include: 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; the Series A-1 Convertible Preferred Stock and Series A-1 Warrants issued in the Series A-1 Preferred Stock Units private placement; and, the Series A-1 Warrants modification resulting from the Series A-1 Amendment No. 1 - with each utilizing the Company's common stock price along with certain Level 3 inputs, as discussed below, in the development of discounted cash flow analyses and /or Black-Scholes valuation models. Further information regarding these non-recurring estimated fair values are discussed in both: 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*.

The estimated fair values presented herein are subjective and are affected by changes in inputs to the valuation models, including the Company's common stock price, the Company's dividend yield, the risk-free rates based on U.S. Treasury security yields, and certain other Level-3 inputs including, assumptions regarding the estimated volatility in the value of the Company's common stock price and probabilities associated with the likelihood and timing of future dilutive transactions. Changes in these assumptions can materially affect the estimated fair values.

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, the Company issued to Scopia and its designees, a Senior Secured Note with an initial principal amount of $5.0 million ("Senior Secured Note"), and 2,660,000 Series S Warrants to purchase a corresponding number of shares of common stock of the Company. The aggregate remaining unpaid principal balance of the Senior Secured Note is due on June 30, 2019.

The Senior Secured Note and the Series S Warrants are freestanding financial instruments, as the Series S Warrants were immediately legally detachable from the Senior Secured Note and were immediately exercisable. The Series-S Warrants are classified as equity in the 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 Senior Secured Note and the Series S Warrants based on their respective relative fair value, as discussed below, resulting in an allocation of $1,408,125 to the Senior Secured Note and $3,434,452 to the Series S Warrants, with the resulting difference of $3,591,875 between the Senior Secured Note initial principal amount and the allocated amount accounted for as debt discount, amortized as interest expense over the term of the Senior Secured Note.

The Senior Secured 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 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 unpaid semi-annual interest payment added to the outstanding interest-bearing principal balance of the Senior Secured Note.

During the year ended December 31, 2017, interest expense recognized totaled $724,684, including $377,083 with respect to the semi-annual 15.0% interest payment, with 50% of such amount or $188,542 added to the outstanding interest-bearing principal balance of the Senior Secured Note, and $347,601 with respect to the amortization of debt discount.

As of December 31, 2017, the Senior Secured Note principal balance is $5,188,542, including $188,542 of unpaid interest added to the interest-bearing principal balance, as discussed above. The Senior Secured Note remaining unamortized debt discount is $3,244,274 at December 31, 2017.

At the discretion of the Company, the aggregate principal balance of the Senior Secured Note and any earned and unpaid interest may be repaid at any time without penalty or premium. Additionally, under the Senior Secured Note, if at the Company's discretion, it sells its implantable intraosseous vascular access device (the "PortIO™ Product"), then the Senior Secured Note holders' may require the Company to repay the then outstanding aggregate principal amount of the Senior Secured 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 Senior Secured Note remains outstanding. Additionally, 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 Senior Secured Note holders may request the Company to repay the then aggregate remaining unpaid principal balance of the Senior Secured Note. Notwithstanding, as the FDA has indicated the PortIO™ Product will be reviewed for approval and clearance under a regulatory pathway other than a 510(k) clearance, such Note and Securities Purchase Agreement provision is not operative;

- 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 such earned but unpaid salary to occur on the earlier 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 Senior Secured Note is repaid-in-full. Subsequently, Scopia irrevocable waived compliance with this provision by the Company and the CEO on a prospective basis commencing February 1, 2018. Notwithstanding, the unpaid CEO salary for the period July 1, 2017 to January 31, 2018, may only be paid upon the Senior Secured Note first being repaid-in-full.

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 Senior Secured 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 Senior Secured Note are guaranteed by the Company, and the obligations under the Senior Secured 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 Senior Secured 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 Senior Secured Note.

As of December 31, 2017, Senior Secured Note had an estimated fair value of $4.6 million. The Senior Secured 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 Senior Secured 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%

As required by the Note and Security Purchase Agreement, the Company filed a registration statement on Form S-3 (File No. 333-221406), declared effective January 8, 2018, ("the January 2018 Form S-3"), to register the issuance of a total of 2,810,654 shares of common stock of the Company, including 1,473,640 shares issuable, and 1,186,080 shares previously issued, upon the exercise of Series S Warrants; and, the registration of (i) the issuance of 150,934 shares of the Company's common stock upon the exercise of 150,934 certain Series W Warrants issued prior to the Company's IPO, but only in the event such certain Series W Warrants are publicly transferred pursuant to Rule 144 prior to their exercise, or (ii) the resale of such 150,934 shares of common stock, but only in the event such certain Series W Warrants are exercised prior to being publicly transferred pursuant to Rule 144.

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.

As of December 31, 2017, 249,667 shares of Series A Convertible Preferred Stock (classified in temporary equity), and 357,259 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 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 November 17, 2017 ("November 17, 2017 Exchange Date"), the Company completed an exchange offer initiated on October 20, 2017 to the 28 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, one Series A Warrant for one Series A-1 Warrant ("Series A Exchange Offer") - resulting in 154,837 shares of Series A Convertible Preferred Stock exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock, and 154,837 Series A Warrants exchanged for 154,837 Series A-1 Warrants, by 13 holders on the November 17, 2017 Exchange Date. See Note 11, *Financial Instruments Fair Value Measurements*, for further detail regarding the Series A Exchange Offer.

As of December 31, 2017, 249,667 shares of Series A Convertible Preferred Stock and 268,001 Series A Warrants were each issued and outstanding, summarized as follows:

	Series A Convertible Preferred Stock	Series A Warrants
Issued and outstanding as of December 31, 2016	—	—
Issued in Series A Preferred Stock Units private placement	422,838	422,838
Series A Exchange Offer	(154,837)	(154,837)
Conversion of Series A Convertible Preferred Stock	(18,334)	—
Issued and outstanding as of December 31, 2017	249,667	268,001

As the Series A Convertible Preferred Stock and the Series A Warrants were first issued in the Series A Preferred Stock Units private placement during the three months ended March 31, 2017, there were no comparable amounts for the prior year ended December 31, 2016.

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 common stock exchange factor, 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.

Series A Preferred Stock Units Private Placement (continued)

The Series A Warrant and the Series A Convertible Preferred Stock conversion option 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 a loss of $3,124,285, resulting from the aggregate initial fair value of each of the Series A Warrant and the Series A Convertible Preferred Stock conversion option derivative liability, being in excess of the gross proceeds of the Series A Preferred Stock Units private placement, 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 derivative liability initial fair value	(4,050,706)
Less: Series A Convertible Preferred Stock conversion option derivative liability initial fair value	(1,221,963)
Excess of initial fair value of derivative liabilities 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)

See Note 11, Financial Instruments Fair Value Measurements, for information with respect to the initial issue date estimated fair value of each of the Series A Warrants derivative liability and the Series A Convertible Preferred Stock conversion option derivative liability.

The Company filed an effective registration statement on Form S-1 (File No. 333-216963), declared effective June 23, 2017, ("the Series A Registration Statement") 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. The Series A 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 the Series A 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

As discussed above, a total of 422,838 shares of Series A Convertible Preferred Stock were issued in the Series A Preferred Stock private placement. Subsequently, at the election of their respective holders, in November 2017, 8,334 shares of Series A Convertible Preferred Stock were converted into 10,021 shares of common stock of the Company, and in December 2017, 10,000 shares of Series A Convertible Preferred Stock were converted into 12,072 shares of common stock of the Company. Further, as noted above, on the Series A Exchange Offer November 17, 2017 Exchange Date, a total of 154,837 shares of Series A Convertible Preferred Stock were exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock. Accordingly, as of December 31, 2017, there were 249,667 shares of Series A Convertible Preferred Stock issued and outstanding. See Note 11, *Financial Instruments Fair Value Measurements*, for further detail regarding the shares of Series A Convertible Preferred Stock converted into shares of common stock of the Company and the Series A Exchange Offer.

The Series A Convertible Preferred Stock is classified in temporary equity in the consolidated balance sheet, 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). 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 derivative liability being in excess of the Preferred Stock Units private placement issuance gross proceeds, with such excess recognized as a current period loss in the consolidated statement of operations, as discussed above.

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

Preferred Stock (continued)

Series A Convertible Preferred Stock (continued)

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 common stock conversion exchange factor equal to a numerator of $6.00 and a denominator currently set at $4.97, with such denominator subject to further adjustment by a prescribed formula should any subsequent issuances by the Company of common stock, or securities convertible into common stock, be at a price lower than such denominator immediately prior to such new issuance. Previously, at issuance, the Series A Convertible Preferred Stock common stock conversion exchange factor denominator was initially $6.00, and was subsequently adjusted to $5.00 upon the issuance of the Series S Warrants on July 3, 2017, then to $4.99 upon the issuance of the Series A-1 Preferred Stock Units on August 4, 2017, and then to $4.97 upon the issuance of Series A-1 Convertible Preferred Stock and Series A-1 Warrants on the November 17, 2017 Exchange Date of the Series A Exchange Offer. As noted, the Series A Convertible Preferred Stock common stock conversion exchange factor denominator is subject to further adjustment, including at the conclusion of the overallotment period with respect to the January 2018 underwritten public offering of shares of common stock of the Company, as discussed herein below.

The Series A Convertible Preferred Stock conversion option is accounted for as a bifurcated derivative liability under FASB ASC 815, as along with other provisions, the Series A Convertible Preferred Stock common stock exchange factor denominator, as discussed above, is subject to potential adjustment resulting from future financing transactions, under certain conditions. The Series A Convertible Preferred Stock conversion option derivative liability is classified as a current liability on the 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 statement of operations. Upon the occurrence of an event resulting in the Series A Convertible Preferred Stock conversion option derivative liability to be subsequently derecognized, its fair value will first be adjusted on such date, with the fair value adjustment recognized as other income or expense, and then such derivative liability will be derecognized. See Note 11, *Financial Instruments Fair Value Measurements*, for further detail regarding the fair value of the Series A Convertible Preferred Stock conversion option derivative liability.

The Series A Convertible Preferred Stock provides for dividends at a rate of 8% per annum on the stated value of the Series A Convertible Preferred Stock, with such dividends 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 December 31, 2017, Series A Convertible Preferred Stock dividends totaling $119,669 or a payment-in-kind of 19,973 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, therefore, such dividends are not being recognized as a dividend payable liability in the consolidated balance sheet until declared by the Company's board of directors. Notwithstanding, the Company has presented such dividends in the calculation of basic and diluted net loss attributable to common stockholders.

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.

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

Preferred Stock (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 date ("Series A-1 Close Date") 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.

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.

At the election of their respective holder, a share of Series A-1 Convertible Preferred Stock is convertible into one share of common stock of the Company at a prescribed common stock exchange factor, and, a Series A-1 Warrant is exercisable for one share of common stock of the Company, or may be exchanged for four Series X-1 Warrants or five Series W Warrants, with each such warrant exercisable for one share of common stock of the Company - each as more fully described herein below.

On October 18, 2017, the Series A-1 Convertible Preferred Stock holders unanimously approved Amendment No. 1 to Series A-1 Preferred Stock Units private placement transaction documents ("Series A-1 Amendment No. 1), wherein: a Series A-1 Warrant may be exchanged for four Series X-1 Warrants, or additionally, exchanged for five Series W Warrants. See herein below for a discussion of the expense recognized resulting from the Series A-1 Amendment No. 1 modification to provide for the additional exchange of one Series A-1 Warrant for five Series W Warrants. The Series X-1 Warrants replaced the previous election to exchange one Series A-1 Warrant for four 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 Securities Purchase Agreement of the Series A-1 Preferred Stock Units private placement. See herein below for a discussion of the Series X-1 Warrants or Series W Warrants issued upon exchange of a Series A-1 Warrant.

Additionally, the Series A-1 Amendment No. 1 removed the requirement for the Company to file an initial registration statement within sixty days of the Series A-1 Close Date. Further, on December 29, 2017, the Series A-1 Convertible Preferred Stock holders unanimously approved Amendment No.2 to Series A-1 Preferred Stock Units private placement transaction documents ("Series A-1 Amendment No. 2), wherein, the due date for an effective registration statement was changed to 210 days from 150 days of the Series A-1 Close Date - see below for further information with respect to the "Series A-1 Registration Statement" on Form S-1 (File 333-222234), declared effective on January 8, 2018.

On November 17, 2017 ("November 17, 2017 Exchange Date"), the Company completed an exchange offer initiated on October 20, 2017 to the 28 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, one Series A Warrant for one Series A-1 Warrant ("Series A Exchange Offer") - resulting in 154,837 shares of Series A Convertible Preferred Stock exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock, and 154,837 Series A Warrants exchanged for 154,837 Series A-1 Warrants, by 13 holders on the November 17, 2017 Exchange Date. See Note 11, *Financial Instruments Fair Value Measurements*, for further detail regarding the Series A Exchange Offer.

As of December 31, 2017, 357,259 shares of Series A-1 Convertible Preferred Stock and 279,837 Series A Warrants were each issued and outstanding, summarized as follows:

	Series A-1 Convertible Preferred Stock	Series A-1 Warrants
Issued in Series A Preferred Stock Units private placement	125,000	125,000
Series A Exchange Offer	232,259	154,837
Converted to shares of common stock	—	—
Issued and outstanding as of December 31, 2017	357,259	279,837

As the Series A-1 Convertible Preferred Stock and the Series A-1 Warrants were first issued on the Series A-1 Close Date, there were no comparable amounts for the prior year ended December 31, 2016.

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

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 estimated using a combination of the Series A-1 Convertible Preferred Stock's present value of its cash flows using 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 estimated 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
Allocated fair value	$ 189,550
Shares of Series A-1 Convertible Preferred Stock	125,000
Required rate of return	27.0%
Common stock conversion factor numerator	$ 4.00
Common stock conversion factor 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 Warrants	Issue Date
Allocated fair value	$ 310,450
Exercise price per share - Series X Warrants	$ 6.00
Value of common stock	$ 2.98
Expected term (years)	6.74
Volatility	52%
Risk free rate	2.0%
Dividend yield	0%

The Company filed a registration statement on Form S-1 (File No. 333-222234), declared effective January 8, 2018, ("the Series A-1 Registration Statement") registering for resale the maximum number of the Company's shares of common stock issuable upon conversion of the Series A-1 Convertible Preferred Shares and the exercise of the Series A-1 Warrants, or if exchanged, the Series X-1 Warrants or Series W Warrants (as discussed below). Such registration statement also registers the resale of the Series X-1 Warrants or Series W Warrants, and the initial issuance of the shares of common stock of the Company underlying the Series X-1 Warrants or Series W Warrants to the extent the Series X-1 Warrants or Series W Warrants are publicly sold prior to the exercise of such Series X Warrants. The Series A-1 Registration Statement January 8, 2018 effectiveness date was consistent with the requirements of the registration rights agreement, as amended, entered into in connection with the Series A-1 Preferred Stock Units private placement. If the Series A-1 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.

Series A-1 Convertible Preferred Stock

As discussed above, a total of 125,000 shares of Series A-1 Convertible Preferred Stock were issued in the Series A-1 Preferred Stock private placement, and a total of 154,837 shares of Series A Convertible Preferred Stock were exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock as a result of the Series A Exchange Offer. Accordingly, as of December 31, 2017, there were 357,259 shares of Series A-1 Convertible Preferred Stock issued and outstanding. See Note 11, *Financial Instruments Fair Value Measurements*, for further detail regarding the Series A Exchange Offer.

The Series A-1 Convertible Preferred Stock is classified in permanent equity in the consolidated balance sheet, has a par value of $0.001 per share, no voting rights, a stated value of $4.00 per share, and was immediately convertible upon its issuance.

At the holders' election, a share of Series A Convertible Preferred Stock is convertible into one share of common stock of the Company at a common stock conversion exchange factor equal to a numerator of $4.00 and a denominator of $4.00, with such denominator 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.

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

Preferred Stock (continued)

Series A-1 Convertible Preferred Stock (continued)

As discussed above, the Series A-1 Preferred Stock Units private placement cash proceeds allocated to the Series A-1 Convertible Preferred Stock 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, with such deemed dividend included as a component of net loss attributable to attributable to common stockholders.

The Series A-1 Convertible Preferred Stock provides for dividends at a rate of 8% per annum on the stated value of the Series A-1 Convertible Preferred Stock, with such dividends 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 December 31, 2017, Series A-1 Convertible Preferred Stock dividends totaling $79,788 or a payment-in-kind of 19,962 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, therefore, such dividends are not being recognized as a dividend payable liability in the consolidated balance sheet until declared by the Company's board of directors. Notwithstanding, the Company has presented such dividends in the calculation of basic and diluted net loss attributable to common stockholders.

Series A and Series A-1 Exchange Offer - Series B Convertible Preferred Stock and Series Z Warrants

Subsequently, on February 14, 2018 the Company initiated an exchange offer to the holders of both the Series A Convertible Preferred Stock and Series A Warrants, and the Series A-1 Convertible Preferred Stock and Series A-1 Warrants ("Series A and Series A-1 Exchange Offer"), as follows: one (1) share of Series A Convertible Preferred Stock exchanged for two (2) shares of Series B Convertible Preferred Stock, and one (1) Series A Warrant exchanged for five (5) Series Z Warrants; and one (1) share of Series A-1 Convertible Preferred Stock exchanged for 1.33 shares of Series B Convertible Preferred Stock, and one (1) Series A-1 Warrant exchanged for five (5) one Series Z Warrants. A condition of the Series A and Series A-1 Exchange Offer is for all outstanding shares of Series A Convertible Preferred Stock and all Series A Warrants, and all shares of Series A-1 Convertible Preferred Stock and all Series A-1 Warrants, must be tendered, else, if not all are tendered, then the Company reserves the right to not accept any tenders, if any. The Series A and Series A-1 Exchange Offer is scheduled to expire on March 15, 2018, unless extended by the Company, at its sole discretion.

The Series B Convertible Preferred Stock has a par value of $0.001 per share, no voting rights, a stated value of $3.00 per share, and is immediately convertible upon its issuance. At the holders' election, a share of Series B Convertible Preferred Stock is convertible into a number of shares of common stock of the Company at a common stock conversion exchange factor equal to a numerator of $3.00 and a denominator of $3.00, with such denominator 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 B Convertible Preferred Stock shall not be redeemed for cash and under no circumstances shall the Company be required to net cash settle the Series B Convertible Preferred Stock.

The Series B Convertible Preferred Stock provides for dividends at a rate of 8% per annum on the stated value of the Series B Convertible Preferred Stock, with such dividends compounded quarterly, accumulate, and are payable in arrears upon being declared by the Company's Board of Directors. The Series B Convertible Preferred Stock dividends from April 1, 2018 through October 1, 2021 are payable-in-kind ("PIK") in additional shares of Series B 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 B Convertible Preferred Stock, shares of common stock, and /or cash payment.

The Series Z Warrants issued in the Series A and Series A-1 Exchange Offer will be immediately exercisable upon issuance and expire after the close of business on April 30, 2024, and each may be exercised for one share of common stock of the Company at an exercise price of $3.00 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. The Series Z Warrants are redeemable by the Company under certain conditions. See herein below for further information with respect to the Series Z Warrant.

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

Common Stock

The Company is authorized to issue 50,000,000 shares of common stock with a par value of $0.001 per share.

As of December 31, 2017 and 2016, there were 14,551,234 and 13,330,811 shares of common stock and 10,567,845 and 10,580,095 Series W Warrants issued and outstanding, respectively, each as discussed herein below and summarized as follows:

	Common Stock	Series-W Warrants
Issued and outstanding December 31, 2015	12,250,000	9,560,295
Issued in the initial public offering	1,060,000	1,060,000
Exercise of Series W Warrants	20,811	(40,200)
Issued and outstanding as of December 31, 2016	13,330,811	10,580,095
Exercises of Series W Warrants	12,250	(12,250)
Exercises of Series S Warrants	1,186,080	—
Conversion of Series A Convertible Preferred Stock	22,093	—
Issued and outstanding as of December 31, 2017	14,551,234	10,567,845

- In June 2014, in connection with the organization of the Company, 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 ("Pre-IPO Private Placement 1"), a total of 418,089 units, consisting of one share of common stock and one warrant to purchase a share of common stock of the Company, were sold to the initial investors ("Initial Investors") for an aggregate purchase price of $75,000 less offering costs of $7,500.

- In November 2014, the Company completed an additional private placement (Pre-IPO Private Placement 2) of 2,355,233 units, consisting of one share of common stock and one warrant to purchase one share of common stock of the Company, raising $845,000 in gross offering proceeds less offering costs of $46,500. Taken together, the two pre-IPO private placements are referred to collectively as the "Pre-IPO Private Placements".

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

- In September 2015, 1,393,629 Pre-IPO Private Placements warrants were exercised for cash proceeds of $1.25 million, resulting in the issuance of a corresponding number shares of common stock of the Company.

- 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, 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 9,560,295 remaining unexercised warrants previously issued in the Pre-IPO Private Placements were converted into identical Series W Warrants issued in the Company's 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.

- 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.

- 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.

- In March 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.

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

Common Stock (continued)

- 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; in November 2017, 122,080 shares of common stock were issued, resulting from the cashless exercise of 122,360 Series S Warrants; and, in November 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.

- In November and December 2017, 10,021 and 12,072 shares of common stock were issued upon the conversion of 8,334 and 10,000 shares of Series A Convertible Preferred Stock, respectively.

- Subsequently, on January 17, 2018, the Company filed an initial registration statement on Form S-1 (File No. 333-222581), currently under SEC review, related to a proposed offering wherein, as currently proposed, the Company will distribute one transferable equity subscription right for each issued and outstanding share of common stock of the Company as of a record date to be determined by the Company's Board of Directors ("Equity Subscription Rights Offering" or "Rights Offering"). As currently proposed, the Equity Subscription Rights Offering is to commence upon an effective registration statement. Further, as currently proposed, for a period of 30 days from their distribution date, the transferable equity subscription right may be exercised for $2.25 per unit to purchase a common stock unit comprised of one share of common stock of the Company and one Series Z Warrant. As currently proposed, the common stock unit will trade for up to 90 days, after which it will separate into its underlying components of one share of common stock of the Company and one Series Z Warrant. The Series Z Warrant may be exercised for one share of common stock of the Company at an exercise price of $3.00 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 will expire after the close of business on April 30, 2024. The Series Z Warrants are redeemable by the Company under certain conditions. See herein below for a further discussion of the Series Z Warrant.

- Subsequently, in January 2018, the Company conducted an underwritten public offering of shares of common stock of the Company pursuant to its previously filed and effective shelf registration statement on SEC Form S-3 (File No. 333-220549), declared effective October 6, 2017, along with a corresponding prospectus supplement dated January 19, 2018. On January 19, 2018, the Company entered into an underwriting agreement with Dawson James Securities, Inc., as sole underwriter, under which the company agreed to issue to the underwriter at $1.80 per share, 2,415,278 shares of common stock on a firm commitment basis and up to an additional 362,292 shares solely to cover underwriter over-allotments, if any, at the option of the underwriter, exercisable within 45 calendar days from January 19, 2018. The Company issued the 2,415,278 shares on January 23, 2018, and on January 25, 2018, issued 234,540 shares of common stock, under the underwriter's over-allotment, resulting in net cash proceeds of $4,263,099, after deductions of underwriting discounts of $381,574 and estimated offering costs.

- Subsequently, on February 8, 2018, the Company issued at total 34,345 shares of common stock from the exercise of a corresponding number of Series W Warrants, resulting in $68,690 of cash proceeds. See herein below for a discussion of the "Series W Warrants Offer-to-Exercise".

- Subsequently, on March 5, 2018, the Company received a notice from the Nasdaq Listing Qualifications Department stating, for the prior 30 consecutive business days through March 2, 2018, the market value of the Company's listed securities ("MVLS") had been below the minimum of $35 million required for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). The notification letter stated the Company would be afforded 180 calendar days, or until September 4, 2018, to regain compliance. In order to regain compliance, the MVLS must remain at or above $35 million for a minimum of ten consecutive business days. The notification letter also states in the event the Company does not regain compliance within the 180 day period, its securities may be subject to delisting. In the event of a delisting determination, the Company may appeal such determination to a Nasdaq Hearings Panel.

Unit Purchase Options

On April 28, 2016, the Company issued 53,000 unit purchase options ("UPO") to the selling agents in the Company's IPO. The holder of the UPO may purchase a unit identical to the unit issued in the Company's IPO, as discussed above, at an exercise price of $5.50 per unit. The UPO was recognized as an offering cost of the Company's IPO, with an estimated the fair value of $105,100, 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 13 — Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants (continued)

Warrants

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

	Warrants Issued and Outstanding at				
	December 31, 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
UPO - Series W Warrants	53,000	$ 5.00	53,000	$ 5.00	January 2022
Series S Warrants	1,473,640	$ 0.01	---	$ ---	June 2032
Series A-1 Warrants	279,837	$ 6.67	---	$ ---	April 2024
Liability classified warrants					
Series A Warrants	268,001	$ 6.61	---	$ ---	April 2024
Total	12,642,323	$ 4.49	10,580,095	$ 5.00	

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 IPO date were automatically converted into identical Series W Warrants issued in the 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 December 31, 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 of the Company. 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 of the Company, respectively.

Subsequently, on January 11, 2018, the Company filed with the SEC a Tender Offer Statement on Schedule TO offering Series W Warrants holders a temporary exercise price of $2.00 per share ("Series W Warrants Offer-to-Exercise"). As of the February 8, 2018 expiry of the Series W Warrants Offer-to-Exercise, a total of 34,345 Series W Warrants were exercised at the temporary exercise of $2.00 per share, resulting in $68,690 of cash proceeds, and the issue of a corresponding number of shares of common stock of the Company.

Subsequently, on February 20, 2018, the Company filed with the SEC a Tender Offer Statement on Schedule TO offering to exchange two (2) Series W Warrants for one (1) Series Z Warrant, with such exchange offer having a March 19, 2018 expiration date ("Series W Warrants Offer-to-Exchange"). The Series Z Warrants issued upon exchange of the Series W Warrants will be immediately exercisable upon issuance and expire after the close of business on April 30, 2024, and each may be exercised for one share of common stock of the Company at an exercise price of $3.00 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. The Series Z Warrants are redeemable by the Company under certain conditions. See herein below for a further discussion of the Series Z Warrant.

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.

The Company filed a registration statement on Form S-3 (File No. 333-221406), declared effective January 8, 2018, ("the January 2018 Form S-3"), to register the issuance of a total of 2,810,654 shares of common stock of the Company, including 1,473,640 shares issuable, and 1,186,080 shares previously issued, upon the exercise of Series S Warrants; and, the registration of (i) the issuance of 150,934 shares of the Company's common stock upon the exercise of 150,934 certain Series W Warrants issued prior to the Company's IPO, but only in the event such Series W Warrants are publicly transferred pursuant to Rule 144 prior to their exercise, or (ii) the resale of such 150,934 shares of common stock, but only in the event such Series W Warrants are exercised prior to being publicly transferred pursuant to Rule 144.

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 ("Senior Secured Note"), and 2,660,000 Series S Warrants. The Series S Warrants were immediately exercisable upon issuance and expire after the close of business on June 30, 2032, and each may be exercised for one share of common stock of the Company at an exercise price of $0.01 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 may be exercised for cash or on a cashless basis, with any Series S Warrants outstanding on the expiration date will be automatically exercised on a cashless basis.

In each of October 2017 and November 2017, 532,000 (or a total of 1,064,000) Series S Warrants were exercised for total cash proceeds of $10,640, resulting in the issuance of a corresponding number of shares of common stock of the Company, and in November 2017, a total of 122,360 Series S Warrants were exercised on a cashless basis, resulting in the issuance of a total of 122,080 shares of common stock of the Company. Accordingly, at December 31, 2017, there were 1,473,640 Series S Warrants issued and outstanding.

The Senior Secured Note and the Series S Warrants are freestanding financial instruments, as the Series S Warrants were immediately legally detachable from the Senior Secured Note and were immediately exercisable. The Series-S Warrants are classified as equity in the consolidated balance sheet. The Senior Secured Note net cash proceeds were allocated to the Senior Secured Note and the Series S Warrants based on their respective relative fair value, resulting in an allocation of $1,408,125 to the Senior Secured 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 Senior Secured Note and Series S Warrants.

The Company filed a registration statement on Form S-3 (File No. 333-221406), declared effective January 8, 2018, ("the January 2018 Form S-3"), to register the issuance of a total of 2,810,654 shares of common stock of the Company, including 1,473,640 shares issuable, and 1,186,080 shares previously issued, upon the exercise of Series S Warrants; and, the registration of (i) the issuance of 150,934 shares of the Company's common stock upon the exercise of 150,934 certain Series W Warrants issued prior to the Company's IPO, but only in the event such certain Series W Warrants are publicly transferred pursuant to Rule 144 prior to their exercise, or (ii) the resale of such 150,934 shares of common stock, but only in the event such certain Series W Warrants are exercised prior to being publicly transferred pursuant to Rule 144.

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

Warrants (continued)

Series A-1 Warrants

As discussed above, a total of 125,000 Series A-1 Warrants were issued in the Series A-1 Preferred Stock private placement and a total of 154,837 Series A Warrants were exchanged for 154,837 Series A-1 Warrants resulting from the Series A Exchange Offer. Accordingly, as of December 31, 2017, there were 279,837 Series A-1 Warrants issued and outstanding. See Note 11, *Financial Instruments Fair Value Measurements*, for further detail regarding the Series A Exchange Offer.

The Series A-1 Warrants were immediately exercisable upon issuance and expire after the close of business on April 30, 2024, and each may be exercised for one share of common stock of the Company 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, through April 30, 2024, each Series A-1 Warrant, at the option of the holder, may be exchanged into either five Series W Warrants of 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 December 31, 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.

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.

As noted above, the Series A-1 Amendment No.1 provided for a Series A-1 Warrant to be exchanged for four Series X-1 Warrants, or additionally, exchanged for five Series W Warrants. The Series X-1 Warrants replaced the previous election to exchange one Series A-1 Warrant for four Series X Warrants. Notwithstanding, 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 A-1 Amendment No.1 modification to the Series A-1 Warrants' exchange elections was accounted for under the analogous guidance of FASB ASC 718, wherein, the incremental fair value is measured as the difference between the fair value immediately after the modification as compared to the fair value immediately before the modification, with such incremental fair value, to the extent an increase, recognized as a modification expense. On the October 18, 2017 date of the Series A-1 Amendment No.1, the Company recognized a current period expense related to the Series A-1 Warrants' modification of $222,000, with such expense included in other income (expense) on the consolidated statement of operations, with a corresponding increase in additional paid-in capital in the consolidated balance sheet, as the Series A-1 Warrants are equity classified. Such incremental fair value was estimated using a Black-Scholes valuation model, assuming the exchange of one Series A-1 Warrant for five Series W Warrants after the Series A-1 Warrant modification, as compared to an exchange of one Series A-1 Warrant for four Series X Warrants before such modification, using the following assumptions:

	Series A-1 Amendment No. 1 Series A-1 Warrants Modification Fair Value - October 18, 2017	
	Immediately After Modification	Immediately Before Modification
Aggregate fair value	$ 1,531,000	$ 1,309,000
Exercise price per share - Series W Warrant	$ 5.00	$ —
Exercise price per share - Series X Warrant	$ —	$ 6.00
Value of common stock per share	$ 5.40	$ 5.40
Expected term - years	4.3	6.5
Volatility	55%	52%
Risk free interest rate	1.9%	2.1%
Dividend yield	0%	0%

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

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 December 31, 2017 no Series A-1 Warrants had been exchanged for Series W Warrants nor 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, as discussed herein 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 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 expire on April 30, 2024, 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 Z Warrants

A Series Z Warrant may be exercised for one share of common stock of the Company at an exercise price of $3.00 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 will expire after the close of business on April 30, 2024.

Commencing on May 1, 2019, the Company may redeem the outstanding Series Z Warrants, at the Company's option, in whole or in part, at a price of $0.01 per Series Z Warrant at any time while the Series Z Warrants are exercisable, upon a minimum of 30 days' prior written notice of redemption, if, and only if, the volume weighted average closing price of the Common Stock equals or exceeds $9.00 (subject to adjustment) for any 20 out of 30 consecutive trading days ending three business days before the Company issues its notice of redemption, and provided the average daily trading volume in the Common Stock during such 30-day period 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 Series Z Warrants.

The Series Z Warrants issued upon exchange of the Series W Warrants under the Series W Warrants Offer-to-Exchange, as discussed herein above, and the Series Z Warrants issued in the Series A and Series A-1 Exchange Offer, as discussed herein above, will be immediately exercisable upon issuance. The Series Z Warrants included as a component of the common stock unit issued in the Equity Subscription Rights Offering, as discussed herein above, will be exercisable when such common stock units separate into their underlying components of one share of common stock of the Company and one Series Z Warrant, which, as currently proposed, is expected to be up to 90 days from the date of issuance of such common stock unit.

There were no Series Z Warrants issued and outstanding as of December 31, 2017 or 2016. Subsequent to December 31, 2017, in February 2018, upon their resignation, the Company issued 100,000 Series Z Warrants each to two former members of the Company's board of directors, with such Series Z Warrants immediately exercisable and having the terms and conditions as described herein above.

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

Warrants (continued)

Series A Warrants

As discussed above, a total of 422,838 Series A Warrants were issued in the Series A Preferred Stock private placement and a total of 154,837 Series A Warrants were exchanged for 154,837 Series A-1 Warrants resulting from the Series A Exchange Offer. Accordingly, as of December 31, 2017, there were 268,001 Series A Warrants issued and outstanding. See Note 11, *Financial Instruments Fair Value Measurements*, for further detail regarding the Series A Exchange Offer.

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 currently set at $6.61 per share. Previously, upon issuance, the Series A Warrant exercise was initially $8.00 per share, and then 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, and then to $6.61 per share upon the issuance of Series A-1 Convertible Preferred Stock and Series A-1 Warrants on the November 17, 2017 Exchange Date of the Series A Exchange Offer. 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. 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 below.

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 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 consolidated statement of operations. Upon the occurrence of an event resulting in the Series A Warrant derivative liability to be subsequently derecognized, its fair value will first be adjusted on such date, with the fair value adjustment recognized as other income or expense, and then such derivative liability will be derecognized. See Note 11, *Financial Instruments Fair Value Measurements*, for further detail regarding the fair value of the Series A Warrants derivative liability.

Series X Warrants Issued Upon Exchange of Series A Warrants

A Series A Warrant, as discussed above, at the election of the holder, may be exchanged for four Series X Warrants. As of December 31, 2017, no Series A Warrants had been exchanged for 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. 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.

Note 14 —Loss Per Share

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

	Year Ended December 31,	
	2017	2016
Numerator		
Net loss - as reported	$ (9,519,269)	$ (5,650,851)
Undeclared and accumulated dividends:		
Series A Convertible Preferred Stock[1]	(112,570)	—
Series A-1 Convertible Preferred Stock[2]	(79,788)	—
Series A-1 Convertible Preferred Stock deemed dividend[3]	(182,500)	—
Series A Exchange Offer deemed dividend[4]	(504,007)	—
Net loss attributable to common stockholders	$ (10,398,134)	$ (5,650,851)
Denominator		
Weighted-average common shares outstanding basic and diluted[5]	13,495,951	12,972,153
Loss per share[6]		
Basic and diluted		
- Net loss - as reported	$ (0.71)	$ (0.44)
- Net loss attributable to common stockholders	$ (0.77)	$ (0.44)

(1) As discussed herein above, as of December 31, 2017, Series A Convertible Preferred Stock dividends totaling $119,669 or a payment-in-kind of 19,973 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, therefore, such dividends are not be recognized as a dividend payable liability in the consolidated balance sheet until declared by the Company's board of directors. Notwithstanding, the Company has presented such dividends in the calculation of basic and diluted net loss attributable to common stockholders. See Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a further discussion of the Series A Convertible Preferred Stock dividends.

(2) As discussed herein above, as of December 31, 2017, such Series A-1 Convertible Preferred Stock dividends totaling $79,788 or a payment-in-kind of 19,962 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, therefore, such dividends are not be recognized as a dividend payable liability in the consolidated balance sheet until declared by the Company's board of directors. Notwithstanding, the Company has presented such dividends in the calculation of basic and diluted net loss attributable to common stockholders. See Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a further discussion of the Series A-1 Convertible Preferred Stock dividends.

(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) In the Series A Exchange Offer, 154,837 shares of Series A Convertible Preferred Stock were exchanged for 232,259 shares of Series A-1 Convertible Preferred Stock, resulting in an excess of fair value of $504,007, of the 232,259 shares of Series A-1 Convertible Preferred Stock issued as compared to the Series A conversion option derivative liability extinguished, with such excess fair value recognized as a deemed dividend and included as a component of net loss attributable to attributable to common stockholders. See Note 11, *Financial Instruments Fair Value Measurements*, for further detail regarding the Series A Exchange Offer.

(5) Basic weighted-average number of shares of common stock outstanding for the period excludes incremental shares resulting from common stock equivalents, while diluted weighted average number of shares outstanding includes such incremental shares. However, as the Company was in a loss position for all periods presented, basic and diluted weighted average shares outstanding are the same, as the inclusion of common stock equivalent incremental shares would be anti-dilutive.

(6) 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.

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:

	December 31,	
	2017	2016
Stock Options	1,936,924	1,633,313
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[10]	10,567,845	10,580,095
Series A Convertible Preferred Stock[7]	249,667	—
Series A Warrants[8]	268,001	—
Series X Warrants[8]	—	—
Series A-1 Convertible Preferred Stock[9]	357,259	—
Series A-1 Warrants[10]	279,837	—
Series X-1 Warrants[10]	—	—
Series S Warrants	1,473,640	—
Series Z Warrants[11]	—	—
Total	15,239,173	12,319,408

(7) The 249,667 shares of Series A Convertible Preferred Stock, issued and outstanding at December 31, 2017, if converted at the election of the holder, would result in 301,416 additional outstanding shares 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 Convertible Preferred Stock common stock conversion election.

(8) The 268,001 Series A Warrants, issued and outstanding at December 31, 2017, at the election of the holder, may be exchanged for four Series X Warrants under the terms of the Series A Warrant agreement. At December 31, 2017, no Series A Warrants had been exchanged for Series X Warrants. Notwithstanding, 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 would not result in common stock equivalent incremental shares for purposes of diluted weighted average shares outstanding as of December 31, 2017.

(9) The 357,259 shares of Series A-1 Convertible Preferred Stock issued and outstanding at December 31, 2017, if converted at the election of the holder, would result in 357,259 additional outstanding shares of common stock of the Company. See Note 13, *Series A-1 Convertible Preferred Stock, Stockholders' Deficit, and Warrants*, for a further discussion of the Series A-1 Convertible Preferred Stock common stock conversion election.

(10) The 279,837 Series A-1 Warrants, issued and outstanding at December 31, 2017, 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. As of December 31, 2017, no Series A-1 Warrants had been exchanged for either Series W Warrants or Series X1 Warrants. 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 therefore would not result in common stock equivalent incremental shares for purposes of diluted weighted average shares outstanding as of December 31, 2017.

(11) There were no Series Z Warrants issued and outstanding as of December 31, 2017 or 2016. Subsequently, in February 2018, upon their resignation, the Company issued 100,000 Series Z Warrants each to two former members of the Company's board of directors, with such Series Z Warrants immediately exercisable and having the terms and conditions as described in Note 13, *Series A Convertible Preferred Stock, Stockholders' Deficit, and Warrants*.

Note 15 — Subsequent Events

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 14, 2018, with respect to the consolidated financial statements in the Annual Report of PAVmed Inc. on Form 10-K for the year ended December 31, 2017. We consent to the incorporation by reference of said report in Registration Statements of PAVmed Inc. on Form S-1 (File No's: 333-214288, 333-216963, 333-222234 and 333-222581) and on Form S-3 (File No's: 333-220549 and 333-221406). Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ CITRIN COOPERMAN & COMPANY, LLP

New York, New York
March 14, 2018

Exhibit 31.1

CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER

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

1. I have reviewed this annual report on Form 10-K 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: March 14, 2018

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 annual report on Form 10-K 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: March 14, 2018

By: */s/ Dennis M. McGrath*
Dennis M. McGrath, EVP & 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 Annual Report on Form 10-K of PAVmed Inc. (the "Company") for the year ended December 31, 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: March 14, 2018

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 Annual Report on Form 10-Q of PAVmed Inc. (the "Company") for the year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Dennis M. McGrath, EVP & 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: March 14, 2018

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