UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2016

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 **Suite 4600** **New York, NY** **(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
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 ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark 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	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒

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

As of June 30, 2016 (the last business day of the registrant's most recently completed second fiscal quarter), the registrant did not have any common equity trading by itself and only had common equity trading with warrants in the form of units. Based on the last reported sales price of the units, the aggregate market value of the registrant's voting stock held by non-affiliates was approximately $15.1 million on June 30, 2016.

As of February 10, 2017 there were 13,330,811 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2017 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, 2016.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K of PAVmed Inc. (“we”, “us”, “our” 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
- our expectations regarding the time during which we will be an Emerging Growth Company ("ECG") under the Jumpstart Our Business Startups Act of 2012, or JOBS Act.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. 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

We are a highly-differentiated multi-product medical device company organized to conceive, develop and commercialize a diversified pipeline of innovative products we believe address unmet clinical needs and possess attractive market opportunities. Our goal is to enhance and accelerate value creation by employing a business model focused on capital and time efficiency. We intend to continuously explore promising ideas and opportunities that fulfill our project selection criteria without limiting ourselves to any target specialty or condition. Our current pipeline includes the following six lead projects, all of which are the subject of filed patent applications. One of these projects, NextFlo, also has two issued patents and one, DisappEAR is based on a family of patents and patent applications licensed from a group of academic centers. These projects are all in the development phase and have not yet received regulatory approval.

- *PortIO:* A novel long-term implantable intraosseous vascular access device with no indwelling intravascular component.
- *CarpX:* Completely percutaneous device to treat carpal tunnel syndrome.
- *NextCath:* Self-anchoring catheters which do not require suturing, traditional anchoring techniques or costly add-on catheter securement devices.
- *DisappEAR*: Antibiotic-eluting resorbable ear tubes, developed from a proprietary aqueous silk technology.
- *NextFlo:* Highly accurate disposable infusion pumps using stored potential energy and variable flow resistors.
- *Caldus:* Completely disposable tissue ablation devices which can also be used for renal denervation to treat hypertension.

In addition to our six lead projects, we are working on projects which are currently in the conceptual phase. As is the case with our lead projects, these additional projects cover a wide range of clinical conditions and procedures, including sleep apnea, extracorporeal membrane oxygenation (ECMO), laparoscopic hernia repair, cardiac surgery, interventional cardiology and endotracheal intubation.

Our leadership team is comprised of three accomplished medical device entrepreneurs, Dr. Lishan Aklog, Michael J. Glennon and Dr. Brian J. deGuzman. These three individuals founded Pavilion Holdings Group ("PHG"), a medical device holding company, in 2007 and Pavilion Medical Innovations ("PMI"), a venture-backed medical device incubator, in 2009. 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 awaiting initiation of 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.

Recent Events

In November 2016, we 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 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.

On December 17, 2016, we filed a 510(k) premarket notification submission with the FDA for our first product, the PortIO™ Intraosseous Infusion System.

On January 26, 2017, we entered into a Securities Purchase Agreement pursuant to which we may issue and sell to investors up to an aggregate of $3,000,000 (subject to increase) of units (“Preferred Stock Units”) in a private placement transaction (“Preferred Stock Private Placement”) at a price of $6.00 per Preferred Stock Unit. At closings which took place on January 26, 2017 and January 31, 2017, 251,334 Preferred Stock Units were sold for aggregate gross proceeds of approximately $1.5 million and net proceeds of approximately $1.2 million, after placement agent fees and closing costs. Additional closings may occur in the future.

Each Preferred Stock Unit consists of (i) one share of Series A Convertible Preferred Stock (“Series A Preferred Stock”) that is initially convertible into one share of common stock and (ii) one Series A Warrant exercisable for one share of common stock at $8.00 per share. Each Series A Warrant is also exchangeable for four Series X Warrants. The shares of Series A Preferred Stock and Series A Warrants are immediately separable upon their issuance. Further descriptions of the shares of Series A Preferred Stock, Series A Warrants and Series X Warrants are set forth in our Current Report on Form 8-K filed with the SEC on February 1, 2017.

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. 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. We retain the flexibility to fully commercialize our products ourselves or 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. We currently expect to commercialize our products 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 to commercialize some or all of our products if it is in our long-term interests. As our pipeline grows, we may choose to jointly commercialize subsets of related products which target certain medical specialties or healthcare locations.

Our Pipeline

Since our inception, we have conceived and developed a pipeline of projects which fulfill our selection criteria. Our initial five lead projects focused on medical infusion, tissue ablation and hand surgery. Our sixth project, whose underlying technology we recently 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 we anticipate additional submissions in 2017 for other products in our pipeline. Our pipeline is dynamic and we make adjustments to our development and commercialization plans based on real-time progress, changes in market conditions, commercial opportunity and availability of resources.

PortIO — Implantable Intraosseous Vascular Access Device

The Market. Long-term vascular access devices, including 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 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. 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. 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. 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 that the absence of an intravascular component will result in a very low infection rate. We have filed a final nonprovisional patent application and advanced the product from concept to working prototypes, benchtop, animal and cadaver testing, commercial design and development and verification and validation testing. In December 2016, we filed a 510(k) premarket notification submission to the FDA and expect to receive clearance and initiate commercialization later this year. Our initial submission was for short-term use and we plan on submitting additional data for longer term use in the near future. 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 initial target will be patients with poor venous access, but the addressable market includes all patients requiring long-term vascular access.

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 percutaneous 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 percutaneously placed 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 activated it creates space within the tunnel, confirms that the nerve is protected from the cutting element and divides the ligament. As a completely percutaneous technology, 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 the product from concept to working prototypes, successful benchtop and cadaver testing confirming that the device consistently cuts the transverse carpal ligament and commercial design and development. We have begun pre-submission verification and validation testing and anticipate 510(k) FDA submission, clearance and initial commercialization this year. 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.

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, completed initial design work on the interventional radiology drainage catheter and completed head-to-head testing of retention forces, comparing our working prototype to several competing products, which has validated our approach. We have begun design and development of the commercial embodiment. Once this product is commercialized, we believe it will garner premium pricing based on fewer complications and reduced overall costs.

DisappEAR — Antibiotic-eluting 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 antibiotic-eluting 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 antibiotics eluted from the device 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. We have completed our market, regulatory and manufacturability analysis including target cost of goods and average sale price. We have also engaged a design and contract manufacturing firm to initiate the design and development of the device. 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.

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 device, including a redesign which dramatically simplifies the product, lowers the projected cost of goods, and expands its application to routine inpatient infusion sets. 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.

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 take advantage of the fact that all currently available devices, except those utilizing cryoablation, ultimately act by increasing the tissue temperature to cytotoxic levels for a given period of time. Our device uses a proprietary infusion device to continuously deliver heated fluid to a specially designed balloon catheter which heats the target tissue above its cytotoxic threshold according to a specified pattern. We have completed proof-of-concept work, thermal fine element analysis simulations validating our approach and working prototypes of the infusion device and balloon catheter. We have filed two provisional patent applications and have initiated design work on the proprietary infusion system and balloon catheter. We decided to initially target fistula tracts, namely *fistula-in-ano,* as the most promising opportunity for this technology. We believe the balloon catheter will provide circumferential ablation of the tract which is difficult to do with other ablation technologies and will result in a much less invasive, and less painful treatment option than the current surgical approach. We anticipate an FDA 510(k) pathway for traditional tissue ablation targets and a PMA pathway in the United States and European CE mark for renal denervation. Regarding the renal denervation application, we will closely monitor the progress of technologies working their way through U.S. regulatory clearance and tailor our regulatory and commercial strategy accordingly. We anticipate that, in the early phases, our strategy will likely focus on European regulatory clearance and target emerging markets where the clinical opportunity (high incidence of hypertension with less coordinated primary care) and commercial opportunity (difficulties acquiring and maintaining capital equipment) may be greatest. Once this product is commercialized, we believe that our completely disposable system will have significantly lower procedural costs and higher margins than existing technologies. We anticipate applying this technology to other target tissues including endovenous ablation and soft tissue tumors, as resources permit.

Additional Projects

In addition to our six lead projects, we are working on projects which are currently in the conceptual phase. As is the case with our lead projects, these additional projects cover a wide range of clinical conditions and procedures, including extracorporeal membrane oxygenation (ECMO), sleep apnea, laparoscopic hernia repair, cardiac surgery, interventional cardiology and endotracheal intubation. We believe these additional projects meet our selection criteria and will result in products addressing unmet clinical needs in attractive markets. We anticipate filing provisional patent applications on some of these additional projects and initiating proof-of-concept and early prototyping work as resources permit.

Our Implementation Strategy

We intend to advance our lead projects towards commercialization as quickly and efficiently as possible and expand our project 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 projects 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 projects which offer the opportunity for more rapid commercialization, generating revenue to support development of longer-term projects. As each project moves through our pipeline from concept to commercialization, we continuously reassess the project's long-term commercial potential, balance it against other projects 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 project and increase or decrease resources applied to a project based on a variety of factors including available capital, shifts in the regulatory, clinical, market and/or intellectual property landscape for a particular project, the emergence of one or more projects 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 others 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.

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. 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 before marketing can begin.

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.

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.

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."

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.

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.

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. In addition, it 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.

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

We have three employees and four executive officers, two of whom are also members of our Board of Directors. We do not currently have any other employees. No employees are covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Our Corporate History

We were incorporated on June 26, 2014 in the State of Delaware under the name PAXmed Inc. In April 2015, we changed our name to PAVmed Inc. In January 2016, the registration statement on SEC Form S-1 (File No. 333-203569) for our initial public offering was declared effective by the Securities and Exchange Commission. On April 28, 2016, we consummated the initial public offering of 1,060,000 units, each unit consisting of one share of common stock and one warrant. The units were sold at an offering price of $5.00 per Unit, generating gross proceeds of $5.3 million, and net cash proceeds of $4.2 million, after deducting cash selling agent discounts and commissions and offering expenses. Each warrant entitles the holder to purchase one share of common stock at $5.00 per share until January 29, 2022, or earlier upon redemption.

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, or 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 information contained on, or that can be accessed through, our website is not a part of or incorporated by reference in this Annual Report on Form 10-K.

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 Associated with Our Business

Since we have a very 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 very 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 our products failed to perform as designed. 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, or 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. 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.

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 seek to protect our know-how and other unpatented proprietary technology 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. 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 will depend, 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 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. For the years ended December 31, 2016 and 2015, we had net losses of $5,650,851 and $1,776,600, respectively. To date, we have financed our operations through private placements of securities and our April 2016 IPO. 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, 2016 consolidated financial statements, we have concluded and stated our recurring losses from operations, recurring cash flows used in operations, accumulated deficit, and the requirement we raise additional capital in order to fund our ongoing operations beyond March 2017 raise substantial doubt regarding our ability to continue as a going concern. Additionally, our independent registered public accounting firm's report on our consolidated financial statements 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 closings of the Preferred Stock Private Placement initiated in January 2017 and 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.

Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt financing that we raise may contain terms that are not favorable to us or our stockholders. 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 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 that 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 trials also entail significant risk, and the data that results 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 that 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; 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.

Risks Associated with Ownership of Our Common Stock

We may issue shares of our capital stock or debt securities 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.

Similarly, if we issue debt securities, it could result in:

- default and foreclosure on our assets if our operating revenues were insufficient to pay our debt obligations;
- acceleration of our obligations to repay the indebtedness even if we have made all principal and interest payments when due if the debt security contains covenants that require the maintenance of certain financial ratios or reserves and any such covenant is breached without a waiver or renegotiation of that covenant;
- our immediate payment of all principal and accrued interest, if any, if the debt security is payable on demand;
- our inability to obtain additional financing, if necessary, if the debt security contains covenants restricting our ability to obtain additional financing while such security is outstanding; and
- our inability to conduct acquisitions, joint ventures or similar arrangements if the debt security contains covenants restricting such transactions or the funding thereof or requiring prior approval of the debt holders.

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

Our management and their affiliates collectively own approximately 68.2% 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.

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.

Our common stock is listed on Nasdaq, but we cannot assure you our common stock will continue to trade on this market or another national securities exchange. In addition, 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. In addition, our founders are subject to a lock-up agreement that restricts their ability to publicly sell the shares held by them until April 28, 2017. Accordingly, a substantial number 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 12,822,076 shares of our common stock, including the 251,334 shares of Series A Preferred Stock convertible into shares of common stock and 251,334 Series A Warrants issued in the January 2017 closing of the Preferred Stock Private Placement, in each case subject to adjustment as described elsewhere in this Annual Report. The Preferred Stock Private Placement will remain open through June 30, 2017 for subsequent closings, if any, in which an additional 248,666 authorized Preferred Stock Units may be issued. In addition, 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; and, each Series A Warrant may be exchanged for four (4) Series X Warrants, each to purchase one share of our common stock. Furthermore, we have committed to file a registration statement under the Securities Act registering the resale to the public of the shares of our common stock underlying the Series A Preferred Stock, the Series A Warrants, and the Series X Warrants. The sale, or even the possibility of sale, of the warrants, the shares of Series A Preferred Stock or the shares underlying the warrants or shares of Series A Preferred Stock 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.

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," 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 January 2016 rental agreement amended in May and June 2016, which expires May 31, 2017. We also rent approximately 220 square feet of research, laboratory, and office space at 375 West Street, West Bridgewater, MA 02379 under a month-to-month arrangement with one of our contract research suppliers which is cancellable at any time by either party. We consider these facilities adequate for our current operations and intend to obtain additional space as our operations expand.

Item 3. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures

None

PART II

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

Our securities have been traded on the Nasdaq Capital Market, or Nasdaq, since July 27, 2016, when the units issued in our initial public offering on April 28, 2016 (trading under the symbol "PAVMU") were split into our common stock, trading under the symbol "PAVM" and our warrants, trading under the symbol "PAVMW". In connection with the initiation of separate trading of our common stock and warrants, the trading of the units was suspended and delisted from Nasdaq. Prior to our initial public offering, there was no public market for our securities. The following table shows the high and low sale prices per share of our securities as reported on the Nasdaq for the periods indicated:

	Common Stock		Warrants	
	High	Low	High	Low
Third Quarter 2016 (beginning July 27, 2016)	$ 15.24	$ 5.00	$ 4.85	$ 4.00
Fourth Quarter 2016	$ 14.00	$ 6.80	$ 8.00	$ 5.51
First Quarter 2017 (through February 8, 2017)	$ 8.30	$ 4.50	$ 5.84	$ 3.00

Holders

As of February 10, 2017, there were 13,311,811 shares of common stock outstanding. Our shares of common stock are held by 19 stockholders of record and we believe there were more than 600 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 10K 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, 40,000 warrants were exercised on a cashless basis, resulting in the issuance of 20,732 shares of common stock.

In December 2016, 200 warrants were exercised on a cashless basis, resulting in the issuance of 79 shares of common stock.

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.

In January 2017, our Board of Directors authorized the sale of up to 500,000 Preferred Stock Units in the Preferred Stock Private Placement, with each Preferred Stock Unit consisting of one Series A Convertible Preferred Share and one Series A Warrant, to purchase one share of common stock at an initial exercise price of $8.00 per share. Subsequently, in January 2017, we completed an initial closing of the Preferred Stock Private Placement of 251,334 Preferred Stock Units at a price of $6.00 per unit, resulting in gross proceeds of $1.5 million and approximately $1.2 million of net proceeds, after deducting placement agent fees and other offering costs. The Preferred Stock Private Placement will remain open through June 30, 2017 for subsequent closings, if any, in which the remaining 248,666 authorized Preferred Stock Units may be issued.

Each Series A Warrant is exercisable for one share of our common stock at an exercise price of $8.00 per share, subject to adjustment. Each share of Series A Preferred Stock is convertible into a number of shares of our common stock equal to the stated value of $6,00 per share divided by the conversion price of $6.00, subject to adjustment. Each Series A Warrant can be exchanged through April 30, 2024 for four Series X Warrants. Each Series X Warrant is exercisable for one share of Common Stock at an initial exercise price of $6.00 per share. The Series A Warrants and Series X Warrants are not exercisable and the Series A Preferred Stock is not convertible prior to the time that final stockholder approval has been obtained under Nasdaq Stock Market Rule 5635(d).

Xzerta Trading LLC d/b/a HCFP/Capital Markets ("HCFP/Capital Markets"), an affiliate of certain of our directors and officers, is acting as the exclusive placement agent in the offering of securities. HCFP/Capital Markets is entitled to a fee of 7.0% of the gross proceeds realized in the offering, plus reimbursement of certain out-of-pocket costs.

The Preferred Stock Units were offered and sold in a private placement pursuant to exemptions from the registration requirements of the Securities Act, afforded by Section 4(a)(2) and Rule 506 of Regulation D promulgated thereunder.

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
- our expectations regarding the time during which we will be an ECG under the JOBS Act.

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

You should read this 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 commercialization while protecting our intellectual property, expanding our management team, Board of Directors, and Medical Advisory Board, raising initial working capital through two private placements completed before our initial public offering, consummating our initial public offering in April 2016, and the initial closing of the issuance of Preferred Stock Units in the Preferred Stock Private Placement in January 2017.

With regard to the products in our pipeline — PortIO, CarpX, NextCath, DisappEAR, NextFlo, and Caldus - among other things, we have:

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

- advanced, in partnership with our design and contract manufacturing partners, our PortIO product from concept to working prototypes, benchtop, animal, and cadaver testing, commercial design and development, verification and validation testing, and finally submission to the FDA for 510(k) clearance;

- 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 we have begun pre-submission verification and validation testing;

- engaged a design and contract manufacturing firm with experience in extrusions which has completed initial design work on the first product in the NextCath project and completed head-to-head testing of retention forces, comparing our working prototype to several competing products, which has validated our approach;

- engaged a design and contract manufacturing firm to initiate the design and development of the DisappEAR product in collaboration with our academic partners at Tufts University and Harvard Medical School;

- 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;

- selected three initial applications for our Caldus disposable tissue ablation platform technology – endovenous ablation of varicose veins, endoluminal ablation of *fistula-in-ano* and renal denervation for the treatment of hypertension; in collaboration with our design, engineering and manufacturing partners we have completed proof of principle testing demonstrating we can deliver temperatures of >90C to a balloon catheter for at least 20 minutes of ablation time and histologically confirmed tissue necrosis in a wide variety of tissues and organs in a pig model; we are currently optimizing the design of the renal denervation balloon and catheter and enhancing the design of the infusion device to higher specifications including temperatures up to 140C and significantly higher flow rates; we anticipate initiating animal testing for the initial three applications in the near future and verification and validation testing of the varicose vein and *fistula-in-ano* applications in early 2017;

- 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; and

- we continue to advance additional internal conceptual phase projects in clinical areas including delivery of tumescent local anesthesia, ECMO, sleep apnea and endotracheal intubation; and will accelerate their development commensurate with available capital and other resources.

Going Concern

The Company has adopted the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40,*Presentation of Financial Statements - Going Concern* (ASC 205-40). 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.

We are an early stage and emerging growth company and have not generated any revenues to date. As such, we are subject to all of the risks associated with early stage and emerging growth companies. Since inception, the Company has incurred losses and negative cash flows from operating activities. We do not expect to generate positive cash flows from operating activities in the near future.

The Company incurred net losses of $5,650,851, and had net cash flows used in operating activities of $4,454,857 for the year ended December 31, 2016. At December 31, 2016, the Company had an accumulated deficit of $7,701,835, negative working capital of $448,316 and cash of $585,680. The Company does not expect to experience positive cash flows from operating activities in the near future, if at all. The Company anticipates incurring operating losses for the next several years as it completes the development of its products and seeks requested regulatory clearances to market such products. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued.

We estimate our current cash resources, including the approximately $1.2 million of net proceeds received in the January 2017 initial closing of the Preferred Stock Private Placement, absent any additional sources of cash, is sufficient to fund our operations through March 2017. Accordingly, the Company does not have sufficient cash resources to fund its anticipated operating losses for the next twelve months and the Company must raise additional funds to support its operating and capital needs beyond March 2017.

The Company’s ability to fund its operations is dependent upon management's plans, which include raising additional capital, obtaining regulatory clearance for its products currently under development, commercializing and generating revenues from products currently under development, and continuing to control expenses. The Company has engaged financial advisory firms to assist with its financing efforts, including selling additional securities under the Preferred Stock Private Placement (which will remain open through June 30, 2017). However, there is no assurance the Company will be successful in these efforts, including the sale of the remaining authorized Preferred Stock Units.

A failure to raise sufficient capital, 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.

Recent Developments

In April 2016, we consummated our IPO with the issuance of 1,060,000 common stock units, with each common stock unit consisting of one share of common stock and one warrant to purchase one share of common stock at an exercise price of $5.00 per share. The common stock units were sold at an offering price of $5.00 per unit, generating gross cash proceeds of $5.3 million and net cash proceeds of approximately $4.2 million, after deducting cash selling agent discounts and commissions and other IPO offering expenses. In connection with the consummation of the IPO, the common stock units were approved for listing on the Nasdaq Capital Market, or Nasdaq, under the symbol "PAVMU". The common stock and warrants comprising the common stock units began separate trading on July 27, 2016 under the symbols "PAVM" and "PAVMW", respectively, and the common stock unit and symbol PAVMU ceased being quoted and traded on Nasdaq.

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.

On December 17, 2016, we filed a 510(k) premarket notification submission with the FDA for our first product, the PortIO™ Intraosseous Infusion System.

The Company's Board of Directors authorized the sale of up to 500,000 Preferred Stock Units in the Preferred Stock Private Placement, with each Preferred Stock Unit consisting of one Series A Convertible Preferred Share and one Series A Warrant to purchase one share of common stock at an initial exercise price of $8.00 per share. Subsequently, in January 2017, the Company completed an initial closing of the Preferred Stock Private Placement of 251,334 Preferred Stock Units at a price of $6.00 per unit, resulting in gross proceeds of $1.5 million and approximately $1.2 million of net proceeds, after deducting placement agent fees and offering costs. The Preferred Stock Private Placement will remain open through June 30, 2017 for subsequent closings, if any, in which the remaining 248,666 authorized Preferred Stock Units may be issued.

Financial Results of Operations

Revenue

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

General and administrative expenses

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

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

Research and development expenses

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

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

Research and development costs are expensed as incurred.

We incurred approximately $2.2 million in research and development costs from June 26, 2014 (inception) through December 31, 2016. We plan to increase our research and development expenses for the foreseeable future as we continue development of our products.

Our current and 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 suppliers;
- 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.

Income Taxes

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

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

As of December 31, 2016, our federal net operating loss (“NOL”) carryforward amounted to $6,432,797, and expires from 2034 to 2036. Additionally, as of December 31, 2016, our research and development credit carryforward amounted to $91,535, and expires from 2035 to 2036.

Results of Operations

Comparison of the years ended December 31, 2016 and 2015.

	Year Ended December 31,	
	2016	2015
Revenue	$ —	$ —
Operating expenses:		
General and administrative expenses	3,931,264	1,287,273
Research and development expenses	1,719,587	489,327
Total operating expenses	5,650,851	1,776,600
Net loss	$ (5,650,851)	$ (1,776,600)

Revenue

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

General and administrative expenses

The following table summarizes our general and administrative expense incurred during the year ended December 31, 2016 and 2015:

	Year Ended December 31, 2016	Year Ended December 31, 2015	$ Change	%Change
Compensation and related personnel costs	$ 728,125	$ 587,060	$ 141,065	24%
Stock-based compensation	664,068	—	664,068	100%
Outside professional services	1,846,497	619,714	1,226,783	198%
Facility related costs	165,775	7,309	158,466	2,168%
Travel related costs	194,639	45,037	149,602	332%
Board related costs	193,333	—	193,333	100%
Other operating costs	138,827	28,153	110,674	393%
Total general and administrative expenses	$ 3,931,264	$ 1,287,273	$ 2,643,991	205%

In general, the higher general and administrative expenses incurred during the year ended December 31, 2016 is principally driven by additional costs from the broader scale of our operations during the year ended December 31, 2016 as well as increased costs for investor relations and public company reporting requirements when compared to the year ended December 31, 2015.

Our general and administrative expenses for the year ended December 31, 2016 were $3,931,264 and for the year ended December 31, 2015 were $1,287,273. The increased expense of $2,643,991 for the period is principally due to higher compensation costs of $141,065, increased stock-based compensation expense of $664,068, increased outside professional services of $1,226,783, increased facility and office related costs of $158,466 related to our leased corporate office space, and board of directors fees of $193,333. The increase in Other operating costs includes higher premiums for directors and officers insurance as a public company.

The increase in outside professional services during the year ended December 31, 2016 of $1,226,783 is principally comprised of higher consulting and professional fees of $293,457 (which includes consulting fees incurred of $300,000 under the HCP /Advisors consulting agreement and $115,000 related to the HCFP /Strategy Advisors and Swartwood Hesse agreements, all of which are affiliated with certain of our officers and directors — see “Contractual Obligations” below for further details on these agreements); along with increased investor relations and marketing costs of $297,155, increased accounting, legal, printing, and stockholder related costs of $491,333 associated with SEC reporting and public company requirements, increased regulatory consulting costs of $136,059, and higher legal fees and costs related to intellectual property matters of $8,779. During the year ended December 31, 2015 the Company incurred $60,000 of fees under the HCP /Advisors consulting agreement, but did not incur any costs under the HCFP /Strategy Advisors and Swartwood Hesse agreements. Additionally, during 2015, the Company had lower comparable costs for investor relations and compliance with SEC reporting and public company requirements, as the Company did not fully transition to a public reporting entity until our IPO in April 2016.

Additionally, we issued stock options which resulted in the recognition of stock-based compensation expense in the amount of $664,068 during the year ended December 31, 2016. Upon the completion of our IPO on April 28, 2016, board of director compensation commenced resulting in the recognition of $193,333 of fees to members of the Company's board of directors during the year ended December 31, 2016.

Research and development expenses

The following table summarizes our research and development expenses incurred during the year ended December 31, 2016 and 2015:

	Year Ended December 31, 2016	Year Ended December 31, 2015	$ Change	%Change
Compensation and related personnel costs	$ 215,790	$ —	$ 215,790	100%
Stock-based compensation	83,297	—	83,297	100%
Outside professional services	1,365,810	489,327	876,483	179%
Patent license fees	50,000	—	50,000	100%
Regulatory filing fees	4,690	—	4,690	100%
Total research and development expenses	$ 1,719,587	$ 489,327	$ 1,230,260	251%

In general, the increased research and development expenses incurred during the year ended December 31, 2016 are due to the increased activities in support of advancing all of the Company's products toward FDA submittals as compared with limited and early research and development efforts on just certain of the products during the year ended December 31, 2015.

Research and development expenses incurred for the year ended December 31, 2016 were $1,719,587 and for the year ended December 31, 2015 were $489,327. The increase in costs of $1,230,260 during the period was principally due to the Company being engaged in the development of all of its products while during the year ended December 31, 2015 we incurred limited research and development expenses on just certain our products.

We incurred $215,790 of compensation expenses classified as research and development cost, principally related to the services provided by our Chief Medical Officer from July 2016 (date-of-hire) to December 31, 2016. Additionally, we issued stock options which resulted in the recognition of stock-based compensation expense classified as research and development expense in the amount of $83,297 during the year ended December 31, 2016. Research and development spending through outside service providers increased by $876,483 during the year ended December 31, 2016 when compared to the same period in 2015. Additionally, in the year ended December 31, 2016, we also incurred $50,000 of research and development expense related to the payment upon the execution of the Tufts Patent License Agreement, and incurred $4,690 of regulatory fees associated with the filing of our 510(k) premarket notification submission with the FDA for our PortIO™ Intraosseous Infusion System product.

Liquidity and Capital Resources

We are an early stage and emerging growth company and have not generated any revenues to date. As such, we are subject to all of the risks associated with early stage and emerging growth companies. Since inception, the Company has incurred losses and negative cash flows from operating activities. We do not expect to generate positive cash flows from operating activities in the near future. These factors raise substantial doubt of the Company's ability to continue as a going concern.

Since June 26, 2014 (inception), we have financed our operations principally through an aggregate of approximately $7.5 million of equity financing, including: approximately $2.1 million of net proceeds from private offerings of our common stock and warrants issued prior to our IPO; approximately $4.2 million of net cash proceeds resulting from our IPO on April 28, 2016; and, approximately $1.2 million from the initial closing of Preferred Stock Private Placement in January 2017.

We have incurred net losses of $5,650,851 and $1,776,600 for the years ended December 31, 2016 and 2015, respectively. The net cash flows used in operating activities was $4,454,857 and $1,249,605 during the years ended December 31, 2016 and 2015, respectively. At December 31, 2016, we had an accumulated deficit of $7,701,835, negative working capital of $448,316 and cash of $585,680. We anticipate incurring losses for the next several years as we complete the development of our products and file for and request regulatory clearances to market our products.

In January 2017, the Company's Board of Directors authorized the sale of up to 500,000 Preferred Stock Units in the Preferred Stock Private Placement, with each Preferred Stock Unit consisting of one share of Series A Convertible Preferred Stock and one Series A Warrant to purchase one share of common stock at an initial exercise price of $8.00 per share. Subsequently, in January 2017, the Company completed initial closings of the Preferred Stock Private Placement of 251,334 Preferred Stock Units at a price of $6.00 per unit, resulting in gross proceeds of $1.5 million and approximately $1.2 million of net proceeds, after deducting placement agent fees and offering costs. The Preferred Stock Private Placement will remain open through June 30, 2017 for subsequent closings, if any, in which the remaining 248,666 authorized Preferred Stock Units may be issued.

We estimate our current cash resources, including the $1.2 million of net proceeds from the Preferred Stock Private Placement discussed above, absent any additional sources of cash, is sufficient to fund our operations through March 2017. We have based this estimate on assumptions which may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Accordingly, we do not have sufficient cash resources to fund our anticipated operating losses for the next twelve months and we must raise additional funds to support our operating and capital needs beyond March 2017.

The Company’s ability to fund its operations is dependent upon management's plans, which include raising additional capital, obtaining regulatory clearance for its products currently under development, commercializing and generating revenues from products currently under development, and continuing to control expenses. The Company has engaged financial advisory firms to assist with its financing efforts, including selling additional securities under the Preferred Stock Private Placement (which will remain open through June 30, 2017). However, there is no assurance the Company will be successful in these efforts, including the sale of the remaining authorized Preferred Stock Units.

A failure to raise sufficient capital, 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.

Cash flows and liquidity

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

	Year Ended December 31,	
	2016	2015
Net cash flows (used in) or provided by: Operating activities	$ (4,454,857)	$ (1,249,605)
Investing activities	(21,793)	—
Financing activities	4,295,062	1,177,796
Net decrease in cash	$ (181,588)	$ (71,809)

Net cash flows used in operating activities

The net cash flows used in operating activities was $4,454,857 for the year ended December 31, 2016 and consisted of a net loss of $5,650,851, adjusted for depreciation of $3,793 and stock based compensation of $747,365, offset by a net increase in operating assets and liabilities of $444,836. The significant items in the change in operating assets and liabilities include a net increase in accounts payable and accrued expenses of $591,565, offset by an increase of $146,729 in prepaid expenses and other current assets.

During the year ended December 31, 2015, net cash flows used in operating activities was $1,249,605 and consisted of a net loss of $1,776,600 adjusted for non-cash contributed services of $133,333 and a net increase in operating assets and liabilities of $393,662. The significant items in the net change in operating assets and liabilities included increases in accounts payable and accrued expenses of $399,423, offset by an increase of $5,761 in prepaid and other current assets.

Net cash flows used in investing activities

In the year ended December 31, 2016, cash flows used in investing activities included purchases of computer and research equipment totaling $21,793. There were no investing activities cash flows during the year ended December 31, 2015.

Net cash flows provided by financing activities

In the year ended December 31, 2016, cash flows provided by financing activities totaled $4,295,062, consisting of the cash proceeds, net of offering costs, received through the Company's IPO closing on April 28, 2016. In the year ended December 31, 2015, net cash flows provided by financing activities amounted to $1,177,796, principally resulting from $1,250,000 of proceeds from the issuance of common stock upon the exercise of warrants, offset by $72,204 of payments of deferred offering costs associated with the Company's IPO.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Research and Development Expense

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

Stock Based Compensation

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

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

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

Income Taxes

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

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

Going Concern

The Company has adopted the provisions of FASB ASC Topic 205-40,*Presentation of Financial Statements - Going Concern*(ASC 205-40). 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. As a result of adopting ASC Topic 205-40, we have incorporated specific disclosures within our December 31, 2016 consolidated financial statements stating there is substantial doubt regarding the Company’s ability to continue as a going concern within one year from the consolidated 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. 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.

Recently Issued Accounting Standards

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

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

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

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

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

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

Contractual Obligations

The Company leases space for its corporate office, which initially provided for two consecutive six month terms beginning on February 1, 2016, rent payments of $9,500 per month and the option to cancel the lease agreement at the end of the initial six-month term at the election of the Company. Subsequently, the lease agreement was amended to add approximately 200 sq. ft. of rentable office space at an additional rate of $4,400 per month; and, extended the lease term through May 31, 2017. Total rent expense under this office space lease arrangement for the year ended December 31, 2016 was $134,356. At December 31, 2016, the Company's aggregate future minimum lease payments were $71,400, through the May 31, 2017 lease termination date.

Effective October 2015, the Company entered into a three-year management services agreement with HCP/Advisors LLC, an affiliate of a director of the Company, which replaced a prior contemplated management services agreement with HCFP LLC, another affiliate of the director and certain other officers and directors of the Company. Pursuant to the HCP/Advisors LLC agreement, such entity has agreed to provide the Company with certain management services, including without limitation identifying potential corporate opportunities, general business development, corporate development, corporate governance, marketing strategy, strategic development and planning, coordination with service providers, and other advisory services as may be mutually agreed upon. The Company has agreed to pay HCP/Advisors LLC an initial monthly fee of $35,000 commencing as of November 1, 2015 and thereafter a monthly fee of $25,000. Under this agreement, the Company incurred fees of $300,000 and $60,000 during the years ended December 31, 2016 and 2015, respectively.

Effective November 1, 2014, the Company entered into an employment agreement with its CEO (the "CEO Employment Agreement") for a five-year term with an initial base salary of $240,000 per year, from November 1, 2014 to October 31, 2015. The base salary of $240,000 from November 1, 2014 to October 31, 2015 along with a $124,583 bonus payment was payable to the CEO only upon and subject to the consummation of the Company's IPO. As of December 31, 2015, the Company determined the likelihood of the IPO was probable and, therefore, a liability of $364,583 was recognized at December 31, 2015. In May 2016, as a result of the closing of the Company's IPO on April 28, 2016, the accrued salary and bonus compensation payable at December 31, 2015 was paid to the CEO. Effective November 1, 2015, the base salary was increased to $295,000 per year. The CEO Employment Agreement provides for a guaranteed bonus equal to 50% of base salary, beginning on January 1 of each year effective January 1, 2016. Additionally, the CEO will also be eligible to earn 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.

Effective as of October 8, 2015, the Company entered into a two-year employment agreement with its Chief Financial Officer (the "CFO Employment Agreement") with a base salary of $275,000 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 (the "CMO Employment Agreement") 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.

Effective October 1, 2016, the Company and Michael Glennon, Vice Chairman and member of the Company's Board of Directors, entered into a consulting agreement (the "Glennon Consulting Agreement"), under which Mr. Glennon will provide the Company with services and advice relating to the successful development and commercialization of medical device products, including interfacing with outsourced contract manufacturers, assisting with development of the supply chain, and establishing commercialization channels with independent distributors and strategic corporate partners, and will provide such other services as requested by the Company's Chairman and Chief Executive Officer. As compensation for his services, Mr. Glennon was to have received a monthly retainer of $12,500 and an initial payment of $37,500 upon execution of the Consulting Agreement. As of December 31, 2016, Mr. Glennon waived his right to compensation under the consulting agreement for the year ended December 31, 2016. The Glennon Consulting Agreement may be terminated by either party upon 30 days' prior written notice, except either party may terminate the Glennon Consulting Agreement immediately for cause (which includes an uncured material breach of the agreement). The Glennon Consulting Agreement also will terminate immediately if the parties agree to the employment of Mr. Glennon on a full-time basis. The Glennon Consulting Agreement contains covenants for the protection of the Company's confidential information and a mutual indemnity provision for claims arising out of the services.

Effective September 2016, the Company entered into a consulting agreement with HCFP /Strategy Advisors LLC, an affiliate of certain directors and officers of the Company (the "HCFP Strategic Advisory Agreement"). Under the HCFP Strategic Advisory Agreement, HCFP /Strategy Advisors LLC has been engaged to provide various strategic advisory services, including: strategic business planning, to identify and assist with potential sources of financing arrangements, promotion of 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. The Company incurred expense of $100,000 in the year ended December 31, 2016 under the HCFP Strategic Advisory Agreement.

Effective September 2016, the Company also entered into a consulting agreement with Swartwood Hesse, Inc., an affiliate of HCFP /Strategy Advisors (which, as noted above, is an affiliate of certain directors and officers of the Company) (the "Swartwood Hesse Financial Advisory Agreement"). Under the Swartwood Hesse Financial Advisory Agreement, Swartwood Hesse, Inc. has been engaged to provide advisory services regarding potential financing arrangements, assisting the Company with its investors relations, and provide other financial advisory services as reasonably requested by the Company. The Swartwood Hesse Financial Advisory Agreement total fee amounts to $15,000, which was paid upon execution of the agreement. The Company may incur additional fees for investment banking services under a separate written agreement to be executed between the Company and Swartwood Hesse, Inc. The Company incurred expense of $15,000 in the year ended December 31, 2016 under the Swartwood Hesse Financial Advisory Agreement.

In January 2017, the Company entered into an agreement with HCFP /Capital Markets, an affiliate of certain directors and officers of the Company, wherein HCFP /Capital Markets was engaged to be the Company's exclusive placement agent in an offering of securities ("the HCFP /Capital Markets Placement Agent Agreement"), including the Preferred Stock Private Placement . Under the HCFP /Capital Markets Placement Agent Agreement, HCFP /Capital Markets is to be 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 later of June 30, 2017 or the completion or termination of any other potential transactions in conjunction with the Preferred Stock Private Placement.

JOBS Act

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

Off-Balance sheet arrangements

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

Effect of Inflation and Changes in Prices

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

Item 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 on pages F-1 through F-31 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, 2016. 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 misstatements. Further, because of changes in conditions, effectiveness of internal controls over financial reporting may vary over time. Our system contains self-monitoring mechanisms, and actions are 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, 2016.

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

On February 15, 2017, the Company and its Chief Executive Officer executed an amendment to the CEO Employment Contract, effective as of December 31, 2016, whereby the CEO elected to permanently waive his right to receive guaranteed bonus compensation due and payable for services rendered during the year ended December 31, 2016. Except for the waiver of 2016 guaranteed bonus compensation, all other provisions of the CEO Employment Agreement shall remain in full force and effect.

On February 15, 2017, the Company and its Vice Chairman executed an amendment to the Glennon Consulting Agreement, effective as of December 31, 2016, whereby the Vice Chairman elected to permanently waive all 2016 consulting compensation that would have been otherwise due and payable to him through and including December 31, 2016. Except for the waiver of all 2016 consulting compensation, all other provisions of the Glennon Consulting Agreement shall remain in full force and effect.

The foregoing information is filed in accordance with and in satisfaction of the requirements of Item 5.02 of Form 8-K.

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 2017 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2016.

Item 11. Executive Compensation

The information required by this Item 11 is incorporated by reference to our Proxy Statement for the 2017 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2016.

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 2017 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2016.

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 2017 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2016.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 is incorporated by reference to our Proxy Statement for the 2017 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2016.

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	Bylaws (1)
4.1	Specimen Common Stock Certificate (1)
4.2	Specimen Warrant Certificate (1)
4.3	Form of Series A Warrant (2)
4.4	Form of Series X Warrant (2)
4.5	Warrant Agreement, dated April 28, 2016, between Continental Stock Transfer & Trust Company and the Registrant (3)
4.6	2014 Long-Term Equity Incentive Plan (1)
4.7	Form of Unit Purchase Option (1)
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
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	Employment Agreement between PAVmed and Richard Fitzgerald (1)
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 Glennon
10.10	Securities Purchase Agreement (6)
10.11	Registration Rights Agreement (6)
14	Form of Code of Ethics (1)
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 February 1, 2017.

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.

February 16, 2017

By: /s/ Lishan Aklog, M.D.
Lishan Aklog, M.D.
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 Lishan Aklog, M.D. and Richard F. Fitzgerald 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 Securities and Exchange Commission.

Signature	Title	Date
/s/ Lishan Aklog, M.D. Lishan Aklog, M.D.	Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	February 16, 2017
/s/ Richard F. Fitzgerald Richard F. Fitzgerald	Chief Financial Officer (Principal Financial and Accounting Officer)	February 16, 2017
/s/ James L. Cox, M.D. James L. Cox, M.D.	Director	February 16, 2017
/s/ Ira Scott Greenspan Ira Scott Greenspan	Director	February 16, 2017
/s/ Joshua R. Lamstein Joshua R. Lamstein	Director	February 16, 2017
/s/ Ronald M. Sparks Ronald M. Sparks	Director	February 16, 2017
/s/ David Weild IV David Weild IV	Director	February 16, 2017

PAVMED INC. AND SUBSIDIARY
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
PAVmed Inc.

We have audited the accompanying consolidated balance sheets of PAVmed Inc. and Subsidiary (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform audits of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of PAVmed Inc. and Subsidiary as of December 31, 2016 and 2015, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's recurring losses from operations, recurring cash used in operating activities and accumulated deficit 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 consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ CITRIN COOPERMAN & COMPANY, LLP

New York, New York
February 16, 2017

PAVMED INC.
and SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

	December 31, 2016	December 31, 2015
ASSETS		
CURRENT ASSETS		
Cash	$ 585,680	$ 767,268
Prepaid expenses and other current assets	155,490	8,761
Total Current Assets	741,170	776,029
Equipment, net	18,000	—
Deferred offering costs	111,249	438,061
TOTAL ASSETS	$ 870,419	$ 1,214,090
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 949,413	$ 165,321
Accrued expenses and other current liabilities	240,073	414,851
Total Current Liabilities	1,189,486	580,172
COMMITMENTS AND CONTINGENCIES (NOTE 8)		
STOCKHOLDERS' (DEFICIT) EQUITY		
Preferred stock, par value $0.001, 20,000,000 shares authorized; no shares issued and outstanding at December 31, 2016 and 2015	—	—
Common stock, par value $0.001; 50,000,000 shares authorized, 13,330,811 and 12,250,000 shares issued and outstanding at December 31, 2016 and 2015, respectively	13,331	12,250
Additional paid-in capital	7,369,437	2,672,652
Accumulated deficit	(7,701,835)	(2,050,984)
TOTAL STOCKHOLDERS' (DEFICIT) EQUITY	(319,067)	633,918
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	$ 870,419	$ 1,214,090

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2016	**2015**
Revenue	$ —	$ —
General and administrative expenses	3,931,264	1,287,273
Research and development expenses	1,719,587	489,327
Total operating expenses	5,650,851	1,776,600
Net loss	$ (5,650,851)	$ (1,776,600)
Net loss per share, basic and diluted	(0.44)	(0.16)
Weighted average common shares outstanding - basic and diluted	12,972,153	11,278,755

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARY

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' Equity (deficit)
	Shares	Par Value			
Balance at December 31, 2014	10,856,371	$ 10,856	$ 1,058,356	$ (274,384)	$ 794,828
Warrants issued for legal services			272,357		272,357
Common stock issued upon exercise of warrants	1,393,629	1,394	1,248,606		1,250,000
Value of contributed services of Chief Executive Officer and former Chief Financial Officer			333,333		333,333
Chief Executive Officer contributed services deemed payable			(240,000)		(240,000)
Net loss				(1,776,600)	(1,776,600)
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 cashless exercise of warrants	20,811	21	(21)		—
Stock-based compensation expense			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 STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2016	2015
Cash flows from operating activities		
Net loss	$ (5,650,851)	$ (1,776,600)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation expense	3,793	—
Stock-based compensation	747,365	—
Expense attributable to contributed services	—	133,333
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(146,729)	(5,761)
Accounts payable	877,592	100,572
Accrued expenses and other current liabilities	(286,027)	298,851
Net cash used in operating activities	(4,454,857)	(1,249,605)
Cash flows from investing activities		
Purchase of equipment	(21,793)	—
Net cash used in investing activities	(21,793)	—
Cash flows from financing activities		
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)	(72,204)
Proceeds from common stock issued upon exercise of warrants	—	1,250,000
Net cash provided by financing activities	4,295,062	1,177,796
Net decrease in cash	(181,588)	(71,809)
Cash, beginning of period	767,268	839,077
Cash, end of period	$ 585,680	$ 767,268
Supplemental non-cash financing activities		
Deferred offering costs in connection with initial public offering	$ —	$ 365,857
Deferred offering costs in connection with an in-process financing transaction	$ 111,249	$ —
Issuance of common stock upon cashless exercise of warrants	$ 21	$ —

See accompanying notes to the consolidated financial statements.

PAVMED INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

PAVmed Inc. ("PAVmed" or the "Company") was organized under the laws of the State of Delaware on June 26, 2014, originally under the name of PAXmed Inc. On April 19, 2015, the Company changed its name to PAVmed Inc. The Company operates in one segment as a medical device company organized to advance a broad pipeline of innovative medical technologies from concept to commercialization using a business model focused on capital and time efficiency.

Initial Public Offering

On April 28, 2016, 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 with the issuance of 1,060,000 common stock units at an offering price of $5.00 per unit, with each common stock unit consisting of one share of common stock and one warrant to purchase one share of common stock at an exercise price of $5.00 per share. The IPO resulted in gross cash proceeds of $5.3 million and net cash proceeds of $4.2 million, after deducting cash selling agent discounts and commissions and offering expenses. The warrants issued in the IPO became exercisable on October 28, 2016 and expire on January 29, 2022 or earlier upon redemption by the Company under certain conditions (see Note 10, *Stockholders' Equity (Deficit)*). Upon consummation of the IPO, the Company's 9,560,295 previously outstanding warrants converted into identical warrants issued in the IPO.

In connection with the consummation of the IPO, the common stock units were approved for listing on the Nasdaq Capital Market ("Nasdaq") under the symbol "PAVMU". Subsequently, the common stock and warrants comprising the common stock units began separate trading on Nasdaq on July 27, 2016 under the symbols "PAVM" and "PAVMW", respectively, and the common stock unit and symbol PAVMU ceased to be quoted and traded on Nasdaq.

Preferred Stock Units Private Placement

In January 2017, the Company's Board of Directors authorized the sale of up to 500,000 Preferred Stock Units in a private placement transaction, with each Preferred Stock Unit consisting of one share of Series A Convertible Preferred Stock and one Series A Warrant, to purchase one share of common stock at an initial exercise price of $8.00 per share. Subsequently, in January 2017, the Company completed initial closings of a private placement of 251,334 Preferred Stock Units at a price of $6.00 per unit, resulting in gross proceeds of approximately $1.5 million and approximately $1.2 million of net proceeds, after deducting placement agent fees and offering costs. The Preferred Stock Units private placement transaction will remain open through June 30, 2017 for subsequent closings, if any, in which the remaining 248,666 authorized Preferred Stock Units may be issued. See Note 14, *Subsequent Events*, for a discussion of the Preferred Stock Units private placement transaction.

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

Going Concern

The Company has adopted the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40,*Presentation of Financial Statements - Going Concern* (ASC 205-40). 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.

The Company incurred net losses of $5,650,851, and had net cash flows used in operating activities of $4,454,857 for the year ended December 31, 2016. At December 31, 2016, the Company had an accumulated deficit of $7,701,835, negative working capital of $448,316 and cash of $585,680. The Company does not expect to experience positive cash flows from operating activities in the near future, if at all. The Company anticipates incurring operating losses for the next several years as it completes the development of its products and seeks requested regulatory clearances to market such products. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued.

The Company estimates its current cash resources, including the approximately $1.2 million of net proceeds received in the January 2017 initial closings of the Preferred Stock Units private placement transaction (see Note 14, *Subsequent Events* for a discussion of the Preferred Stock Units private placement transaction), absent any additional sources of cash, is sufficient to fund its operations through March 2017. Accordingly, the Company does not have sufficient cash resources to fund its anticipated operating losses for the next twelve months and the Company must raise additional funds to support its operating and capital needs beyond March 2017.

The Company’s ability to fund its operations is dependent upon management's plans, which include raising additional capital, obtaining regulatory clearance for its products currently under development, commercializing and generating revenues from products currently under development, and continuing to control expenses. The Company has engaged financial advisory firms to assist with its financing efforts, including selling additional securities under the Preferred Stock Unit private placement transaction (which will remain open through June 30, 2017). However, there is no assurance the Company will be successful in these efforts, including the sale of the remaining authorized Preferred Stock Units.

A failure to raise sufficient capital, 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, 2016 and 2015. 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 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 stock-based compensation, the fair value of warrants, research and development expenses, contingent liabilities, the provision or benefit for income taxes and the valuation allowance on deferred tax assets. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. On an ongoing basis, the Company evaluates its estimates, judgements, and methodologies. The Company bases its estimates on historical experience and on various other assumptions believed to be reasonable. Due to the inherent uncertainty involved in making estimates, actual results could differ materially from those estimates.

Cash

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

Research and Development Expenses

Research and development expenses are recognized as incurred and include the salary and stock-based compensation of the Company's Chief Medical Officer 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.

Deferred Offering Costs

The Company capitalizes certain legal, accounting, and other third-party fees directly associated with in-process capital financing as deferred offering costs. The deferred offering costs are recognized as an offset against the financing proceeds upon consummation of the offering. The deferred offering costs at December 31, 2016 relate to legal fees incurred with respect to an in-process financing transaction involving a Preferred Stock Units private placement (see Note 14, *Subsequent Events* for further details regarding the Preferred Stock Units private placement transaction). The deferred offering costs at December 31, 2015 relate to the Company's IPO, and were subsequently recognized as an offset against the gross proceeds of the IPO.

Patent Costs

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.

Purchased Patent License Rights

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

Fair Value Measurements

Fair value is defined 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 the measurement date. A three-tier fair value hierarchy which 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.

At December 31, 2016 and 2015, the carrying amounts of the Company's financial instruments, including cash, accounts payable, and accrued expenses, approximate their respective fair value due to the short-term nature of these instruments.

At December 31, 2016 and 2015, the Company does not have any assets or liabilities required to be measured at fair value in accordance with FASB ASC Topic 820, *Fair Value Measurement.*

Note 2 — Summary of Significant Accounting Policies (continued)

Stock-Based Compensation

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

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

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

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

Note 2 — Summary of Significant Accounting Policies (continued)

Income Taxes

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

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

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

The Company's policy for recording interest and penalties associated with audits is to record such expense as a component of income tax expense. There were no amounts accrued for penalties or interest as of December 31, 2016 and 2015, or during the years ended December 31, 2016 and 2015. As of December 31, 2016, the Company does not have any unrecognized tax benefits resulting from uncertain tax positions. The Company is not aware of any issues under review to potentially result in significant payments, accruals, or material deviations from its position.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the sum of the weighted-average number of common shares outstanding during the reporting period, and, if dilutive, the potential dilutive effects of stock options and warrants outstanding in accordance with the treasury stock method. As the Company's financial results resulted in a net loss for all periods presented, basic net loss per share is the same as diluted net loss per share, due to the exclusion of incremental shares resulting from stock options and warrants as their inclusion would have been anti-dilutive.

Segment Data

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

Note 2 — Summary of Significant Accounting Policies (continued)

Stock Split Effected in the Form of a Stock Dividend

On September 21, 2015, the Company's board of directors declared a 2.7872582-for-1 stock split to be effected in the form of a stock dividend. All basic and diluted earnings per share, average shares outstanding information and all applicable footnotes have been adjusted for the stock split. The number of authorized shares of common stock and preferred stock were not affected by the stock split and remain at 50,000,000 shares and 20,000,000 shares, respectively.

JOBS Act Accounting Election

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

Recent Accounting Pronouncements

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

Note 2 — Summary of Significant Accounting Policies (continued)

Recent Accounting Pronouncements (continued)

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

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

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

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

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

Note 3 — Prepaid Expenses and Other Current Assets

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

	December 31, 2016	December 31, 2015
Security deposits	$ 48,350	$ —
Prepaid insurance	35,947	—
Advanced payments to suppliers	71,193	8,761
Total prepaid expenses and other current assets	$ 155,490	$ 8,761

Note 4 — Equipment, Net

Equipment, net consisted of the following as of:

	December 31, 2016	December 31, 2015
Research and development equipment	$ 10,156	$ —
Computer equipment	11,637	—
	21,793	—
Less: accumulated depreciation	(3,793)	—
Total Equipment, net	$ 18,000	$ —

Depreciation expense for the year ended December 31, 2016 was $3,793. No depreciation expense was incurred during the year ended December 31, 2015.

Note 5 — Accrued Expenses and Other Current Liabilities

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

	December 31, 2016	December 31, 2015
Chief Executive Officer contributed services deemed payable	$ —	$ 240,000
Accrued bonus payable	—	124,583
Accrued board of director fees	72,500	—
Accrued vacation	28,324	5,879
Accrued professional fees	111,249	36,000
Other	28,000	8,389
Total accrued expenses and other current liabilities	$ 240,073	$ 414,851

In December 2016, the Company reversed the accrued bonus payable previously recognized throughout 2016 as the Company's board of directors determined no discretionary bonuses would be paid for 2016. In addition, the Company's Chief Executive Officer ("CEO") waived his right to receive a guaranteed bonus payment due under the CEO Employment Agreement. See Note 8, *Commitments and Contingencies*, for further details regarding compensation paid to the CEO.

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

The accrued professional fees at December 31, 2016 relate to deferred offering costs incurred with respect to an in-process financing transaction of a private placement of Preferred Stock Units. See Note 14, *Subsequent Events*, for a discussion of the Preferred Stock Units private placement transaction.

Included in "Other" is $10,000 of accrued expense due to a related party under the HCFP /Strategy Advisory Agreement. See Note 7, *Related Party Transactions*, for further details regarding the HCFP /Strategy Advisory Agreement.

In May 2016, the Company paid $364,583 of aggregate accrued compensation due to its CEO upon the successful completion of the Company's IPO. The salary and bonus compensation was accrued as of December 31, 2015 as the Company's IPO closing was deemed probable. See Note 8, *Commitments and Contingencies*, for further details regarding compensation paid to the CEO.

Note 6 — Income Taxes

Income tax (benefit) expense consisted of the following for the year ended December 31, 2016 and 2015:

	December 31, 2016	December 31, 2015
Current:		
Federal, state, and local	$ —	$ —
Deferred:		
Federal	(1,945,638)	(593,739)
State and local	(424,840)	(169,758)
	(2,370,478)	(763,497)
Less: Valuation allowance	2,370,478	763,497
	$ —	$ —

At December 31, 2016 and 2015, the reconciliation of the federal statutory income tax rate to the effective income tax rate is as follows:

	December 31, 2016	December 31, 2015
U.S. statutory rate	(35.0)%	(35.0)%
State income taxes (net of federal benefit)	(7.5)%	(10.4)%
Permanent differences	1.8%	3.6%
Tax credits	(1.3)%	(1.2)%
Valuation allowance	42.0%	43%
Effective tax rate	0.0%	0.0%

At December 31, 2016 and 2015, the approximate tax effects of temporary differences which give rise to the net deferred tax assets are as follows:

Noncurrent deferred tax assets:		
Net operating loss	$ 2,795,050	$ 568,721
Stock-based compensation	199,921	—
Deferred compensation	—	165,404
Accrued expenses	12,307	—
Section 195 deferred start-up costs	39,746	38,749
Patent licenses	25,466	—
Research and development tax credit carryforwards	91,535	20,674
Deferred tax assets	3,164,025	793.548
Less: valuation allowance	(3,164,025)	(793,548)
Deferred tax assets, net of valuation allowance	$ —	$ —

The Company has federal and state net operating loss ("NOL") carryforwards of $6,432,797 and $1,243,538 at December 31, 2016 and 2015, respectively. The NOL carryforward amount is available to reduce future taxable income and expires from 2034 to 2036. Additionally, the Company generated $70,861 and $20,674 of estimated research and development tax credit carryforwards during the years ended December 31, 2016 and 2015, respectively. The research and development tax credit carryforwards are available to reduce future tax expense and expires from 2035 to 2036.

As required by ASC Topic 740, a "more-likely-than-not" criterion is applied when evaluating the realization of a deferred tax asset. The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company’s history of operating losses, the Company has concluded it is more-likely-than-not the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2016 and 2015.

The Company files income tax returns in the United States in federal and applicable state jurisdictions. The Company's tax filings for the year 2015 and for its initial period of operations from June 26, 2014 (inception) through December 31, 2014 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 7 — Related Party Transactions

Effective October 2015, the Company entered into a three-year management services agreement with HCP/Advisors LLC, an affiliate of a director of the Company, which replaced a prior contemplated management services agreement with HCFP LLC, another affiliate of the director and certain other officers and directors of the Company. Pursuant to the HCP/Advisors LLC agreement, such entity has agreed to provide the Company with certain management services, including without limitation identifying potential corporate opportunities, general business development, corporate development, corporate governance, marketing strategy, strategic development and planning, coordination with service providers, and other advisory services as may be mutually agreed upon. The Company has agreed to pay HCP/Advisors LLC an initial monthly fee of $35,000 commencing as of November 1, 2015, and thereafter, a monthly fee of $25,000. Under this agreement, the Company incurred fees of $300,000 and $60,000 during the years ended December 31, 2016 and 2015, respectively, which are included in "General and administrative expenses" in the accompanying consolidated statements of operations.

Effective September 2016, the Company entered into a consulting agreement with HCFP /Strategy Advisors LLC, an affiliate of certain directors and officers of the Company (the "HCFP Strategic Advisory Agreement"). Under the HCFP Strategic Advisory Agreement, HCFP /Strategy Advisors has been engaged for an initial term of five months to provide various strategic 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. The Company incurred expense of $100,000 in the year ended December 31, 2016 under the HCFP Strategic Advisory Agreement, which is 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 directors and officers of the Company) (the "Swartwood Hesse Financial Advisory Agreement"). Under the Swartwood Hesse Financial Advisory Agreement, Swartwood Hesse Inc. has been 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 provides for total fee payments to Swartwood Hesse of $15,000, which was paid upon execution of the agreement. The Company may incur additional fees for investment banking services under a separate written agreement to be executed between the Company and Swartwood Hesse, Inc. The Company incurred expense of $15,000 in the year ended December 31, 2016 under the Swartwood Hesse Financial Advisory Agreement, which is included in "General and administrative expenses" in the accompanying consolidated statements of operations.

In January 2017, the Company entered into an agreement with Xzerta Trading LLC d/b/a HCFP /Capital Markets ("HCFP /Capital Markets"), an affiliate of certain directors and officers of the Company, wherein HCFP /Capital Markets was engaged to be the Company's exclusive placement agent in an offering of securities ("the HCFP /Capital Markets Placement Agent Agreement"), including the Preferred Stock Units private placement transaction. (See Note 14, Subsequent Events for a discussion of the Preferred Stock Units private placement transaction.) Under the HCFP /Capital Markets Placement Agent Agreement, HCFP /Capital Markets is to be 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 later of June 30, 2017, or the completion or termination of any other potential transactions in conjunction with the Preferred Stock Units private placement transaction.

Note 7 — Related Party Transactions (continued)

Effective October 1, 2016, the Company and Michael J. Glennon, Vice Chairman and a member of the Company's board of directors, entered into a consulting agreement (the "Glennon Consulting Agreement"), under which Mr. Glennon provides the Company with services and advice relating to the successful development and commercialization of medical device products, including interfacing with outsourced contract manufacturers, assisting with development of the supply chain and establishing commercialization channels with independent distributors and strategic corporate partners, and providing such other services as requested by the Company's Chairman and CEO. As compensation for his services, Mr. Glennon was due an initial payment of $37,500 upon execution of the consulting agreement and a monthly retainer of $12,500 for each month thereafter. 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. The Glennon Consulting Agreement may be terminated by either party upon 30 days' prior written notice, except either party may terminate the Glennon Consulting Agreement immediately for cause (which includes an uncured material breach of the agreement). The Glennon Consulting Agreement also will terminate immediately if the parties agree to the employment of Mr. Glennon on a full-time basis.

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 "P. Glennon Consulting Agreement"). Under the terms of the P. Glennon Consulting Agreement, Mr. P. 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 of 20,000 stock options on November 28, 2016, with an exercise price of $9.50 per share, and vesting ratably on a quarterly basis commencing December 31, 2016 through September 30, 2019.

In September 2015, the Company exercised an option to purchase for $10,000 a patent from Pavilion Holdings Group LLC (PHG), a medical device holding company founded by the Company's CEO and Chairman, Vice Chairman, and Chief Medical Officer. The payment was recognized as an expense at the time of payment and is included in general and administrative expenses in the accompanying consolidated statement of operations for the year ended December 31, 2015.

Note 8 — Commitments and Contingencies

Employment Agreements & Compensation

Chief Executive Officer Employment Agreement

Effective November 1, 2014, the Company entered into an employment agreement with its CEO (the "CEO Employment Agreement") for a five-year term with an initial base salary of $240,000 per year, from November 1, 2014 to October 31, 2015. The base salary of $240,000 from November 1, 2014 to October 31, 2015, along with a $124,583 bonus payment, was payable to the CEO only upon and subject to the consummation of the Company's IPO. As of December 31, 2015, the Company determined the likelihood of the IPO was probable and, therefore, a liability of $364,583 was recognized at December 31, 2015. In May 2016, as a result of the closing of the Company's IPO on April 28, 2016, the accrued salary and bonus compensation payable at December 31, 2015 was paid to the CEO. Effective November 1, 2015, the base salary was increased to $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. The CEO Employment Agreement provides for a guaranteed bonus equal to 50% of base salary, beginning on January 1 of each year effective January 1, 2016. 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. 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."

Chief Financial Officer Employment Agreement

Effective October 8, 2015, the Company entered into a two-year employment agreement with its Chief Financial Officer (the "CFO Employment Agreement") with a base salary of $275,000 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. The Company also agreed to reimburse up to $2,200 per month to cover temporary housing and travel expenses for up to 12 months and to reimburse additional relocation expenses in the future. On April 28, 2016, upon the consummation of the IPO, the Chief Financial Officer also was granted a stock option to purchase 125,000 shares of the Company's common stock with an exercise price equal to $5.00 per share. 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 CEO with "good reason".

Chief Medical Officer Employment Agreement

Effective July 1, 2016, the Company entered into a five-year employment agreement with its Chief Medical Officer (the "CMO Employment Agreement") with a base salary of $285,000 per year, plus an initial bonus of $50,000 for services provided before the agreement's effective date. 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 April 28, 2016, upon the consummation of the IPO, the Chief Medical Officer also was granted a stock option to purchase 278,726 shares of the Company's common stock with an exercise price equal to $5.00 per share. The 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".

Contributed Services

The Company's CEO and former CFO were not paid a salary during the period June 26, 2014 (inception) through October 2015. The Company has recognized the value of their services as contributed services by recognizing $333,333 of compensation expenses in general and administration expenses in the consolidated statement of operations for the year ended December 31, 2015, and additional paid-in capital in the consolidated balance sheet at December 31, 2015.

Note 8 — Commitments and Contingencies (continued)

Leases

The Company leases space for its corporate office, which initially provided for two consecutive six month terms beginning on February 1, 2016, rent payments of $9,500 per month and the option to cancel the lease agreement at the end of the initial six-month term at the election of the Company. Subsequently, the lease agreement was amended to add approximately 200 sq. ft. of rentable office space at an additional rate of $4,400 per month, and extended the lease term through May 31, 2017. Total rent expense under this office space lease arrangement for the year ended December 31, 2016 was $134,356. At December 31, 2016, the Company's aggregate future minimum lease payments were $71,400 through the May 31, 2017 lease termination date.

Beginning on May 1, 2015, the Company rents access to a research and development facility for monthly rent of $1,000 on a month-to-month basis. Either the landlord or the Company may cancel this rental arrangement at any time. Total rental expense under this facility lease arrangement amounted to $12,000 and $8,000 for the years ended December 31, 2016 and 2015, respectively.

Legal Proceedings

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

Note 9 — Agreement Related to Intellectual Property Right

Tufts Patent License Agreement - Antibiotic-Eluting Resorbable Ear Tubes

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

The Company 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. The Company recognized as expense the acquired intellectual property rights as of the transaction date on the basis of the costs of an intangible asset purchased from others for use in a research and development activity, and for which there are no alternative future uses, are research and development expense at the time the costs are incurred. Accordingly, the Company recognized the $50,000 payment as research and development expenses 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 10 — Stockholders' Equity (Deficit)

Preferred Stock

The Company is authorized to issue 20,000,000 shares of preferred stock with a 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, 2016 and 2015, there were no shares of preferred stock issued or outstanding.

In January 2017, the Company's board of directors authorized the sale of up to 500,000 Preferred Stock Units in a private placement transaction, with each Preferred Stock Unit consisting of one share of Series A Convertible Preferred Stock and one Series A Warrant, to purchase one share of common stock at an initial exercise price of $8.00 per share. Subsequently, in January 2017, the Company completed initial closings of a private placement of 251,334 Preferred Stock Units at a price of $6.00 per unit, resulting in gross proceeds of approximately $1.5 million and approximately $1.2 million of net proceeds, after deducting placement agent fees and offering costs. The Preferred Stock Units private placement will remain open through June 30, 2017 for subsequent closings, if any, in which the remaining 248,666 authorized Preferred Stock Units may be issued. See Note 14, *Subsequent Events* for a discussion of the Preferred Stock Units private placement transaction.

Common Stock

The Company is authorized to issue 50,000,000 shares of common stock with a par value of $0.001 per share. There were 13,330,811 and 12,250,000 shares of common stock outstanding as of December 31, 2016 and 2015, respectively.

In connection with the organization of the Company in June 2014, a total of 8,083,049 shares of the Company's common stock and 8,710,182 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. The terms and conditions of the Founders' Warrants converted into the same terms and conditions of the warrants issued in the Company's IPO.

In June 2014 and July 2014, in a private placement (Private Placement 1), a total of 418,089 units, consisting of one share of common stock and one warrant, were sold to the initial investor investors ("Initial Investors") for an aggregate purchase price of $75,000 less offering costs of $7,500. In November 2014, the Company completed another private placement (Private Placement 2) of 2,355,233 units, consisting of one share of common stock and one warrant, raising $845,000 in gross offering proceeds less offering costs of $46,500. The warrants issued in the 2014 private placements ("Private Placement Warrants") converted into the same terms and conditions of the warrants issued in the Company's IPO.

In September 2015, the Company issued 1,393,629 shares of common stock in connection with the exercise of 1,393,629 Private Placement Warrants.

On April 28, 2016, the Company's IPO was consummated with the issuance of 1,060,000 units at an offering price of $5.00 per unit, with each unit consisting of one share of common stock and one warrant. The IPO resulted in gross cash proceeds of $5.3 million and $4.2 million of net cash proceeds, after deducting cash selling agent discounts and commissions and offering expenses. 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.

Note 10 — Stockholders' Equity (Deficit) (continued)

In November 2016, the Company issued 20,732 shares of common stock resulting from the exercise of 40,000 warrants on a cashless basis.

In December 2016, the Company issued 79 shares of common stock resulting from the exercise of 200 warrants on a cashless basis.

Warrants

The table below summarizes warrants outstanding and warrant activity during the years ended December 31, 2016 and 2015:

Balance at December 31, 2014	10,856,370
Issued	97,554
Exercised	(1,393,629)
Balance at December 31, 2015	9,560,295
Issued in connection with IPO	1,060,000
Exercised	(40,200)
Balance at December 31, 2016	10,580,095

The 9,560,295 warrants outstanding as of December 31, 2015 automatically converted into warrants having the same terms and conditions as the 1,060,000 warrants issued in the Company's IPO on April 28, 2016, including a $5.00 per share warrant exercise price and a warrant term of six years.

The warrants issued in the IPO have an exercise price of $5.00 per share and became exercisable on October 28, 2016 and expire on January 29, 2022 or earlier upon redemption by the Company under certain conditions, as discussed below.

Commencing April 28, 2017, the Company may redeem the outstanding 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 warrants are exercised prior to the date specified in the notice of redemption. On and after the redemption date, a record holder of a warrant will have no further rights except to receive the redemption price for such holder's warrant upon surrender of such warrant.

In August 2015, the Company issued 97,554 warrants with an exercise price of $5.00 to an outside advisor in exchange for services. The estimated fair value of the warrants was $272,357 using the Black-Scholes option pricing model with the following assumptions: fair value of underlying common stock of $5.00, dividend yield of 0%, expected volatility of 58%, risk-free interest rate of 2.3%, and an expected term of six years.

In September 2015, certain holders of the Private Placement Warrants exercised 1,393,629 warrants for aggregate proceeds to the Company of $1,250,000.

Note 10 — Stockholders' Equity (Deficit) (continued)

In November 2016, 40,000 warrants were exercised on a cashless basis, resulting in the issuance of 20,732 shares of common stock.

In December 2016, 200 warrants were exercised on a cashless basis, resulting in the issuance of 79 shares of common stock.

The Company filed a Registration Statement on Form S-1 (File No. 333-214288), declared effective February 3, 2017, to register the issuance of 1,020,000 shares of the Company's common stock upon the exercise of 1,020,000 remaining unexercised warrants issued in the Company's IPO. The Registration Statement also registers (i) the issuance of 1,062,031 shares of the Company's common stock upon the exercise of 1,062,031 of the unexercised 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 (but only in the event such warrants are exercised prior to being publicly transferred pursuant to Rule 144). In January 2017, the Company's CEO executed a transaction with a shareholder who had previously purchased shares of common stock and warrants in the Company's private financings prior to its IPO, under which the CEO purchased 25,000 warrants from the shareholder. Accordingly, the shares of common stock underlying the 25,000 warrants were not registered within the Registration Statement on Form S-1 (File No. 333-214288) as discussed above.

Unit Purchase Options

On April 28, 2016, the Company issued unit purchase options to the selling agents in the Company's IPO. The unit purchase options provide for the purchase of 53,000 units at an exercise price of $5.50 per unit. Each unit covered by the unit purchase options is identical to the units sold in the Company's IPO and consists of one share of common stock and one warrant to purchase a share of common stock at $5.00 per share. The Company estimated the fair value of the unit purchase options issued to the selling agents was $105,100, which was accounted for as offering costs of the Company's IPO. The fair value of the unit purchase options was determined using a Black-Scholes option pricing model with the following assumptions: fair value of the underlying unit of $5.00, dividend yield of 0.00%, expected volatility of 50%, risk free rate of 1.28% and remaining contractual term of 4.6 years.

Note 11 — Stock Based Compensation

In November 2014, the Company's board of directors and stockholders adopted the 2014 Long-Term Incentive Equity Plan (the "2014 Stock Plan"). The 2014 Stock Plan is designed to enable the Company to offer employees, officers, directors and consultants, as defined, an opportunity to acquire a proprietary interest in the Company. The types of awards that may be granted under the 2014 Stock Plan include stock options, stock appreciation rights, restricted stock, and other stock-based awards subject to limitations under applicable law. All awards are subject to approval by the compensation committee of the Company's board of directors. The 2014 Stock Plan reserves 1,951,081 shares of common stock for issuance in accordance with the 2014 Stock Plan's terms. At December 31, 2016, there were 317,768 shares of common stock available for grant under the 2014 Stock Plan.

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

	Number Stock Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 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
Vested or expected to vest at December 31, 2016	1,633,313	$ 5.14	

On April 28, 2016, upon the closing of the Company's IPO, a total of 1,588,313 stock options were granted, including 961,178 to management, 487,770 to members of the board of directors, and 139,365 to members of the Company's medical advisory board. The stock options have a ten year contractual term from date of grant, an exercise price of $5.00 per share, and vest 3/36 on the third month after the grant date and 1/36 on each successive month thereafter for the following 33 months.

In November 2016, the Company granted 25,000 stock options to a new member of the Company's medical advisory board, with a ten year contractual term from date of grant, an exercise price of $10.50 per share, and vesting ratably on a quarterly basis commencing December 31, 2016 and ending September 30, 2019.

In November 2016, the Company granted 20,000 stock options to a (related party) consultant, with a ten year contractual term from date of grant, an exercise price of $9.50 per share, and vesting ratably on a quarterly basis commencing December 31, 2016 and ending September 30, 2019.

The aggregate intrinsic value is computed as the difference between the exercise price of the underlying stock options and the quoted price of the common stock on December 31, 2016, to the extent the exercise price is less than the quoted price.

The weighted average remaining contractual term of stock options outstanding was 9.3 years at December 31, 2016. The weighted average remaining contractual term of stock options vested and exercisable was 9.3 years at December 31, 2016.

Note 11 — Stock Based Compensation (continued)

The cost of stock-based compensation awards granted to employees and directors is determined based on the grant-date fair value for stock options granted to employees and members of the board of directors and the vesting date fair value for stock options granted to non-employees, with the cost recognized on a straight-line basis over the award's requisite service period. Stock-based compensation expense for the years ended December 31, 2016 and 2015 was recognized as follows:

	Year Ended December 31,	
	2016	2015
General and administrative expenses	$ 664,068	$ —
Research and development expenses	83,297	—
	$ 747,365	$ —

At December 31, 2016, there was $2,196,566 of total unrecognized compensation cost related to stock options, which is expected to be recognized over the next 2.3 years (which represents the weighted average remaining requisite service periods for such awards).

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.

Stock options issued to employees:

The grant date fair value of stock options granted to employees and members of the board of directors was $1.32 per share, calculated using the following Black-Scholes valuation model assumptions:

	Year Ended December 31,	
	2016	2015
Risk-free interest rate	1.40%	—%
Expected term of options (in years)	5.8	—
Expected stock price volatility	50%	—%
Expected dividend yield	0%	—%

Stock options issued to non-employees:

The weighted average fair value of stock options granted to non-employees was $5.60 per share as of December 31, 2016, with such fair value calculated using the following weighted-average Black-Scholes valuation model assumptions:

	Year Ended December 31,	
	2016	2015
Risk-free interest rate	1.85%	—%
Expected term of options (in years)	9.6	—%
Expected stock price volatility	60%	—%
Expected dividend yield	0%	—%

Note 11 — Stock Based Compensation (continued)

The weighted-average valuation assumptions for all stock-based awards were determined as follows:

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

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

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

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

Note 12 —Loss Per Share

Basic loss per share is calculated by dividing the loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive common shares. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive common shares would have been anti-dilutive.

The following table sets forth the comparison of basic and fully diluted net loss per share for the periods indicated:

	Year Ended December 31,	
	2016	2015
Net loss attributable to common stockholders	$ 5,650,851	$ 1,776,600
Weighted-average common shares outstanding	12,972,153	11,278,755
Net loss per common share - basic and diluted	$ (0.44)	$ (0.16)

The following securities at December 31, 2016 and 2015 have been excluded from the computation of diluted weighted shares outstanding, as their inclusion would be anti-dilutive:

	December 31,	
	2016	2015
Warrants	10,580,095	9,560,295
Stock options	1,633,313	—
Unit purchase options as to shares of common stock	53,000	—
Unit purchase options as to shares underlying warrants	53,000	—
Total	12,319,408	9,560,295

In January 2017, the Company's board of directors authorized the sale of up to 500,000 Preferred Stock Units in a private placement transaction, with each Preferred Stock Unit consisting of one share of Series A Convertible Preferred Stock and one Series A Warrant, to purchase one share of common stock at an initial exercise price of $8.00 per share. Subsequently, in January 2017, the Company completed initial closings of a private placement of 251,334 Preferred Stock Units. (See Note 14, *Subsequent Events* for a discussion of the Preferred Stock Units private placement transaction.) While the Series A Convertible Preferred Stock and Series A Warrants are convertible into common shares, if they had been outstanding at December 31, 2016, they would have been excluded from the computation of diluted weighted average shares outstanding, as their inclusion would be anti-dilutive.

Note 13 — Selected Quarterly Financial Data (unaudited)

The following tables contain (unaudited) quarterly financial statement information for the years ended December 31, 2016 and 2015. The Company believes the following information includes all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of financial results for any future period.

	2016 Quarters Ended:			
	March 31	June 30	September 30	December 31
Revenues	$ —	$ —	$ —	$ —
General and administrative expenses	517,739	959,734	1,350,248	1,103,543
Research and development expenses	179,141	355,001	578,474	606,971
Total operating expenses	696,880	1,314,735	1,928,722	1,710,514
Net loss	(696,880)	(1,314,735)	(1,928,722)	(1,710,514)
Net loss per share, basic and diluted[1]	$ (0.06)	$ (0.10)	$ (0.14)	$ (0.13)
Weighted average common shares outstanding - basic and diluted	12,250,000	12,299,495	13,310,000	13,317,672

	2015 Quarters Ended:			
	March 31	June 30	September 30	December 31
Revenues	$ —	$ —	$ —	$ —
General and administrative expenses	130,337	293,158	274,371	589,407
Research and development expenses	16,000	67,450	264,532	141,345
Total operating expenses	146,337	360,608	538,903	730,752
Net loss	(146,337)	(360,608)	(538,903)	(730,752)
Net loss per share, basic and diluted[1]	$ (0.01)	$ (0.03)	$ (0.05)	$ (0.06)
Weighted average common shares outstanding - basic and diluted	10,856,371	10,856,371	11,138,505	12,250,000

(1) Net loss per share, basic and diluted is computed independently for each quarter and year presented, and as such, the sum of the quarters may not equal the full year amounts.

Note 14 — Subsequent Events

Preferred Stock Units Private Placement Transaction

In January 2017, the Company's board of directors authorized the sale of up to 500,000 preferred stock units (the "Preferred Stock Units") in a private placement transaction, with each Preferred Stock Unit consisting of one share of Series A Convertible Preferred Stock ("Series A Convertible Preferred Share") and one Series A Warrant ("Series A Warrant"), as discussed below. Subsequently, in January 2017, the Company completed initial closings of a private placement of 251,334 Preferred Stock Units at a price of $6.00 per unit, resulting in gross proceeds of approximately $1.5 million and approximately $1.2 million of net proceeds, after deducting placement agent fees and offering costs. The Preferred Stock Units private placement transaction will remain open through June 30, 2017 for subsequent closings, if any, in which the remaining 248,666 authorized Preferred Stock Units may be issued.

Registration Rights Agreement

In connection with the Preferred Stock Units private placement, the Company has entered into a registration rights agreement (the "Registration Rights Agreement") with participating private placement investors, requiring the Company to file a registration statement with the Securities and Exchange Commission registering for resale the maximum number of common shares that could be issued upon conversion of the issued Series A Convertible Preferred Shares and the exercise of the Series A Warrants or, if converted as described below, the Series X Common Warrants. The Registration Rights Agreement requires the Company to file a registration statement registering the underlying common shares no later than sixty (60) days from the closing of the Preferred Stock Units private placement and to use commercially reasonable best efforts to have such registration statement declared effective no later than one hundred and fifty (150) days from the private placement closing. Delays in the filing of the registration statement or maintaining its effectiveness would result in the Company having to pay damages of 2% of each investor's subscription amount on the date of a Filing Failure, Effectiveness Failure, and Maintenance Failure, as well as every 30th day thereafter (pro-rated for periods totaling less than 30 days) until the failure is cured.

Series A Convertible Preferred Shares

The Series A Convertible Preferred Shares have a par value of $0.001 per share and a stated value of $6.00 per share and are convertible into common shares at the holders' election initially at a stated conversion price of $6.00 per share. The holders of the Series A Convertible Preferred Shares may elect conversion at any time after the Company has obtained shareholder approval of the private placement transaction in accordance with Nasdaq Stock Market Rule 5635(d). The conversion price of the Series A Convertible Preferred shares will be reduced by a prescribed formula should any subsequent issuances of convertible securities by the Company be sold at a price lower than the conversion price of the Series A Convertible Preferred Shares immediately prior to such issuance. The Series A Convertible Preferred Shares have a liquidation preference, provide for dividends at an 8% annual rate which is compounded quarterly. The dividends may be settled, after April 1, 2017, at the option of the Company, through any combination of the issuance of additional Series A Convertible Preferred Shares, common shares and /or cash payment. The Series A Convertible Preferred Shares have no voting rights. In the case of a Deemed Liquidation Event, the Series A Convertible Preferred Shares can become redeemable at the election of at least two-thirds of holders of the then outstanding Series A Convertible Preferred Shares 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.

Note 14 — Subsequent Events (continued)

Series A Warrants

Each of the Series A Warrants may be exercised after the Company obtains shareholder approval of the private placement transaction, for one share of common stock at an initial exercise price of $8.00 per share. The exercise price of the Series A Warrants will be reduced by a prescribed formula in the event the Company issues common stock, options, or convertible securities at a price lower than the exercise price of Series A Warrants immediately prior to such securities issuance. The Series A Warrants may be exercised any time after the Company has obtained shareholder approval of the private placement in accordance with Nasdaq Stock Market Rule 5635(d) ("Initial Exercise Date") and expire after the close of business on April 30, 2024. If at any time after the six (6) month anniversary of the date of the Closing, there is no effective registration statement registering, or no current prospectus available for, the resale of the shares underlying the Series A Warrants, then the Series A Warrants may also be exercised, in whole or in part, at such time by means of a "cashless exercise".

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.

The Series A Warrants are not subject to redemption.

Series A Warrants Exchange Option

Each Series A Warrant constituting a component of each Unit can be exchanged through April 30, 2024 for four (4) Series X Warrants. Each Series X Warrant is exercisable for one share of Common Stock at an initial exercise price of $6.00 per share (the "Series X Exercise Price"). The Series X Warrants are exercisable at any time after the later of (i) the date the final stockholder approval has been obtained under Nasdaq Stock Market Rule 5635(d) and (ii) October 31, 2018, and until April 30, 2024. The Series X Exercise Price and number of shares of Common Stock issuable upon exercise of a Series X Warrant are subject to appropriate adjustment in the event of stock dividends, stock splits or similar events affecting the common stock. Holders may exercise Series X Warrants by paying the exercise price in cash or, at any time after the six-month anniversary of the Closing Date, if there is no effective Registration Statement registering, or no current prospectus available for, the resale of the Series X Warrant Shares by the holder, then the Series X Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise". At any time after April 30, 2019, the Company, may at its option, redeem all, but not less than all, of the outstanding Series X Warrants at a price of $0.01 per Series X Warrant if the volume weighted average price per share of the Common Stock has been at least $18.00 (as adjusted for stock splits, stock dividends, or similar events occurring after the Closing Date) for twenty Trading Days out of the thirty Trading Day period ending three Business Days prior to the notice of redemption in addition to certain other conditions.

On February 10, 2017, there were 251,334 Series A Warrants issued and outstanding which if fully exchanged for Series X Warrants would result in an aggregate issuance of 1,005,336 Series X Warrants.

Other Matters

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 events requiring adjustments to the consolidated financial statements or disclosures therein.

Exhibit 10.2.4

PAVmed Inc.
One Grand Central
Place, Suite 4600
60 East 42nd Street
New York, NY 10170
212-949-4319
info@pavmed.com
www.pavmed.com

February 15, 2017

Dr. Lishan Aklog

Dear Dr. Aklog:

This letter will serve to amend the Employment Agreement, dated as of October 24, 2014, and amended on April 8, 2015 and November 17, 2015 ("Employment Agreement"), between you and PAVmed Inc.

Regarding Section 3.2 of the Employment Agreement, you have notified the Company of your election to permanently waive your right to receive bonus compensation due and payable to you on January 1, 2017 for services rendered during the year ended December 31, 2016 and the Company has accepted your election relative to this waiver of 2016 bonus compensation. The non-payment of such bonus compensation shall not be considered the occurrence of a "Good Reason" for purposes of Section 4.4 of the Employment Agreement.

Except as amended herein, all other provisions of the Employment Agreement shall remain in full force and effect.

Please sign this letter in the place below to confirm your agreement.

Sincerely,

PAVMED INC.

By: /s/ Richard F. Fitzgerald
Name: Richard F. Fitzgerald
Title: Chief Financial Officer

AGREED TO:

/s/ Lishan Aklog, M.D.
Lishan Aklog, M.D

Exhibit 10.9.2

PAVmed Inc.
One Grand Central
Place, Suite 4600
60 East 42nd Street
New York, NY 10170
212-949-4319
info@pavmed.com
www.pavmed.com

February 15, 2017

Michael Glennon

Dear Mr. Glennon:

This letter will serve to amend the Consulting Agreement ("Consulting Agreement"), dated as of October 12, 2016, between you and PAVmed Inc.

Regarding Section 3 of the Consulting Agreement, you have notified the Company of your election to permanently waive your right to receive all accrued and unpaid compensation due to you through and including December 31, 2016 for services rendered under the Consulting Agreement during the year ended December 31, 2016 and the Company has accepted your election relative to this waiver of your 2016 consulting compensation.

Except as amended herein, all other provisions of the Consulting Agreement shall remain in full force and effect.

Please sign this letter in the place below to confirm your agreement.

Sincerely,

PAVMED INC.

By: /s/ Richard F. Fitzgerald
Name: Richard F. Fitzgerald
Title: Chief Financial Officer

AGREED TO:

/s/ Michael Glennon
Michael Glennon

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated February 16, 2017, with respect to the consolidated financial statements in the Annual Report of PAVmed Inc. on Form 10-K for the year ended December 31, 2016. We consent to the incorporation by reference of said report in the Registration Statement of PAVmed Inc. on Form S-1 (File No. 333-214288).

/s/ CITRIN COOPERMAN & COMPANY, LLP

New York, New York
February 16, 2017

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: February 16, 2017

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

Exhibit 31.2

CERTIFICATION BY PRINCIPAL FINANCIAL OFFICER

I, Richard F. Fitzgerald, 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: February 16, 2017

By: /s/ Richard F. Fitzgerald
Richard F. Fitzgerald, 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, 2016 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: February 16, 2017

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

Exhibit 32.2

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

In connection with the Annual Report on Form 10-Q of PAVmed Inc. (the "Company") for the year ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Richard F. Fitzgerald, 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: February 16, 2017

By: /s/ Richard F. Fitzgerald
Richard F. Fitzgerald, Chief Financial Officer
(Principal Financial and Accounting Officer)