UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2015**

☐ 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	**47-1214177**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Grand Central Place, Suite 4600 New York, New York	**10165**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (212) 401-1951

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
Units, each consisting of one share of Common Stock and one Warrant	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 filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
(Do not check if a 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, 2015, the last business day of the registrant's most recently completed second fiscal quarter, the registrant's common stock was not publicly traded. Accordingly, there was no market value for the registrant's common stock on such date.

As of April 11, 2016, there were 12,250,000 shares of common stock, $.001 par value per share, outstanding.

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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. All information presented herein is based on the Company's fiscal calendar. The Company assumes no obligation to revise or update any forward-looking statements for any reason, except as required by law.

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;
- 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 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 acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that 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 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 five lead projects, all of which are the subject of patent applications. One of these projects, NextFlo, also has an issued patent. These projects are all in the development phase and have not yet received regulatory approval.

- *PortIO:* A novel long-term implantable vascular access device with no indwelling intravascular component.
- *Caldus:* Completely disposable tissue ablation devices which can also be used for renal denervation to treat hypertension.
- *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.
- *NextFlo:* Highly accurate disposable infusion pumps using stored potential energy and variable flow resistors.

In addition to our five 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. They 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 nextgeneration endoscopic vessel harvest device for use during coronary artery bypass surgery, which received U.S. Food and Drug Administration (“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.
- *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. Its submission is currently under review.
- *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.

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.

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. 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 bandwith 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 focus is on five lead projects in the areas of medical infusion, tissue ablation and hand surgery. We will need to receive regulatory clearance in order to commercialize these products. We believe it will require $1.5 million to $3.0 million and 12 to 24 months to achieve initial regulatory clearance for each product. Additional capital may be required for us to commercialize these products and/or pursue additional regulatory clearances. The foregoing are estimates and it may take more time or funding than we anticipate to commercialize our products. In addition, there is no assurance that any of our products will ever be commercialized or, if commercialized, will achieve the results we expect.

PortIO — Long-term Implantable 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). 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 resulting in thrombosis or scarring. Finally, most long-term vascular access devices require surgical insertion and removal and require careful handling by trained clinicians to prevent the introduction of air into the circulation.

Our Solution. We have developed a novel, implantable 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 provisional patent application, performed proof-of-concept testing in animals, developed a working prototype and completed our design work for the first-generation device. We are working with our contract manufacturing partners to build a commercial product. We anticipate an FDA 510(k) pathway, with our without clinical safety studies. We believe that it will require up to $1.5 million and 12 to 18 months to receive FDA 510(k) clearance. 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.

Caldus — Disposable Tissue Ablation Devices, Including Renal Denervation for Hypertension

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 to generate $4.0 billion to $5.0 billion in annual revenue. More recently, the renal nerves have been identified as a therapeutic target for ablation in patients with refractory hypertension. Despite a widely publicized clinical trail 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 a 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 a particular burden 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 anticipate an FDA 510(k) pathway for traditional tissue ablation targets and a PMA pathway for renal denervation. With regard to 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. We believe that it will take 12 to 24 months and up to $3.0 million to receive FDA 510(k) clearance for traditional tissue ablation targets and European CE Mark clearance for renal denervation. 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 also believe that a completely disposable tissue ablation device has the potential to gain market share in traditional tissue ablation applications by competing on price and eliminating the need for on-going maintenance and monitoring of capital equipment.

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 have to be performed in a surgical operating room. Endoscopic approaches are less invasive, but are more technically challenging, more expensive and have been associated with a higher complication rates. They 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 technique to treat CTS. We believe our device will allow the surgeon 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 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 that 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 less-invasive approaches. We have filed a provisional patent application and tested working prototypes in cadavers. We anticipate a 510(k) FDA pathway with or without clinical safety studies. We believe that it will take 12 to 18 months and up to $3.0 million to receive FDA 510(k) clearance. 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 and (iii) accelerate the patient's return to full activity. 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 most commonly to infuse fluids, medications or other substances into a vein or other structures. They are also used for monitoring physiologic parameters and draining visceral organs or cavities. The most commonly used short-term catheters are peripheral and central venous catheters. According to a report by iData Research Group, over 90% of hospitalized patients receive a peripheral venous catheter (PVC) during their stay and up to seven million patients receive a short-term central venous catheter (CVC) or peripherally inserted central catheter (PICC). They estimate the market for these catheters alone to be several billion dollars annually. The market is highly commoditized with very few product features commanding premium pricing. 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. Many of the central features of venous catheters have not evolved over decades despite several limitations. For example, venous catheters may need to remain in place for 72 hours or longer, but carry a significant risk of dislodgement during that period. Currently marketed short-term catheters are not self anchoring. PVC's and PICC's 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. CVC's are usually sutured to the skin, a process which leads to increased pain and exposure to needle sticks. 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 simpler and less risky PVC's and will proceed to CVC's thereafter. Our self-anchoring technique, however, is applicable to most, if not all, short-term catheters such as gastrointestinal tubes and drainage catheters. The self-anchoring mechanism is integral to the catheter. It allows insertion with standard techniques and the use of simple clear sterile dressings. We believe that the force required to dislodge our catheters will be significantly greater than traditional techniques and at least as high as add-on catheter securement devices. We also believe that they will be more resistant to micromotion than other techniques. We have filed a

provisional patent application and completed head-to-head testing of retention forces, comparing our working prototype to several competing products, which has validated our approach. To achieve commercialization, we will need to receive regulatory clearance. We anticipate an FDA 510(k) pathway without clinical safety studies. We believe that it will take 12 to 18 months and up to $1.5 million to receive FDA 510(k) clearance. Once this product is commercialized, we believe it will garner premium pricing based on fewer complications and reduced overall costs.

NextFlo — Highly-Accurate Disposable Infusion Pumps

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). An increasing number of these patients are receiving infusions of medications or other substances outside of a hospital, in ambulatory facilities and at home. Infusion pump errors, however, 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. Disposable infusion pumps ("DIPs") have many attractive features that favor their use in these settings over 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 opiods. According to a report by Transparency Market Research, the overall global infusion market is estimated to be over $5.0 billion annually and DIPs account for approximately 10% of this market.

Current Devices and their Limitations. 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.

Our Solution. We are developing highly-accurate disposable infusion pumps using stored potential energy and 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 initiated design work for the first embodiment. Upon completion of this analysis, we will file additional patent applications and begin our design process. The device is designed to be completely disposable and manufactured from inexpensive plastic and rubber parts. We anticipate an FDA 510(k) pathway without clinical safety studies. We believe that it will take 12 to 18 months and up to $2.0 million to receive FDA 510(k) clearance. Once this product is commercialized, we believe it will command a premium price over existing, low-accuracy, DIPs without significantly higher cost-of-goods and expand the market for DIPs. We also believe the accuracy of our device will allow it to be used with a broader range of drugs, thereby significantly expanding the addressable market. Finally, we believe it will significantly decrease costs by reducing or eliminating the need for trained healthcare personnel to initiate or monitor the infusion. We also believe that our variable resistor technology may also be applicable to inpatient infusions, allowing them to be accurately delivered with gravity instead of electric infusion pumps.

Additional Projects

In addition to our five 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. 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 these additional projects over the next several months and will begin 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 that 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 that, 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 are developing 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.

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.

Our current patent portfolio consists of the following:

Project	Inventors	Title	Number	Date
PortIO	Aklog and deGuzman	"Intraosseous Infusion Ports and Methods of Use"	Application # US62/0.79.266 US14940889 PCT/US15/60669	Filed 13-Nov-2014 13-Nov-2015 13-Nov-2015
Caldus	Aklog and deGuzman	"Continuous Flow Balloon Catheter Systems and Methods of Use"	Application # 62/131.214	Filed 10-Mar-2015
	Aklog and deGuzman	"Continuous Flow Thermal Ablation Balloon Catheter Systems and Methods of Use"	Application # 62/131.217	Filed 10-Mar-2015
CarpX	Aklog and deGuzman	"Systems and Methods for Percutaneous Division of Fibrous Structures"	Application # 62/086.950	Filed 03-Dec-2014
NextCath	Aklog and deGuzman	"Self-Anchoring Catheters and Methods of Use"	Application # 62/085.838	Filed 01-Dec-2014
NextFlo	Aklog, deGuzman, Glennon, Cronin and Barker	"Systems and Methods for Infusion of Fluids Using Stored Potential Energy and a Variable Flow Resistor"	U.S. Patent 8,622,976(1)	Issued 07-Jan-2014
	Aklog, deGuzman, Glennon, Cronin and Barker	"Systems and Methods for Infusion of Fluids Using Stored Potential Energy and a Variable Flow Resistor"	U.S. Patent 9,255,834(2)	Issued 13-Oct-2015

(1) This patent has a priority date of March 4, 2010 and will remain in effect until 2031.

(2) This patent has a priority date of March 4, 2010 and will remain in effect until 2034.

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. Most recently, the Protecting Access to Medicare Act of 2014, signed into law in April 2014, provided for a 0.5% update from 2013 payment rates under the Medicare Physician Fee Schedule through 2014 and a 0% update from January 1 until April 1, 2015.

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.

Research and development costs

Research and development costs increased by approximately $478,000 from $11,000 to approximately $489,000 during the year ended December 31, 2015 when compared to the period from June 26, 2014 (inception) through December 31, 2014. This increase was due to contract research spending on all five of our product candidates during the year ended December 31, 2015 as compared to limited early product design costs on just our PortIO product candidate incurred during the period from June 26, 2014 (inception) through December 31, 2014. We expect research and development costs to increase as we advance our five product candidates toward the point of seeking regulatory clearance in late 2016 and early 2017.

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 pre-market approval ("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 recent 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, President Obama signed into law the American Taxpayer Relief Act of 2012, 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.

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 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 two employees and four executive officers, two of whom are also members of our Board of Directors. We do not currently have any other employees.

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 for our initial public offering was declared effective by the Securities and Exchange Commission. As of the date of this Annual Report on Form 10-K, we have not consummated our initial public offering and there is no assurance that we will be successful in doing so. Our website address is http://www.pavm.com.

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 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 Securities Exchange Act of 1934, as amended, or 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.

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. Please see page ii of this Annual Report on Form 10-K for a discussion of some of the forward-looking statements that are qualified by these risk factors. 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 will 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, our revenues may decline 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 that 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 other 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;
- 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; and
- otherwise have a material adverse effect on our business, financial condition and results of operations.

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 year ended December 31, 2015 and for the period from June 26, 2014 (inception) through December 31, 2014, we had net losses of $1,776,600 and $274,384, respectively. To date, we have financed our operations through private placements of securities. 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 that 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 forseeable future.

Our independent registered public accounting firm's report contains an explanatory paragraph that expresses substantial doubt about our ability to continue as a "going concern."

The report of our independent registered public accountants on our consolidated financial statements includes an explanatory paragraph stating that our recurring losses from operations, recurring cash used in operating activities and accumulated deficit raise substantial doubt about our ability to continue as a going concern. Our plans concerning these matters include the consummation of our initial public offering. The consolidated financial statements do not include any adjustments that might result from our inability to consummate such offering or our ability to continue as a going concern. Moreover, there is no assurance that even if we consummate our initial public offering, we will raise sufficient proceeds in such offering to pay our 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 may 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 premarket approval, or 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or 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, the President 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 Institutional Review Boards, ("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.

There is not now and there may not ever be an active market for our securities. There are restrictions on the transferability of these securities.

There currently is no market for our securities. Although we hope to consummate our initial public offering in the near future, there is no assurance that we will be able to do so. Even if an active market develops for our securities, Rule 144, which provides for an exemption from the registration requirements under the Securities Act of 1933, as amended, or the "Securities Act," under certain conditions, requires, among other conditions, a holding period prior to the resale (in limited amounts) of securities acquired in a non-public offering without having to satisfy the registration requirements under the Securities Act. There can be no assurance that we will fulfill any reporting requirements in the future under the Exchange Act or disseminate to the public any current financial or other information concerning us, as is required by Rule 144 as part of the conditions of its availability. If an active market does not develop or is not sustained, 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 may have an adverse effect on the market price of our common stock.

We have issued and have outstanding warrants to purchase an aggregate of 9,560,296 shares of our common stock. The sale, or even the possibility of sale, of the warrants or the shares underlying the warrants 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 any additional warrants we issue, are exercised, 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 Jumpstart Our Business Startups Act, or 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 will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be 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 any national securities exchange on which our securities are then trading. Compliance with the various reporting and other requirements applicable to public companies will require considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. These rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits on coverage or incur substantial costs to maintain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our Board of Directors, our board committees, or as executive officers.

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, beginning with our annual report on Form 10-K for the fiscal year ending December 31, 2016. 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 will require 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. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our common stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish 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 460 square feet of office space plus common area facilities at One Grand Central Place, East 42nd Street, New York, New York 10165 under a January 2016 rental agreement that expires on January 31, 2017, unless terminated earlier at our election upon an initial six months of occupancy. We also rent approximately 220 square feet of research, laboratory and office space at 375 West Street, West Bridgewater, Massachusetts 02379 under a month-to-month arrangement with one of our contract research suppliers that 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 Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

There is currently no established public trading market in our securities. Our securities are not currently listed for trading on any national securities exchange nor are bid or asked quotations reported in any over-the-counter quotation service.

In connection with our initial public offering (which is still ongoing as of the date of this Annual Report), we have applied to have our units (comprised of common stock and warrants) listed on the Nasdaq Capital Market under the symbol "PAVMU." The common stock and warrants comprising the units will begin separate trading on the 90th day after we hold a closing on our initial public offering. If our units are approved for listing on Nasdaq, then once the securities comprising the units begin separate trading, the common stock and warrants will be traded on Nasdaq under the symbols "PAVM" and "PAVMW," respectively. We cannot assure you that we will hold a closing of our initial public offering or that our securities will be approved for listing on Nasdaq. As a result, an established trading market in our securities may never develop.

Holders

As of April 11, 2016, there were 12,250,000 shares of our common stock outstanding. Our shares of common stock are held by approximately 25 stockholders of record.

Dividend Policy

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.

Recent Sales of Unregistered Securities

Set forth below is information regarding shares of capital stock issued by us during the period since our inception on June 26, 2014. Also included is the consideration received by us for such shares and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed. The information set forth below with respect to our common stock gives effect to a 2.7872582-for-1 stock split effected in the form of a stock dividend on September 21, 2015.

In June 2014 in connection with our organization, we issued (i) 5,658,134 shares of common stock for $0.001 per share, and warrants to purchase an additional 6,097,128 shares of common stock at an exercise price of $0.90 per share for $0.0001 per warrant, for an aggregate purchase price and total consideration of $2,248.75, to HCFP/Capital Partners III LLC and (ii) 2,424,915 shares of common stock for $0.001 per share, and warrants to purchase an additional 2,613,054 shares of common stock at an exercise price of $0.90 per share for $0.0001 per warrant, for an aggregate purchase price and total consideration of $963.75, to Pavilion Venture Partners LLC.

In July 2014, we issued an aggregate of 418,089 units, each consisting of one share of common stock and one warrant to purchase one share of common stock, for $75,000 in cash, or a purchase price of $0.18 per unit, to nine investors.

In October 2014, HCFP/Capital Partners III LLC and Pavilion Venture Partners LLC agreed to contribute 627,133 warrants back to the Company at no cost.

In November 2014, we issued an aggregate of 2,355,233 units, each consisting of one share of common stock and one warrant to purchase one share of common stock, for $845,000 in cash, or a purchase price of $0.36 per unit, to 13 investors.

During August 2015, we issued 97,554 warrants in exchange for services.

During September 2015, we issued an aggregate of 1,393,629 shares of common stock from the exercise of warrants receiving approximately $1.25 million of proceeds.

In September 2015, we effectuated a forward stock split of 2.7872582-for-1 by way of a stock dividend of 1.7872582 shares for each outstanding share, resulting in there being 12,250,000 shares of common stock outstanding.

All of the securities described above were issued pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder, as fewer than 35 investors were non-accredited investors. No underwriting discounts or commissions were paid with respect to such sales.

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 financial condition and results of operations should be read together with our 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 that involve 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 that 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.

Overview

We are a 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 and time efficiency. Since our inception on June 26, 2014, our activities have focused on advancing the lead projects in our pipeline, recruiting our new Chief Financial Officer, Board of Directors and Medical Advisory Board, raising initial working capital through two private placements, preparing for our initial public offering and protecting the Company's intellectual property.

With regard to the five lead projects in our pipeline — PortIO, Caldus, CarpX, NextCath and NextFlo:

- we have filed provisional patent applications for each project, a final nonprovisional patent application for PortIO and acquired a patent and related patent applications for NextFlo;
- we have performed a proof-of-concept animal study for project PortIO, demonstrating good flow through a working prototype at multiple access points;
- we have engaged a design engineering firm which has completed design work on PortIO, delivered working prototypes and transitioned the project to our contract manufacturing partner which has initiated the process of building a commercial product;
- we have performed computerized flow and thermal fine element analysis simulations and analyses for the NextFlo and Caldus projects;
- we have engaged a design and contract manufacturing firm and have developed working prototypes of the infusion device and balloon catheters for the Caldus project, including one specifically designed for renal denervation, and have completed benchtop animal organ testing of the working prototype;

- we have engaged a balloon catheter design and contract manufacturing firm and have tested working prototypes of the CarpX balloon catheter in a benchtop tissue model of the transverse carpal ligament as well as in cadavers;

- we have engaged a design and contract manufacturer with experience in extrusions which has initiated 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;

- we have engaged a full-service regulatory consulting firm which has provided us with its analysis on the likely path to obtaining regulatory clearance on all five lead projects and is engaging with our design and contracting manufacturing partners to establish the appropriate regulatory processes and procedures;

- we have completed flow simulation work on the new NextFlo concept focused on the flow accuracy of our variable resistor design and we have initiated design work on the current embodiment.

We have never been profitable and have incurred net losses since inception. Our net losses were $1,776,600 and $274,384 for the year ended December 31, 2015 and for the period from June 26, 2014 (inception) through December 31, 2014, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from formation and operating costs associated with establishing and advancing our operations. For the year ended December 31, 2015, we incurred $489,327 of research and development costs and approximately $1.3 million of formation and operating costs. For the period from June 26, 2014 (inception) through December 31, 2014, we incurred $11,145 of research and development costs and $263,239 of formation and operating costs.

We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory clearances for, our product candidates, hire additional personnel and initiate commercialization of any approved products. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of any commercial products, we may not become profitable. If we fail to become profitable, or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Through the date of this Annual Report on Form 10-K, we have received aggregate net proceeds from sales of our equity securities of $2,119,212.

Financial operations overview

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 product candidates.

Formation and operating costs

Formation and operating costs consist primarily of salaries and related costs for personnel, including travel expenses, for our employees in executive and research and development functions. Other formation and operating costs include 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 that our formation and operating costs will increase in the future as we increase our headcount to support our continued research and development and the potential commercialization of our product candidates. We also anticipate increased expenses related to costs associated with 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 candidate, 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 costs

Research and development costs consist principally of internal and external costs incurred for the development of our product candidates and include:

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

Research and development costs are expensed as incurred.

From June 26, 2014 (inception) through December 31, 2015, we incurred $500,472 in research and development costs. We plan to increase our research and development expenses for the foreseeable future as we continue development of our product candidates. Our current and planned research and development activities include the following:

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

The successful development of our product candidates 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;
- the cost, timing and our ability to manufacture sufficient prototype and commercial supplies for our product candidates; and
- the risks disclosed in the section entitled “Risk Factors” beginning on Page 17 of this Annual Report on Form 10-K.

Income Taxes

We provide for federal and state income taxes currently payable, as well as those deferred because of temporary differences between reporting income and expenses for financial statement purposes versus 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 rates is recognized as income or expense in the period of the change. 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 that some portion or all of the deferred tax assets will not be realized. If we determine that it is more likely than not that certain future tax benefits may not be realized, a valuation allowance will be recorded against deferred tax assets that are 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 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, 2015, we concluded that a full valuation allowance is necessary for our deferred tax assets.

As of December 31, 2015, our federal net operating loss carryforward was approximately $1.2 million. If not utilized, the federal net operating loss carryforward will expire in 2035.

Critical accounting policies and significant judgements and estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principals generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reporting amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. 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.

Use of Estimates: Common Stock and Warrant Valuation

The fair value of the shares of our common stock and underlying warrants has historically been determined by our Board of Directors. Because there has been no public market for our common stock, our Board of Directors has determined the fair value of our common stock and warrants by considering a number of objective and subjective factors, including valuations of comparable companies and the general and industry-specific economic outlook.

Research and Development Expenses

Research and development expenditures are charged to research and development expense as incurred. Research and development costs include costs related to the Company's various contract research suppliers, engineering studies, supplies and outsourced testing and consulting as well as rental costs for access to certain facilities at one of the Company's contract research suppliers.

Controls and Procedures

We are not currently required to maintain an effective system of internal controls as defined by Section 404 of the Sarbanes-Oxley Act. We will be required to comply with the internal control requirements of the Sarbanes-Oxley Act for the fiscal year ending December 31, 2016. As of the date of this Annual Report on Form 10-K, we have not completed an assessment, nor have our auditors tested our systems of internal controls.

Off-Balance Sheet Arrangements; Commitments and Contractual Obligations

During the year ended December 31, 2015 and for the period from June 26, 2014 (inception) through December 31, 2014, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K nor did we have any commitments or contractual obligations.

JOBS Act

The Company is an "emerging growth company", or EGC as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, 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.

Subject to certain conditions, as an EGC, we intend to rely on certain exemptions under the JOBS Act, including without limitation (i) from the requirement to provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 and (ii) from any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an EGC until the earliest of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; and (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Results of operations

Comparison of the year ended December 31, 2015 and the period from June 26, 2014 (inception) to December 31, 2014

	Year ended December 31, 2015	Period from June 26, 2014 (inception) to December 31, 2014
Revenues	$ —	$ —
Operating expenses:		
Formation and operating costs	1,287,273	263,239
Research and development costs	489,327	11,145
Total operating costs	1,776,600	274,384
Net loss	$ (1,776,600)	$ (274,384)

Revenues

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.

Formation and operating costs

Our formation and operational costs for the year ended December 31, 2015 and for the period from June 26, 2014 (inception) to December 31, 2014 totaled $1,287,273 and $263,239, respectively. This represents an aggregate increased spending of approximately $1,024,000 between the year ended December 31, 2015 and the period from June 26, 2014 (inception) through December 31, 2014. In total, executive compensation costs, under employment contracts in place prior to November 1, 2015, increased by approximately $258,000 from $200,000 during the period from June 26, 2014 (inception) through December 2014 to approximately $458,000 during the year ended December 31, 2015. Executive

compensation included $333,333 and $200,000, of non-cash expense attributable to contributed services by Dr. Aklog, our Chief Executive Officer, and Richard Salute, our former Chief Financial Officer during the year ended December 31, 2015 and for the period ended December 2014, respectively. Additionally, compensation and benefits payable under our respective new employment agreements with our Chief Executive Officer and new Chief Financial Officer began in November 2015 and totaled approximately $129,000 during the year ended December 31, 2015. The remaining increase in formation and operational costs during the year ended December 31, 2015 is primarily attributed to increased spending of approximately $208,000 to support the advancement of our intellectual property portfolio; increased spending on marketing services of approximately $141,000 to develop our corporate website, corporate video and other related corporate branding initiatives, as well as $122,000 of non-recurring executive search fees and initial payments of $60,000 under a management services agreement with HCP/Advisors LLC (see Item 11 for further information on this agreement). During the year ended December 31, 2015, the Company also incurred additional expense increases of $23,000 for regulatory consulting, $19,000 for insurance, $45,000 for business travel and meals as well as increased office related costs of $19,000 when compared to the period from June 26, 2014 (inception) through December 31, 2014.

At December 31, 2015, the Company determined that compensation due to the Company's Chief Executive Officer under his amended November 2014 employment agreement and contingent upon completion of the Company's initial public offering was probable of being paid given the status of the Company's initial public offering. Accordingly, $240,000, plus the CEO's guaranteed 50% annual bonus of $124,000 were recognized as liabilities at December 31, 2015.

Research and development costs

Research and development costs increased by approximately $478,000 from $11,000 during the period from June 26, 2014 (inception) through December 31, 2014 to approximately $489,000 during the year ended December 31, 2015. This increase was due to contract research spending on all five of our product candidates during the year ended December 2015 as compared to limited early product design costs and testing on our PortIO product candidate incurred during the period from June 26, 2014 (inception) through December 31, 2014. We expect research and development costs to increase as we advance our five product candidates toward the point of filing 510(k) applications seeking regulatory clearance during 2016 and early 2017.

Liquidity and capital resources

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

	Year ended December 31, 2015	Period from June 26, 2014 (inception) to December 31, 2014
Net cash provided by (used in):		
Operating activities	$ (1,249,605)	$ (30,135)
Investing activities	—	—
Financing activities	1,177,796	869,212
Net (decrease) increase in cash	$ (71,809)	$ 839,077

Net cash used in operating activities

The net cash used in operating activities was $1,249,605 for the year ended December 31, 2015 and consisted of a net loss of $1,776,600 adjusted for non-cash items, including contributed services of $133,333 plus a net increase in operating assets and liabilities of $393,662. The significant items in the change in operating assets and liabilities include increases in accounts payable and accrued expenses of $100,572 and $298,851, respectively, partially offset by an increase in prepaid expenses and other current assets of $5,761.

For the period from June 26, 2014 (inception) through December, 31, 2014, net cash used in operating activities was $30,135 and consisted of a net loss of $274,384 adjusted for non-cash contributed services of $200,000 and a net increase in operating assets and liabilities of $44,249. The significant items in the change in operating assets and liabilities included increase in accounts payable of $47,249 which was partially offset by an increase in prepaid expenses and other current assets of $3,000.

Net cash provided by (used in) investing activities

No investing related cash flows occurred during the year ended December 31, 2015 or during the period from June 26, 2014 (inception) through December 31, 2014.

Net cash provided by financing activities

Net cash provided by financing activities for the year ended December 31, 2015 was $1,177,796, consisting of $1,250,000 in proceeds from the exercise of warrants during September 2015 offset by approximately $72,000 of payments of deferred offering costs related to our planned IPO. Net cash provided by financing activities from June 26, 2014 (inception) through December 31, 2014 was $869,212 consisting of the sale of common stock and warrants for $923,212 offset by payments of offering costs of $54,000. Since inception, the Company has raised $2,119,212 through the sale of stock and warrants to purchase common shares.

Funding requirements

We expect our costs to increase compared to prior periods in connection with our ongoing activities, particularly as we continue research and development, continue to develop our intellectual property portfolio and seek regulatory approvals for our product candidates. In anticipation of regulatory approval for any of our product candidates, we expect to incur significant pre-commercialization expenses related to product sales, marketing, distribution and manufacturing.

The expected use of our cash represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development programs, the status of, and results from, engineering studies, the potential need to conduct any clinical trials to obtain approval of our product candidates for all intended indications, as well as any technology acquisitions or additional collaborations into which we may enter with third parties for our product candidates and any unforeseen cash needs. As a result, our management retains broad discretion over the allocation of our existing cash and cash equivalents.

Based on our planned use of our cash, we estimate that such funds will be sufficient to enable us to complete and submit 510(k) applications for two of our five initial product candidates, advance the remaining three of our initial five product candidates toward their respective 510(k) submissions, continue to develop and enhance our intellectual property portfolio supporting our initial five candidates and fund our operating costs and capital expenditure requirements into early 2017. The foregoing estimate is based on assumptions the may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Contractual obligations and commitments

At December 31, 2015, the Company did not have any long term contractual obligations but did maintain a month-to-month rental arrangement with one of its contract research supplies for access to certain research and office space at that supplier for a monthly rental fee of $1,000 per month. This rental arrangement is cancellable by the Company or its supplier at any time.

On January 29, 2016, the Company entered a lease agreement for its corporate office location that provides for two consecutive six month terms beginning on February 1, 2016. The lease agreement provides for rental payments of $9,500 per month.

Effect of Inflation and Changes in Prices

We do not believe that 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 financial statements, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-19 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 principal financial and accounting officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2015, our principal executive officer and principal financial and accounting officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's annual report on internal control over financial reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for "emerging growth companies."

Changes in internal control over financial reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The following table sets forth the name, age and position of each of our executive officers, key employees and directors as of April 11, 2016.

Name	Age	Position
Lishan Aklog, M.D.	50	Chairman and Chief Executive Officer
Michael J. Glennon	50	Vice Chairman and Director
Richard F. Fitzgerald	52	Chief Financial Officer and Secretary
Brian J. deGuzman, M.D.	52	Chief Medical Officer
Ira Scott Greenspan	57	Senior Advisor and Director
James L. Cox, M.D.	73	Director
Joshua R. Lamstein	46	Director
Ronald M. Sparks	61	Director
David Weild IV	59	Director

Lishan Aklog, M.D., has been our Chairman and Chief Executive Officer since our inception. Dr. Aklog has also served as Co-Managing Partner of HCFP, a financial advisory and investment firm, since May 2014, and as a co-founding Partner of both Pavilion Holdings Group ("PHG"), a medical device holding company, since its inception in 2007 and Pavilion Medical Innovations ("PMI"), a venture-backed medical device incubator, since its inception in 2009. Dr. Aklog has been a Senior Advisor and/or Director of PMI portfolio companies Saphena Medical Inc. since February 2013, Kaleidoscope Medical LLC since February 2013 and Cruzar Medsystems Inc. since July 2013. Dr. Aklog previously served as Chairman and Chief Technology Officer of Vortex Medical Inc., a PHG portfolio company, from its inception in 2008 until its acquisition in October 2012 by AngioDynamics Inc. (Nasdaq: ANGO) for $55 million. Dr. Aklog has been a consultant to AngioDynamics since 2012, Biomet Inc. since 2009 and Atricure Inc. (Nasdaq: ATRC) since 2007. He previously served as a consultant to Edward Lifesciences Corp. (NYSE: EW), from 2007 to 2012 and On-X Life Technologies Inc. from 2009 to 2012. Dr. Aklog also previously served on the Scientific Advisory Boards of numerous leading medical device companies, including Medtronic, St. Jude Medical, Guidant Cardiac Surgery (now, Maquet Cardiovascular) and Cardiovations (then, a division of Johnson & Johnson). Dr. Aklog is an inventor on 11 issued patents and over 30 patent applications, including the core patents of Vortex Medical's AngioVac system. Prior to entering the medical device industry full-time in 2012, Dr. Aklog was, from 2006 to 2012, Associate Professor of Surgery, Chief of Cardiovascular Surgery and Chair of The Cardiovascular Center at St. Joseph's Hospital and Medical Center's Heart and Lung Institute in Phoenix, Arizona. From 2002 to 2006, Dr. Aklog was Assistant Professor of Cardiothoracic Surgery, Associate Chief of Cardiac Surgery and Director of Minimally Invasive Cardiac Surgery at Mount Sinai Medical Center in New York. From 1999 to 2002, Dr. Aklog was Assistant Professor of Surgery at Harvard Medical School, Director of the Cardiac Surgery Research Laboratory and an attending cardiac surgeon at Brigham and Women's Hospital in Boston. Dr. Aklog received his clinical training in general and cardiothoracic surgery at Brigham and Women's Hospital and Boston Children's Hospital, during which he spent two years as the Medtronic Research Fellow at Harvard Medical School's Cardiac Surgery Research Laboratory. He was then was awarded the American Association of Thoracic Surgery Traveling Fellowship pursuant to which he received advanced training in heart valve surgery under renowned cardiac surgeons Sir Magdi Yacoub at Harefield Hospital in London and Professor Alain Carpentier at L'Hopital Broussais in Paris. Dr. Aklog is a co-author on 38 peer-reviewed articles and 10 book chapters. He has served on the Editorial Board of the *Journal of Cardiothoracic Surgery* since 2006. He is a member of numerous professional societies and has been elected to the American Association of Thoracic Surgery. He served on the Board of Directors of the International Society for Minimally Invasive Cardiothoracic Surgery from 2006 to 2009 and as President of the 21st Century Cardiothoracic Surgery Society in 2011. Dr. Aklog was recognized as one of America's Top Doctors in the *Castle Connolly Guide* from 2002 to 2013. Dr. Aklog received his A.B., *magna cum laude,* in Physics from Harvard University, where he was elected to Phi Beta Kappa. Dr. Aklog received his M.D., *cum laude*, from Harvard Medical School.

We believe Dr. Aklog is well-qualified to serve on our Board of Directors due to his extensive experience in founding and building successful medical device companies, his distinguished career as an academic cardiac surgeon, his recognition as a thought leader and innovator both as a surgeon and a medical device entrepreneur and his widespread relationships in the healthcare and medical device communities.

Michael J. Glennon has served as our Vice Chairman and a Director since October 2014. Mr. Glennon has served as a co-founding Partner of both PHG and PMI since their respective inceptions in 2007 and 2009 and also serves as Chairman and Chief Executive Officer of PMI. Mr. Glennon has served as President, Chief Executive Officer and a director of Saphena Medical since February 2013 and Cruzar Medsystems since July 2013 and as a director of Kaleidoscope Medical since January 2013. Mr. Glennon was the President and Chief Executive Officer of Vortex Medical from its inception in 2008 until its acquisition in October 2012 by AngioDynamics. From 2005 to 2007, Mr. Glennon was Senior Vice President — Sales and Marketing for Accellent Inc., a market-leading provider of outsourced precision manufacturing and engineering services to the medical device industry. Accellent was a portfolio company of DLJ Merchant Banking Partners and was acquired in 2005 by KKR and Bain Capital. From 2004 to 2005, Mr. Glennon was a Cardiac Rhythm Management District Manager at Medtronic. From 1996 to 2004, Mr. Glennon was a Sales Manager at Guidant including seven years at Guidant Cardiac Surgery (now, Maquet Cardiovascular). He was instrumental in the launch and rapid growth of VasoView, the first endoscopic vessel harvesting technology, which became the standard of care in coronary bypass surgery. From 1993 to 1995, Mr. Glennon worked for Origin Medsystems which was acquired by Eli Lilly and subsequently spun out as part of Guidant. Previously, Mr. Glennon was with Stryker Endoscopy and Storz Instrument Company. Mr. Glennon received his B.S. in Business Administration from the University of New Hampshire.

We believe Mr. Glennon is well-qualified to serve on Board of Directors due to his significant experience in the marketing and sale of a broad range of medical devices, his expertise in the development and manufacturing of medical devices, his experience launching, building and running successful medical device companies, and his extensive relationships in the medical device industry and the broader medical community.

Richard F. Fitzgerald has served as our Chief Financial Officer since October 2015. From April 2009 to October 2015, Mr. Fitzgerald was Chief Financial Officer of TechPrecision Inc. (OTCQB: TPCS), a global manufacturer of precision large-scale components for the medical device, defense and energy industries. From 2002 to 2008, he served in various senior financial roles culminating in the role of Vice President and Chief Financial Officer of Nucleonics Inc., a venture-backed biotechnology company and early pioneer in the field of RNAi therapeutics whose assets were sold to Alnylam Pharmaceuticals Inc. (Nasdaq: ALNY) in 2008. During his tenure at Nucleonics, he served as co-Chair of the Biotechnology Industry Organization's (BIO) National CFO and Tax VP Committee, supporting federal tax and finance lobbying efforts, and was active in the Association of Biotechnology Financial Officers. From 1995 to 2002, Mr. Fitzgerald served in the corporate development office and, from 1998 to 2002, as Director of Corporate Development for Exelon Corporation (NYSE: EXC) (formerly PECO Energy), an energy generator and distributor, where he managed business development efforts, mergers and acquisitions, including the $18 billion merger with Unicom and the roll-up of utility contractors which led to the formation of InfraSource (NYSE: IFS). From 1985 to1995, Mr. Fitzgerald served as a Senior Manager in the Audit and Transaction Services Group of Coopers & Lybrand LLP (now PricewaterhouseCoopers). He is a member of the American and Pennsylvania Institutes of Public Accounting and a founding member of the Bucknell University Business Advisory Board. Mr. Fitzgerald received his B.S. in Business Administration and Accounting from Bucknell University.

Brian J . deGuzman, M.D. has served as our Chief Medical Officer since October 2014 and served as a Director from October 2014 to January 2015. Dr. deGuzman has served as a co-founding Partner of PHG and PMI since their respective inceptions in 2007 and 2009. Dr. deGuzman has been President and Chief Executive Officer of Kaleidoscope Medical since its founding in February 2013 and has also served as a Senior Advisor to PMI portfolio companies Saphena Medical since February 2013 and Cruzar Medsystems since July 2013.
Dr. deGuzman served as Chief Medical Officer of Vortex Medical from inception until its sale to AngioDynamics, for whom he continues to serve as a consultant. Dr. deGuzman has also been a

consultant to Biomet and Atricure since 2007, and on the Revascularization Scientific Advisory Board of Maquet Cardiovascular (formerly Boston Scientific and Guidant Cardiac Surgery) since 2006. During his surgical career, Dr. deGuzman also served as a consultant to various medical device companies, including Edward Lifesciences. Prior to moving into the medical device industry full-time in 2012, Dr. deGuzman was Assistant Professor of Surgery, Associate Chief of Cardiovascular Surgery, and Surgical Director of the Atrial Fibrillation Clinic at St. Joseph's Hospital and Medical Center's Heart and Lung Institute from 2006 to 2012. From 2002 to 2006, Dr. deGuzman was Assistant Professor of Surgery at Tufts University School of Medicine and an attending cardiac surgeon at the Lahey Clinic Medical Center in Massachusetts. From 2001 to 2002, Dr. deGuzman was a Clinical Associate of Cardiac Surgery at the Cleveland Clinic. Dr. deGuzman received his general surgical training at the University of Connecticut/Hartford Hospital, was a Research Fellow at Harvard Medical School's Cardiac Surgery Research Laboratory, and received his cardiothoracic surgical training at Brigham and Women's Hospital and Boston Children's Hospital. Dr. deGuzman was recognized as a Top Doctor in Cardiovascular Surgery by *Boston Magazine*. Dr. deGuzman received his B.S. in Biology from Boston College and his M.D. from Georgetown University School of Medicine.

Ira Scott Greenspan has been a Senior Advisor since our inception and a Director since January 2015. Mr. Greenspan serves as Co-Managing Partner of HCFP. For more than 20 years, Mr. Greenspan has been a senior officer and/or director of HCFP and its predecessors and related entities, including having served from 1999 to 2009 as Co-Managing Partner of HCFP/Brenner Equity Partners, the indirect majority shareholder of HCFP/Brenner Securities LLC, a middle market investment bank originally founded by senior officers of Drexel Burnham Lambert. Prior to entering the financial services industry in 1992, Mr. Greenspan practiced corporate and securities law as a Partner of the New York predecessor of Blank Rome, a leading law firm. Mr. Greenspan started his legal career at the New York predecessor of Sidley Austin, also a leading law firm. During law school, Mr. Greenspan was chosen to participate in an internship program in the New York Regional Office (Division of Corporation Finance, Branch of Small Issues) of the Securities and Exchange Commission. Mr. Greenspan received his B.A., with distinction for outstanding academic performance, from Harpur College/Binghamton University, where he was elected to Phi Beta Kappa and Pi Sigma Alpha and was the recipient of a University Foundation Award recognizing him as one of the top students in his graduating class. He received his J.D. from New York University School of Law, where he was selected to be on the Editorial Board of the *Annual Survey of American Law*, an honorary law journal.

We believe Mr. Greenspan is well-qualified to be on our Board of Directors due to his significant experience advising entrepreneurial growth companies as both a financial services executive and corporate and securities lawyer, his pioneering role in numerous innovative corporate finance products and strategies, his investment experience with early-stage companies and his extensive relationships in the financial community.

James L. Cox, M.D. has served as a Director since January 2015. Dr. Cox is a cardiac surgeon, scientific investigator and medical device entrepreneur who pioneered the field of surgical intervention for cardiac arrhythmias, including the eponymous Cox-Maze procedure for the treatment of atrial fibrillation. From 1983 to 1997, Dr. Cox served as Professor of Surgery and Chief of the Division of Cardiothoracic Surgery at Washington University School of Medicine and Cardiothoracic Surgeon-in-Chief at Barnes Hospital in St. Louis. During this tenure, he became the first Evarts A. Graham Professor of Surgery and Vice-Chair of the Department of Surgery. He is currently the Evarts A. Graham Professor of Surgery Emeritus. Dr. Cox was also previously Professor and Chairman of the Department of Thoracic and Cardiovascular Surgery at Georgetown University Medical Center and Associate Professor of Surgery at Duke University Medical Center. Dr. Cox has had a distinguished and highly productive academic career. He has published 360 peer-reviewed scientific articles and has served on the editorial boards of numerous journals, including *Circulation,* the *Journal of Thoracic and Cardiovascular Surgery,* the *Annals of Surgery*, and the *Journal of Electrophysiology.* His laboratory has received continuous NIH funding for its research on the surgical treatment of cardiac arrhythmias. Dr. Cox has served in leadership positions at numerous professional organizations. He was the 81st President of the American Association of Thoracic Surgery and a director of the American Board of Thoracic Surgery. He has been invited to lecture and perform surgery as a visiting professor at dozens of institutions around the world. He has received numerous awards and honors for his clinical and scientific work, most notably as one of 30 "Pioneers in Thoracic and

Cardiovascular Surgery" at a ceremony commemorating the 50th anniversary of the specialty. Dr. Cox holds 15 issued patents. He has been instrumental in the founding of six medical device companies, including Epicor Medical, which was acquired by St. Jude Medical in 2004 for $200 million, and 3F Therapeutics, which was acquired in 2006 by ATS Medical for $40 million. At such time, he became Medical Director of ATS Medical, which was subsequently acquired by Medtronic in 2010 for $370 million. Dr. Cox has served on numerous scientific advisory boards, including Medtronic, St. Jude Medical, Atricure and CorMatrix. He is also the Founder and Chairman of the Board of Directors of the World Heart Foundation, a not-for-profit organization devoted to improving access to cardiac surgery, which is active in over 75 developing countries around the world. Dr. Cox received his general and cardiothoracic surgical training at Duke University School of Medicine, during which time he spent two years in the U.S. Army Medical Corps. Dr. Cox received his M.D. from the University of Tennessee, where he received the Alpha Omega Alpha Distinguished Graduate Award as the outstanding student in his class.

We believe Dr. Cox is well-qualified to serve on our Board of Directors due to his distinguished career as a world-renowned cardiac surgeon and scientific investigator, his recognition as a thought leader and innovator both as a surgeon and medical device entrepreneur, his extensive experience in the medical device industry and his widespread relationships in all segments of the healthcare community.

Joshua R. Lamstein has served as a Director since January 2015. Mr. Lamstein has served as a Partner and Chief Operating Officer of HCFP since July 2014. Mr. Lamstein has been a Partner of KEC Ventures, an early-stage venture capital firm, since July 2014. Mr. Lamstein has also been a General Partner of Isoseles Madefire Investors, LLC since July 2013 and BriefCam Investments L.P. since December 2012, each a special purpose vehicle created to invest in an early-stage technology company. Since June 2013, Mr. Lamstein has been a director of Penske Media Group, a global media company, as a designee of Quadrangle Group, a private equity firm. In August 2010, Mr. Lamstein co-founded Soli, a global mobile marketing company, and served as its Chief Operating Officer until its acquisition in November 2012 by Acision Nederland B.V., a leading SMS provider to the world's largest telecommunication companies. Mr. Lamstein was a founding member of GF Capital Private Equity Fund in 2004 and served as a Director from 2004 to 2008 and a Managing Director from 2008 to September 2010. In 2004, Mr. Lamstein was also a Portfolio Consultant to a family investment office. From 2000 to 2003, Mr. Lamstein was a Partner of LMS Capital, a FTSE-listed investment trust focused on private equity and venture capital investments and established the trust's U.S. operations. Since 1999, Mr. Lamstein has been a Senior Advisor to John Snow Incorporated, a leading public healthcare consulting firm, having also served as its interim CFO from 1999 to 2000. Mr. Lamstein previously worked in London for Apollo Advisors, a global private equity firm. Mr. Lamstein started his financial services career as an investment banker for Lehman Brothers in London and New York. Mr. Lamstein received his B.A., with honors, from Colgate University and his M.B.A. from the MIT Sloan School of Management.

We believe Mr. Lamstein is well-qualified to be on our Board of Directors due to his broad experience in private equity, venture capital, and investing in and managing early ventures, his widespread relationships in the private equity and venture capital communities and his knowledge of public healthcare.

Ronald M. Sparks has served as a Director since January 2015. Mr. Sparks has more than 37 years of executive experience in the medical device industry and has launched over 50 products across a wide spectrum of specialties, including orthopedics, endoscopy, wound management, cardiology, interventional radiology, diagnostic imaging, ophthalmology and otology. From 2007 to October 2013, he served as a Healthcare Industry Executive at Avista Capital Partners, a private equity firm. Mr. Sparks served as Chairman and Chief Executive Officer of Navilyst Medical Inc., which was formed by Avista Capital to acquire the fluid management and venous access business units of Boston Scientific, from its inception in 2008 until its acquisition in May 2012 by AngioDynamics for $372.0 million. From 2003 to 2007, he served as President, Chief Executive Officer and a director of Accellent, a market-leading provider of outsourced precision manufacturing and engineering services to the medical device industry. Accellent was a portfolio company of DLJ Merchant Banking Partners and was acquired in 2005 by KKR and Bain Capital. During his tenure at Accellent, he was recognized as the Credit Suisse/DLJ Merchant Bank 2005 CEO of The Year. From 1986 to 2003, he served in various leadership roles at Smith & Nephew as a member of the Group Executive Committee, President of the Endoscopy Division, President of the Wound Management Division and Vice President of Finance. Earlier in his career, he served in various finance roles at Richards Medical,

Dyonics and Union Carbide Imaging. Mr. Sparks is a fellow of the American Sports Medicine Institute, a Trustee of the Arthroscopy Association of North America Education Foundation and Honorary Lifetime Member of the International Society of Arthroscopy, Knee Surgery and Orthopedic Sports Medicine. He has previously served on numerous boards and industry councils, including AdvaMed, the National Subacute Care Association, the American College of Foot and Ankle Surgeons, the American Council of Orthopedic Surgeons and the Society of Interventional Radiology. Mr. Sparks received his B.S. in Finance and Accounting from the University of Massachusetts and attended the INSEAD Advanced Management Program at the European Institute of Business Administration in Fontainebleau, France.

We believe Mr. Sparks is well-qualified to serve on our Board of Directors due to his executive leadership roles at numerous medical device companies, his history of success in launching over 50 new medical device products in 16 years, his extensive experience in acquiring and integrating 14 medical device companies over 15 years, his execution of public financings, and his strong relationships in the medical community and with private equity and investment banking firms active in the medical device space.

David Weild IV has served as a Director since February 2015. He has been the founding Chairman and Chief Executive Officer of Weild & Co., a technology-driven capital facilitation platform, since 2013, and of its broker-dealer subsidiary, since 2003. Mr. Weild also served as Senior Advisor — Capital Markets to Grant Thornton LLP, a leading public accounting firm, from 2008 to 2012. Previously, Mr. Weild served as Vice Chairman, Executive Vice President and Head of Listed Companies, and a member of the Executive Committee of The Nasdaq Stock Market from 2000 to 2003. Prior to joining Nasdaq, from 1987 to 2000, Mr. Weild held positions of increasing responsibility at Prudential Securities Inc., including Vice President and Equity Syndicate Manager, Managing Director and Head of the Global Equity Transaction Groups, Managing Director and Head of Corporate Finance and President of PrudentialFinancial.com, including PrudentialSecurities.com. Mr. Weild is a recognized expert on capital formation and capital markets structure and has co-authored a number of definitive white papers, studies and articles which have been cited by legislators, regulators, academics, the IPO Task Force, the Equity Capital Formation Task Force and the White House Jobs Council and which are widely regarded as having served as catalysts for reforms and new legislation, including the JOBS Act. Mr. Weild has testified before Congress and the SEC, most recently at the SEC Advisory Committee on Small and Emerging Companies. Mr. Weild has also presented to the Organization of Economic Cooperation and Development (OECD) about the role of stock market reforms in driving economic growth. Mr. Weild received his B.A. from Wesleyan University and his M.B.A. from New York University Stern School of Business and also studied at the Sorbonne and on exchange at the Ecoles des Hautes Etudes Commerciales (HEC Paris) and the Stockholm School of Economics.

We believe Mr. Weild is well-qualified to serve on our Board of Directors due to his extensive experience in corporate finance, including more than 1,000 equity offerings during his career, his deep knowledge and recognized leadership in capital formation and capital markets structure and his widespread relationships in the financial community.

Our Board of Directors is divided into three classes with only one class of directors being elected in each year and each class serving a three-year term. The term of office of the first class of directors, consisting of Mr. Sparks, will expire at our first annual meeting of stockholders. The term of office of the second class of directors, consisting of Dr. Cox and Messrs. Lamstein and Weild, will expire at the second annual meeting. The term of office of the third class of directors, consisting of Dr. Aklog and Messrs. Glennon and Greenspan, will expire at the third annual meeting.

Conflicts of Interest

In order to minimize potential conflicts of interest which may arise from the corporate affiliations described below, each of Dr. Aklog, Mr. Glennon and Dr. deGuzman has contractually agreed, pursuant to a written agreement with us, until such time as he ceases to be an officer, to present to us for our consideration, prior to presentation to any other entity, any suitable business opportunity which may reasonably be required to be presented to us, subject to the existing pre-existing fiduciary obligations set forth below.

As an affiliate of Saphena Medical, Kaleidoscope Medical and Cruzar Medsystems, Mr. Glennon may have a fiduciary responsibility to present certain business opportunities to such entities within their specific lines of business. Saphena Medical’s line of business is endoscopic vessel harvesting, Kaleidoscope

Medical's is inferior vena caval filters and Cruzar Medsystems' is peripheral vascular intervention for chronic total occlusions. Accordingly, it is possible Mr. Glennon may present opportunities to such entities prior to presenting them to us.

As an affiliate of Kaleidoscope Medical, Dr. deGuzman may have a fiduciary responsibility to present certain business opportunities to this entity within its line of business, namely inferior vena caval filters. Accordingly, it is possible he may present opportunities to Kaleidoscope Medical prior to presenting them to us.

Although Drs. Aklog, deGuzman and Mr. Glennon are affiliates of PHG and PMI, there is no potential conflict with them presenting corporate opportunities to these entities over us. PHG is a holding company which holds their stakes in existing entities but does not invest in new companies. Its operating agreement explicitly states that they do not have an obligation to present corporate opportunities to PHG. Similarly, PMI is currently an intellectual property holding company without any ongoing business. Accordingly, they have no fiduciary or contractual obligations to present corporate opportunities or assign intellectual property to either entity.

Audit Committee

Effective January 29, 2016, we established an audit committee of the Board of Directors, which consists of Messrs. Weild, Lamstein and Sparks, each of whom is an independent director under Nasdaq's listing standards. The audit committee's duties, which are specified in our Audit Committee Charter, include, but are not limited to:

- reviewing and discussing with management and the independent auditor the annual audited financial statements, and recommending to the board whether the audited financial statements should be included in our Form 10-K;
- discussing with management and the independent auditor significant financial reporting issues and judgments made in connection with the preparation of our financial statements;
- discussing with management major risk assessment and risk management policies;
- monitoring the independence of the independent auditor;
- verifying the rotation of the lead (or coordinating) audit partner having primary responsibility for the audit and the audit partner responsible for reviewing the audit as required by law;
- reviewing and approving all related-party transactions;
- inquiring and discussing with management our compliance with applicable laws and regulations;
- pre-approving all audit services and permitted non-audit services to be performed by our independent auditor, including the fees and terms of the services to be performed;
- appointing or replacing the independent auditor;
- determining the compensation and oversight of the work of the independent auditor (including resolution of disagreements between management and the independent auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or related work; and
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or reports which raise material issues regarding our financial statements or accounting policies.

Financial Experts on Audit Committee

The audit committee will at all times be composed exclusively of "independent directors" who are "financially literate" as defined under Nasdaq listing standards. Nasdaq listing standards define "financially literate" as being able to read and understand fundamental financial statements, including a company's balance sheet, income statement and cash flow statement.

In addition, we must certify to Nasdaq that the committee has, and will continue to have, at least one member who has past employment experience in finance or accounting, requisite professional certification in accounting, or other comparable experience or background that results in the individual's financial sophistication. The Board of Directors has determined that Messrs. Weild, Lamstein and Sparks qualify as an "audit committee financial expert," as defined under rules and regulations of the SEC.

Nominating Committee

Effective January 29, 2016, we established a nominating committee of the Board of Directors, which consists of Dr. Cox and Messrs. Lamstein and Sparks, each of whom is an independent director under Nasdaq's listing standards. The nominating committee is responsible for overseeing the selection of persons to be nominated to serve on our Board of Directors. The nominating committee considers persons identified by its members, management, stockholders, investment bankers and others.

Guidelines for Selecting Director Nominees

The guidelines for selecting nominees, which are specified in the Nominating Committee Charter, generally provide that persons to be nominated:

- should have demonstrated notable or significant achievements in business, education or public service;
- should possess the requisite intelligence, education and experience to make a significant contribution to the Board of Directors and bring a range of skills, diverse perspectives and backgrounds to its deliberations; and
- should have the highest ethical standards, a strong sense of professionalism and intense dedication to serving the interests of the stockholders.

The Nominating Committee will consider a number of qualifications relating to management and leadership experience, background and integrity and professionalism in evaluating a person's candidacy for membership on the Board of Directors. The nominating committee may require certain skills or attributes, such as financial or accounting experience, to meet specific board needs that arise from time to time and will also consider the overall experience and makeup of its members to obtain a broad and diverse mix of board members. The nominating committee does not distinguish among nominees recommended by stockholders and other persons.

Compensation Committee

Effective January 29, 2016, we established a compensation committee of the Board of Directors, which consists of Dr. Cox and Messrs. Lamstein and Weild, each of whom is an independent director under Nasdaq's listing standards. The compensation committee's duties, which are specified in our Compensation Committee Charter, include, but are not limited to:

- reviewing and approving on an annual basis the corporate goals and objectives relevant to our Chief Executive Officer's compensation, evaluating our Chief Executive Officer's performance in light of such goals and objectives and determining and approving the remuneration (if any) of our Chief Executive Officer's based on such evaluation;
- reviewing and approving the compensation of all of our other executive officers (including through our management services agreements described below);
- reviewing our executive compensation policies and plans;
- implementing and administering our incentive compensation equity-based remuneration plans;
- assisting management in complying with our proxy statement and annual report disclosure requirements;
- approving all special perquisites, special cash payments and other special compensation and benefit arrangements for our executive officers and employees;

- if required, producing a report on executive compensation to be included in our annual proxy statement; and
- reviewing, evaluating and recommending changes, if appropriate, to the remuneration for directors

Code of Ethics

In April 2015, we adopted a code of ethics that applies to all of our respective executive officers, directors and employees. The code of ethics codifies the business and ethical principles that govern all aspects of our business. This code of ethics is posted on our corporate website at www.pavm.com. In addition, we intend to post on our website disclosures that are required by law concerning any amendments to, or waivers from, any provision of our code of ethics.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and certain officers and holders of more than 10% of our common stock to file with the SEC initial reports of ownership of our common stock and other equity securities on Form 3 and reports of changes in such ownership on a Form 4 or Form 5. These Section 16 reporting persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. However, during the fiscal year ended December 31, 2015, we did not have any class of equity security registered under Section 12 of the Exchange Act, accordingly no reports were required to be filed pursuant to Section 16(a) by these Section 16 reporting persons with respect to our common stock during that fiscal year.

Item 11. Executive Compensation

This section describes the material elements of compensation awarded to, earned by or paid to each of our named executive officers. Our named executive officers for 2015 were Lishan Aklog, M.D. who serves as our Chairman and Chief Executive Officer, Michael J. Glennon who serves as our Vice Chairman, Richard F. Fitzgerald who serves as our Chief Financial Officer and Brian J. deGuzman, M.D. who serves as our Chief Medical Officer. This section also provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our executive officers and is intended to place in perspective the data presented in the tables and narrative that follow.

Summary Compensation Table

The following table sets forth the information regarding compensation awarded to, earned by or paid to our named executive officers during 2015 and 2014.

Name and principal position	Year	Salary	Equity awards[1]	Non-equity incentive plan compensation	All other compensation	Total
Lishan Aklog, M.D.	2015	$49,167[2][3]	$—[5]	$—[7]	$ 2,924[8]	$52,091
Chairman & Chief Executive Officer	2014	$ —[2]	$—	$—	$ —	$ —
Richard F. Fitzgerald	2015	$51,562[4]	$—[6]	—[7]	7,860[9]	$59,422
Chief Financial Officer						
Michael J. Glennon	2015	$ —	$—[5]	$—	$ —	$ —
Vice Chairman	2014	$ —	$—	$—	$ —	$ —
Brian J. deGuzman	2015	$ —	$—[5]	$—	$ —	$ —
Chief Medical Officer	2014	$ —	$—	$—	$ —	$ —

(1) The amounts reported in the "Equity awards" column reflect the aggregate fair value of share-based compensation awarded during the year computed in accordance with the provisions of Financial Accounting Standards Board Accounting Standard Codification Topic 718. During 2015 and 2014, we did not issue any options to our executive officers. However, during 2015, we committed to issue options to our executive officers upon consummation of our initial public offering as described below.

(2) Pursuant to Dr. Aklog's Employment Agreement, Dr. Aklog was to be paid an annualized base salary of $240,000 but the salary was only payable upon the completion of our initial public offering. Compensation payable to Dr. Aklog upon consummation of our initial public offering is $240,000 with $200,000 applicable to 2015 and $40,000 applicable to 2014.

(3) Pursuant to Dr. Aklog's Employment Agreement, as amended, Dr. Aklog's annualized base salary was increased from $240,000 to $295,000, effective as of November 1, 2015, and we commenced paying such salary as of that date.

(4) Mr. Fitzgerald joined the Company on October 26, 2015. Pursuant to his Employment Agreement, Mr. Fitzgerald's annualized base salary for 2015 was $275,000.

(5) We have committed to issue Dr. Aklog an option to purchase 278,726 shares of common stock upon consummation of our initial public offering. We have also committed to issue to each of Mr. Glennon, Dr. deGuzman and our Former CFO an option to purchase 278,726 shares, 278,726 shares and 55,745 shares of common stock upon closing of our initial public offering. When issued, these options will have an exercise price of $5.00 per share. No options were granted or outstanding during 2015.

(6) We are obligated under the employment agreement with Mr. Fitzgerald to issue him an option to purchase 125,000 shares of common stock upon consummation of our initial public offering. When issued, these options will have an exercise price of $5.00 per share. No options were granted or outstanding during 2015.

(7) Our executive officers are eligible for incentive compensation under employment agreements. Specifically, Dr. Aklog has a guaranteed bonus of 50% of his base salary beginning on January 1, 2016 and Mr. Fitzgerald is eligible to receive a bonus incentive of up to 35% of his base salary beginning on January 1, 2017. No incentive compensation was earned or awarded during 2015 and 2014. Dr. Aklog's 2015 guaranteed 50% bonus of $124,583 due on January 1, 2016 has been deemed as contingent upon consummation of our initial public offering.

(8) We funded $2,924 of health insurance premiums for Dr. Aklog.

(9) Mr. Fitzgerald received a temporary living allowance of $2,200 per month and we funded $3,460 of health insurance premiums for him.

Although we do not have a formal policy with respect to the grant of equity incentive awards to our named executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that our executives to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our named executive officers and, from time to time, may grant equity incentive awards to them in the form of stock options or other equity awards.

2015 outstanding option awards at fiscal year-end

We did not have any option grants awarded during 2015 nor any outstanding option awards at December 31, 2015 to our named executive officers. However, we have agreed to issue options to purchase 278,726 shares of common stock and 125,000 shares of common stock to Dr. Aklog and Mr. Fitzgerald, respectively, upon consummation of our initial public offering. We have also agreed to issue to each of Mr. Glennon and Dr. deGuzman an option to purchase 278,726 shares of common stock upon consummation of our initial public offering. Additionally we have agreed to issue an option to purchase 55,745 shares of our common stock to our Former CFO, upon consummation of our initial public offering. These options will be issued under our stock plan and when granted, will be exercisable at $5.00 per share and vest in equal increments over 36 months.

Employment agreements

Lishan Aklog

Effective November 1, 2014, we entered into an employment agreement with Dr. Aklog pursuant to which he serves as our Chief Executive Officer, which agreement was amended in November 2015. The

employment agreement is for a five-year term. Dr. Aklog receives a base salary of $295,000 per year, a guaranteed bonus beginning on January 1 of each year beginning on January 1, 2016 equal to 50% of his base salary and will be eligible to earn annual performance bonuses meeting certain objectives as determined by the Board of Directors; provided, however, that the base salary from November 1, 2014 to October 31, 2015 shall be paid at the rate of $240,000 per year and shall be paid only upon, and subject to, the consummation of our initial public offering.

Upon termination of employment, unless terminated by us without "cause" or by Dr. Aklog with "good reason" (as such terms are defined in the employment agreement), Dr. Aklog will be entitled only to his base salary through the date of termination, valid expense reimbursements and unused vacation pay. If terminated by us without "cause" or by Dr. Aklog with "good reason," he is entitled to be paid his base salary through the end of the term at the rate of 150%, valid expense reimbursements and accrued but unused vacation pay.

Dr. Aklog's employment agreement contains provisions for the protection of our intellectual property and contains non-compete restrictions in the event of his termination other than by us without "cause" or by Dr. Aklog with "good reason" (generally imposing restrictions on (i) employment or consultation with competing companies or customers, (ii) recruiting or hiring employees for a competing company and (iii) soliciting or accepting business from our customers for a period of six months following termination). Pursuant to the agreement, Dr. Aklog may serve as a consultant to, or on boards of directors of, or in any other capacity to other companies provided that they will not interfere with the performance of his duties to us.

Richard Fitzgerald

Effective as of October 8, 2015, we entered into an employment agreement with Richard Fitzgerald pursuant to which he serves as our Chief Financial Officer. The employment agreement is for a two-year term. Mr. Fitzgerald receives a base salary of $275,000 per year and will be eligible to earn annual performance bonuses meeting certain objectives as determined by the Board of Directors. He will also be granted an option to purchase 125,000 shares of our common stock with an exercise price equal to $5.00 per share upon consummation of our initial public offering. We also agreed to reimburse him for up to $2,200 per month to cover temporary housing and travel expenses for up to 12 months and to reimburse him for certain additional relocation expenses to be mutually agreed upon between us and him.

Upon termination of employment, unless terminated by us without "cause" or by Mr. Fitzgerald with "good reason" (as such terms are defined in the employment agreement), Mr. Fitzgerald will be entitled only to his base salary through the date of termination, valid expense reimbursements and unused vacation pay. If terminated by us without "cause" or by Mr. Fitzgerald with "good reason," he is entitled to be paid his base salary for nine months or through the end of the term, whichever is earlier, valid expense reimbursements and accrued but unused vacation pay.

Mr. Fitzgerald's employment agreement contains provisions for the protection of our intellectual property and contains non-compete restrictions in the event of his termination other than by us without "cause" or by him with "good reason" (generally imposing restrictions on (i) employment or consultation with competing companies or customers, (ii) recruiting or hiring employees for a competing company and (iii) soliciting or accepting business from our customers for a period of six months following termination).

Potential payments upon termination

As indicated above, each of Dr. Aklog and Mr. Fitzgerald is entitled to severance payments if his employment is terminated under specified circumstances. If we terminate either of their employment without cause, or if such executive officer terminates his employment with us for good reason, each as defined in his employment agreement, such executive officer is entitled to severance compensation as follows: Dr. Aklog will receive 150% of his base salary at the time of termination from the initial date of his termination through the full term of his agreement (December 31, 2019); and Mr. Fitzgerald will be entitled to the lesser of nine months base salary or base salary for the balance of the employment contract term.

To the extent that any severance or other compensation payment to any of our executive officers pursuant to an employment agreement or any other agreement constitutes an "excess parachute payment" within the meaning of Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended (the

"Code"), then such executive officer will receive the full amount of such severance and other payments, or a reduced amount intended to avoid the application of Sections 280G and 4999, whichever provides the executive with the highest amount on an after-tax basis.

Management Services Agreements

We entered into a management services agreement with HCP/Advisors LLC, an affiliate of Ira Greenspan, one of our directors, effective as of October 27, 2015, which replaces a prior agreement we had with HCFP, LLC, another affiliate of Mr. Greenspan and certain of our other officers and directors. Pursuant to the agreement with HCP/Advisors LLC, such entity has agreed to provide us with certain management services, including without limitation services to support our executive officers in identifying potential corporate opportunities, providing financial and accounting resources for assistance in complying with Section 404 of the Sarbanes-Oxley Act of 2002, as well as general business development, corporate development, corporate governance, marketing strategy, including preparing and/or reviewing company presentations, strategic development and planning, coordination with service providers and other advisory services as may be mutually agreed upon. We have 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. The agreement is for a term of three years; provided that either party may terminate the agreement prior to the expiration of the term if the other party materially breaches the terms of the agreement and such breach has not been cured within 30 days of notice of the same. Additionally, we have the right to terminate the agreement if HCP commits any fraud or dishonest action in its relations with us or any of our subsidiaries or affiliates. We also have the right to terminate the agreement for any reason prior to the expiration of the term upon not less than 90 days advance written notice. If HCP terminates the agreement because of our material breach which is not thereafter cured or we terminate the agreement for any reason other than HCP's material breach, we will be required to pay HCP all amounts due under the agreement for the remainder of the term within 30 days of termination. In all other cases, we will just be obligated to pay HCP the amounts owed through the date of termination.

Following the closing of our initial public offering, we also intend to enter into a management services agreement with Pavilion Holdings Group LLC, an affiliate of Dr. Aklog, Mr. Glennon and Dr. deGuzman. Pursuant to the management services agreement with Pavilion Holdings Group LLC, such entity has agreed to make available to us the services of Mr. Glennon and Dr. deGuzman to serve as our Vice Chairman and Chief Medical Officer, respectively. Pavilion Holdings Group will also provide us with such other advisory and consulting services as reasonably requested by us, including but not limited to interfacing with regulatory consultants, designing and executing pre-clinical and clinical studies, participating in design process and recruiting additional resources, business development services, assisting with vendor selection and relationships, strategic relationships, sourcing innovative technologies and other corporate opportunities. We intend to pay Pavilion Holdings Group a monthly fee of $20,000 for such services. The agreement will commence upon consummation of our initial public offering for a term of one year and will be automatically renewed for successive one year periods; provided that either party may terminate the agreement at any time for any reason upon 30 days' prior written notice to the other party and will automatically terminate if Mr. Glennon or Dr. deGuzman ceases to serve as our Vice Chairman and Chief Medical Officer, respectively.

Director Compensation

Directors who are also executive officers receive no additional compensation for serving as Directors. Each of our non-executive Directors receives annual director fees of $40,000. Audit committee, compensation committee and nominating committee members each receive an additional annual fee of $10,000, $7,500 and $5,000, respectively. The chair of each of the audit, compensation and nominating committee receives an additional annual fee of $10,000, $7,500 and $5,000, respectively. Additionally, upon their election or re-election, as the case may be, we will grant our non-executive Directors an option having a fair market value of $100,000. The first option grant to non-executive Directors pursuant to this provision will be made on the closing of our initial public offering and will represent the right to purchase an aggregate of 97,554 shares exercisable at $5.00 per share. The options will be issued under our stock plan and will vest in 36 monthly installments. We will also reimburse Directors for costs incurred in attending board and committee meetings.

The following table sets forth compensation paid to each non-employee director who are not named executive officers who served during the year ended December 31, 2015.

Name	Fees Earned[1]	Option Awards	All Other Compensation	Totals
Ira Scott Greenspan	—	—	$ 60,000[2]	$60,000
Joshua R. Lamstein	—	—	—	—
Ronald M. Sparks	—	—	—	—
James L. Cox, M.D.	—	—	—	—
David Weild IV	—	—	—	—

(1) No fees were earned during 2015 as our director compensation policy is not deemed active until the consummation of the Company's initial public offering.

(2) We have a three-year management services agreement with HCP/Advisors LLC, which is an affiliate of Mr. Greenspan. The management services agreement was effective as of November 1, 2015 and provides for an initial monthly fee of $35,000 and thereafter a monthly fee of $25,000. This amount represents the two months of fees paid under the management services agreement in 2015.

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

The following table sets forth information regarding the beneficial ownership of our shares of common stock as of April 11, 2016, by:

- each person known by us to be the beneficial owner of more than 5% of our outstanding shares;
- each of our officers and directors; and
- all our officers and directors as a group.

Unless otherwise indicated, we believe that all persons named in the table have sole voting and investment power with respect to all shares beneficially owned by them. The following table does not reflect record of beneficial ownership of any shares issuable upon exercise of outstanding warrants as the holders have agreed not to exercise such securities until consummation of our initial public offering.

Name and Address of Beneficial Owner[1]	Amount and Nature of Beneficial Ownership	Percent of Class
Lishan Aklog, M.D.	8,222,412[2][3]	67.1%
Ira Scott Greenspan	5,762,656[3][9]	47.0%
Joshua R. Lamstein	83,617[4]	*
Richard Fitzgerald	0	0%
Michael J. Glennon	0[5]	0%
Brian J. deGuzman, M.D.	0[5]	0%
Ronald M. Sparks	0[6]	0%
James L. Cox, M.D.	0[7]	0%
David Weild IV	0[8]	0
HCFP/Capital Partners III LLC	5,713,879	46.6%
Pavilion Venture Partners LLC	2,508,532	20.5%
All directors and executive officers as a group (nine individuals)	8,354,807[2][3][9]	68.2%

* Less than one percent.

(1) Unless otherwise indicated, the business address of each of the individuals is One Grand Central Place, Suite 4600, New York, New York 10165.

(2) Includes shares held by Pavilion Venture Partners, of which Dr. Aklog is a member and sole manager. Accordingly, he is deemed to have voting and dispositive power over the shares held by this entity. Dr. Aklog disclaims beneficial ownership of shares held by this entity, except to the extent of his proportionate pecuniary interest therein.

(3) Includes shares held by HCFP/Capital Partners III, of which Dr. Aklog and Mr. Greenspan are members and co-managers, and share joint voting and dispositive power over the shares held by this entity. Dr. Aklog and Mr. Greenspan disclaim beneficial ownership of shares held by this entity, except to the extent of their proportionate pecuniary interest therein.

(4) Does not include shares held by HCFP/Capital Partners III, of which Mr. Lamstein is a member.

(5) Does not include shares held by Pavilion Venture Partners or HCFP/Capital Partners III, of which Mr. Glennon and Dr. deGuzman or their affiliates are members.

(6) The business address of Mr. Sparks is 3 Laurel Drive, Wenham, MA 01984.

(7) The business address of Dr. Cox is 8200 Grogans Ferry Road, Atlanta, GA 30350.

(8) The business address of Mr. Weild is 747 3rd Ave, Suite 239, New York, NY 10017.

(9) Includes 20,904 shares held by Mr. Greenspan's son.

Equity Compensation Plans

As of December 31, 2015, we had the following compensation plans (including individual compensation arrangements) under which equity securities were authorized for issuance:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	—	—	1,951,081[(1)]
Equity compensation plans not approved by security holders	—	—	—
Total	—	—	1,951,081

(1) Represents shares of common stock available for issuance under our 2014 Long-Term Incentive Equity Plan.

Item 13. Certain Relationships and Related Transactions and Director Independence

The following is a description of transactions since January 1, 2014 to which we have been a party, and in which any of our directors, executive officers and holders of more than 5% of our voting securities and affiliates of our directors, executive officers and holders of more than 5% of our voting securities, had or will have a direct or indirect material interest. We believe that all of the transactions described below were made on terms no less favorable to us than could have been obtained from unaffiliated third parties.

Compensation arrangements for our directors and named executive officers are described elsewhere in this Form 10-K.

The information in this section reflects and takes into account the forward stock split of 2.7872582-for-1 by way of a stock dividend of 1.7872582 shares for each outstanding share effectuated in September 2015.

In June 2014 in connection with our organization, we issued (i) 5,658,134 shares of common stock for $0.001 per share, and warrants to purchase an additional 6,097,127 shares of common stock at an exercise price of $0.90 per share for $0.0001 per warrant, for an aggregate purchase price and total consideration of $2,248.75, to HCFP/Capital Partners III LLC, an affiliate of Drs. Aklog and deGuzman and Messrs. Glennon, Greenspan and Lamstein, and (ii) 2,424,915 shares of common stock for $0.001 per share, and warrants to purchase an additional 2,613,054 shares of common stock at an exercise price of $0.90 per share for $0.0001 per warrant, for an aggregate purchase price and total consideration of $963.75, to Pavilion Venture Partners LLC, an affiliate of Drs. Aklog and deGuzman and Mr. Glennon.

In July 2014, we issued 418,089 units, each consisting of one share of common stock and one warrant to purchase one share of common stock at an exercise price of $0.90, for $75,000 in cash, or a purchase price of $0.18 per unit, of which 13,936 of such units were sold to Robert M. Greenspan, who is the son of Ira Scott Greenspan, one of our directors. The table below sets forth the number of such units sold to our directors, executive officers or holders of more than 5% of our capital stock:

Name	Number of Shares of Common Stock included in Units	Number of Warrants included in Units	Relationship to Us
HCFP/Capital Partners III LLC	55,745	55,745	Affiliate of Drs. Aklog and deGuzman and Messrs. Glennon, Greenspan and Lamstein
Pavilion Venture Partners LLC	83,618	83,618	Affiliate of Drs. Aklog and deGuzman and Mr. Glennon
Ira Scott Greenspan	27,873	27,873	Senior Advisor and Director
Joshua R. Lamstein	83,617	83,617	Director

In October 2014, HCFP/Capital Partners III and Pavilion Venture Partners contributed an aggregate of 438,992 and 188,140 warrants, respectively, to the capital of PAVmed for no consideration.

In November 2014, we issued 2,355,233 units, each consisting of one share of common stock and one warrant to purchase one share of common stock at an exercise price of $0.90, for $845,000 in cash, or a purchase price of $0.36 per unit, of which 139,363 units were sold to Matthew J. Glennon, who is the brother of Michael Glennon, one of our directors.

In August 2015, we issued our legal counsel a warrant to purchase 97,554 shares of our stock.

In September 2015, warrants to purchase 1,393,629 shares were exercised by the holders generating an aggregate of $1.25 million of proceeds to us. Thereafter, we effectuated the forward stock split by way of a stock dividend as described above resulting in there being 12,250,000 common shares outstanding.

Pursuant to their terms, each outstanding warrant not exercised prior to the closing of our initial public offering will automatically convert into a warrant with the same terms as the warrants being offered in the initial public offering.

In September 2014, we entered into an option agreement with Pavillion Holdings Group LLC, an affiliate of Pavilion Venture Partners LLC which is an affiliate of Dr. Aklog, pursuant to which we had the option to acquire all right, title and interest in and to a certain patent related to a medical infusion device for an aggregate of $10,000 at any time until September 2015. We exercised this option in September 2015 and now own this patent along with associated patent applications.

On November 17, 2015, we entered into a management services agreement with HCP/Advisors, LLC, effective as of October 27, 2015. Additionally, we intend to enter into a management services agreement with Pavilion Holdings Group LLC upon consummation of our initial public offering.

We will reimburse our founders and members of our management team and their affiliates for any reasonable out-of-pocket business expenses incurred by them in connection with activities on our behalf. There is no limit on the amount of accountable out-of-pocket expenses reimbursable by us, which will be reviewed only by our board or a court of competent jurisdiction if such reimbursement is challenged.

All ongoing and future transactions between us and any of our officers and directors or their respective affiliates will be on terms believed by us to be no less favorable to us than are available from unaffiliated third parties. Such transactions will require prior approval by a majority of our uninterested "independent" directors (to the extent we have any) or the members of our board who do not have an interest in the transaction, in either case who had access, at our expense, to our attorneys or independent legal counsel. We will not enter into any such transaction unless our disinterested "independent" directors (or, if there are no "independent" directors, our disinterested directors) determine that the terms of such transaction are no less favorable to us than those that would be available to us with respect to such a transaction from unaffiliated third parties.

Related Party Policy

Our Code of Ethics requires that we avoid, wherever possible, all related party transactions that could result in actual or potential conflicts of interests, except under guidelines approved by the Board of Directors. Related party transactions are defined under SEC rules as transactions in which (1) the aggregate amount involved will or may be expected to exceed the lesser of $120,000 or one percent of the average of our total assets in any calendar year, (2) we or any of our subsidiaries is a participant, and (3) any (a) executive officer, director or nominee for election as a director, (b) greater than 5% beneficial owner of our shares of common stock, or (c) immediate family member, of the persons referred to in clauses (a) and (b), has or will have a direct or indirect material interest (other than solely as a result of being a director or a less than 10% beneficial owner of another entity). A conflict of interest situation can arise when a person takes actions or has interests that may make it difficult to perform his or her work objectively and effectively. Conflicts of interest may also arise if a person, or a member of his or her family, receives improper personal benefits as a result of his or her position.

No director may participate in the approval of any transaction in which he is a related party, but that director is required to provide the other members of the board with all material information concerning the transaction. Additionally, we require each of our directors and executive officers to complete a directors' and officers' questionnaire that elicits information about related party transactions.

These procedures are intended to determine whether any such related party transaction impairs the independence of a director or presents a conflict of interest on the part of a director, employee or officer.

Director Independence

In anticipation of our initial public offering, we determined to adhere to the rules of the NASDAQ Stock Market. Rule 5605 of the NASDAQ Listing Rules requires a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the NASDAQ Listing Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Under Rule 5605(a)(2) of the NASDAQ Listing Rules, a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries. In addition, in affirmatively determining the independence of any director who will serve on a company's compensation committee, Rule 10C-1 under the Exchange Act requires that a company's board of directors consider all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting, advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

During 2015, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from, and provided by, each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Dr. Aklog, Mr. Greenspan and Mr. Glennon, is an "independent director" as defined under Rule 5605(a)(2) of the NASDAQ Listing Rules. Our board of directors also determined that Messrs. Weild Lamstein and Sparks who comprise our audit committee, Dr. Cox, and Messrs. Lamstein and Weild, who comprise our compensation committee, and Dr. Cox, and Messrs. Lamstein and Sparks who comprise our nominating committee, satisfy the independence standards for such committees established by the Securities and Exchange Commission and the NASDAQ Listing Rules, as applicable. In making such determinations, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

Our independent directors will have regularly scheduled meetings at which only independent directors are present.

There are no family relationships among any of our directors or executive officers.

Item 14. Principal Accountant Fees and Services

Auditors' Fees

The following table summarizes the fees of Citrin Cooperman & Company, LLP, our independent registered public accounting firm, billed to us for each of the last two years.

Fee Category	Year ended December 31, 2015	Period from June 26, 2014 (inception) to December 31, 2014
Audit Fees[1]	$ 106,250	$ 51,680
Audit-Related Fees		
Tax Fees		
All Other Fees		
Total Fees	$ 106,250	$ 51,680

(1) Audit fees consist of fees billed for professional services by Citrin Cooperman & Company, LLP for audit and quarterly review of our consolidated financial statements and review of the registration statement on Form S-1 for our initial public offering, and related services that are normally provided in connection with statutory and regulatory filings or engagements.

The aggregate fees included in the Audit Fees are those billed for the fiscal year. The aggregate fees included in the Audit-Related Fees and Tax Fees are those fees billed in the fiscal year.

All such accountant services and fees were pre-approved by our audit committee in accordance with the "Pre-Approval Policies and Procedures" described below.

Pre-approval policies

The audit committee of our board of directors has adopted policies and procedures for the pre-approval of audit and non-audit services for the purpose of maintaining the independence of our independent auditor. We may not engage our independent auditor to render any audit or non-audit service unless either the service is approved in advance by the audit committee, or the engagement to render service is entered into pursuant to the audit committee's pre-approval policies and procedures.

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 Statement of Operations

Consolidated Statement of Changes in Stockholders' Equity

Consolidated Statement of Cash

Notes to Consolidated Financial Statements

(2) The financial statement schedules:

Schedules other than those listed above are omitted for the reason that 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
1.1	Form of Selling Agent Agreement.*
3.1	Certificate of Incorporation.*
3.2	Certificate of Amendment to Certificate of Incorporation.*
3.3	Bylaws.*
4.1	Specimen Unit Certificate.*
4.2	Specimen Common Stock Certificate.*
4.3	Specimen Warrant Certificate.*
4.4	Form of Warrant Agreement between Continental Stock Transfer & Trust Company and the Registrant.*
4.5	2014 Long-Term Equity Incentive Plan.*
4.6	Form of Unit Purchase Option.*
10.1	Patent Option Agreement.*
10.2.1	Employment Agreement between PAVmed and Dr. Aklog.*
10.2.2	Amendment to Employment Agreement between PAVmed and Dr. Aklog.*
10.2.3	Second Amendment to Employment Agreement between PAVmed and Dr. Aklog.*
10.3.1	Form of Subscription Agreement (July 2014).*
10.3.2	Form of Subscription Agreement (November 2014).*
10.4.1	Form of Letter Agreement with HCFP Capital Partners III LLC.*
10.4.2	Form of Letter Agreement with Pavilion Venture Partners LLC.*
10.5.1	Letter agreement regarding corporate opportunities executed by Dr. Lishan Aklog.*
10.5.2	Letter agreement regarding corporate opportunities executed by Michael Glennon.*
10.5.3	Letter agreement regarding corporate opportunities executed by Dr. Brian deGuzman.*
10.6	Management services agreement between PAVmed and HCP/Advisors LLC.*
10.7	Form of Management services agreement between PAVmed and Pavilion Holdings Group.*

Exhibit No.	Description
10.8	Employment Agreement between PAVmed and Richard Fitzgerald.*
14	Form of Code of Ethics.*
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.

* Incorporated by reference to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-203569).

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.

April 11, 2016

By: /s/ Richard F. Fitzgerald
Richard F. Fitzgerald
Chief Financial 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)	April 11, 2016
/s/ Richard F. Fitzgerald Richard F. Fitzgerald	Chief Financial Officer (Principal Financial and Accounting Officer)	April 11, 2016
/s/ James L. Cox, M.D. James L. Cox, M.D.	Director	April 11, 2016
/s/ Ira S. Greenspan Ira S. Greenspan	Director	April 11, 2016
/s/ Joshua R. Lamstein Joshua R. Lamstein	Director	April 11, 2016
/s/ Ronald M. Sparks Ronald M. Sparks	Director	April 11, 2016
/s/ David Weild IV David Weild IV	Director	April 11, 2016

PAVMED INC. (F/K/A PAXMED INC.) AND SUBSIDIARY

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
PAVmed Inc. (formerly known as PAXmed Inc.)

We have audited the accompanying consolidated balance sheets of PAVmed Inc. (formerly known as PAXmed Inc.) and Subsidiary (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the year ended December 31, 2015 and for the period from June 26, 2014 (inception) through December 31, 2014. 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. (formerly known as PAXmed Inc.) and Subsidiary as of December 31, 2015 and 2014, and the results of their operations and their cash flows for the year ended December 31, 2015 and for the period from June 26, 2014 (inception) through December 31, 2014, 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
April 11, 2016

PAVMED INC. (F/K/A PAXMED INC.) AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2015	**2014**
ASSETS		
CURRENT ASSETS		
Cash	$ 767,268	$ 839,077
Prepaid expenses and other current assets	8,761	3,000
Total Current Assets	776,029	842,077
Deferred offering costs	438,061	—
TOTAL ASSETS	$ 1,214,090	$ 842,077
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 165,321	$ 14,749
Accrued expenses	414,851	32,500
Total Current Liabilities	580,172	47,249
COMMITMENT AND CONTINGENCIES (NOTE 5)		
STOCKHOLDERS' EQUITY:		
Preferred stock, par value $0.001; 20,000,000 shares authorized; no shares issued and outstanding at December 31, 2015 and 2014	—	—
Common stock, par value $0.001; 50,000,000 shares authorized; 12,250,000 and 10,856,371 shares issued and outstanding at December 31, 2015 and 2014, respectively	12,250	10,856
Additional paid-in capital	2,672,652	1,058,356
Accumulated deficit	(2,050,984)	(274,384)
TOTAL STOCKHOLDERS' EQUITY	633,918	794,828
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,214,090	$ 842,077

See accompanying notes to the consolidated financial statements.

PAVMED INC. (F/K/A PAXMED INC.) AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31, 2015	Period from June 26, 2014 (inception) to December 31, 2014
Revenues	$ —	$ —
Formation and operating costs	1,287,273	263,239
Research and development costs	489,327	11,145
Operating expenses	1,776,600	274,384
Net loss	$ (1,776,600)	$ (274,384)
Net loss per common share – basic and diluted	$ (0.16)	$ (0.03)
Weighted average common shares – basic and diluted	11,278,755	8,618,278

See accompanying notes to the consolidated financial statements.

PAVMED INC. (F/K/A PAXMED INC.) AND SUBSIDIARY

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Par Value			
Balance at June 26, 2014 (date of inception)	—	$ —	$ —	$ —	$ —
Common shares and 8,083,049 warrants issued to founders	8,083,049	8,083	(4,871)	—	3,212
Units consisting of one share of common stock and one warrant issued to initial stockholders, net of offering costs of $7,500	418,089	418	67,082	—	67,500
Units consisting of one share of common stock and one warrant issued to investors, net of offering costs of $46,500	2,355,233	2,355	796,145		798,500
Value of contributed services of Chief Executive Officer and Chief Financial Officer	—	—	200,000	—	200,000
Net loss	—	—	—	(274,384)	(274,384)
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

See accompanying notes to the consolidated financial statements.

PAVMED INC. (F/K/A PAXMED INC.) AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31, 2015	Period from June 26, 2014 (inception) to December 31, 2014
Cash flows from operating activities:		
Net loss	$(1,776,600)	$(274,384)
Adjustments to reconcile net loss to net cash used in operating activities:		
Expense attributable to contributed services	133,333	200,000
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,761)	(3,000)
Accounts payable	100,572	47,249
Accrued expenses	298,851	—
Net cash used in operating activities	(1,249,605)	(30,135)
Cash flows from financing activities:		
Proceeds from the sale of common stock and warrants	—	923,212
Payments of offering costs	—	(54,000)
Payment of deferred offering costs	(72,204)	—
Proceeds from common stock upon exercise of warrants	1,250,000	—
Net cash provided by financing activities	1,177,796	869,212
Net (decrease) increase in cash	(71,809)	839,077
Cash, beginning of period	839,077	—
Cash, end of period	$ 767,268	$ 839,077
Supplemental disclosures of non-cash financing activities:		
Deferred offering costs	$ 365,857	$ —

See accompanying notes to the consolidated financial statements.

PAVMED INC. (F/K/A PAXMED INC.) AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization and Plan of Business Operations

On April 19, 2015, PAXmed Inc. changed its name to PAVmed Inc. PAVmed Inc. and its wholly-owned subsidiary ("PAVmed" or the "Company") was organized under the laws of the State of Delaware on June 26, 2014 with its corporate headquarters in New York, New York. The Company is 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.

All activity from inception through December 31, 2015 relates to the Company's formation, recruiting its new Chief Financial Officer, Board of Directors and Medical Advisory Board, raising initial working capital through two private placements and the exercise of warrants, preparing for an initial public offering, (the "IPO"), which is expected to be completed in the Company's 2016 fiscal second quarter, advancing the development of its lead product candidates within the Company's pipeline and protecting its intellectual property. The Company has selected December 31st as its year end. The Company is an early stage and emerging growth company and, as such, the Company is subject to all of the risks associated with early stage and emerging growth companies.

Management's Plans and Initial Public Offering

The Company's consolidated financial statements have been prepared assuming that the Company will continue as a going concern. Through December 31, 2015, the Company has primarily funded its operations with proceeds from private placements of its common stock and warrants. As of December 31, 2015, the Company had cash of $767,268 and an accumulated deficit of $2,050,984. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales from its product candidates in development. Additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates.

The Company's initial public offering of its securities is in process. The Company's selling agent is not purchasing any of the securities offered by the Company and is not required to sell any specific number or dollar amount of securities, but is instead arranging for the sale of securities to investors on a "best efforts" basis, meaning that it need only use its best efforts to sell the securities.

The Company is offering up to 1,200,000 units at a public offering price of $5.00; provided, however, that it has the option to sell up to an additional 800,000 units in its sole discretion. There is no minimum number of units the Company must sell and it may close on the sale of any or all of the units offered. Each unit consists of one share of common stock and one warrant. The warrants will be exercisable commencing 6 months from the consummation of the IPO and will expire on or about January 29, 2022, or earlier upon redemption.

The gross proceeds of the IPO will be reduced by an underwriting discount of 7%, a non-accountable expense allowance in the amount of 3% of the gross proceeds and other offering expenses which will approximate $656,000. The Company has until April 28, 2016 to sell all of the securities offered in its IPO. There is presently no public market for the Company's securities. The Company intends to have its securities quoted on the Nasdaq upon completion of the IPO.

The Company believes that the net proceeds of the IPO along with its existing cash will be sufficient to fund its operations for the foreseeable future. However, there is no assurance that the Company can raise enough funds in the IPO to pay its obligations as they become due. The Company's operations will be adversely affected if it is unable to raise or obtain needed funding and may materially affect its ability to continue as a going concern.

In the future, cash requirements and cash resource needs will vary significantly depending on the timing and the financial and other resource needs that will be required to complete ongoing development and pre-clinical and clinical testing of products as well as regulatory efforts and collaborative arrangements necessary for the Company's products that are currently under development. The Company may seek to

raise necessary funds through a combination of additional sales of equity, debt financings, other financing mechanisms or strategic collaborations and licensing arrangements. The Company may not be able to obtain additional financing on terms favorable to it, if at all. No adjustments have been made to the carrying value of assets or liabilities as a result of this uncertainty.

Note 2 — Summary of Significant Accounting Policies

The management of the Company is responsible for the selection and use of appropriate accounting policies and the appropriateness of accounting policies and their application. Critical accounting policies and practices are those that are both most important to the portrayal of the Company's financial condition and results and require management's most difficult, subjective, or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain. The Company's significant and critical accounting policies and practices are disclosed below as required by accounting principles generally accepted in the United States of America ("U.S. GAAP").

Basis of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with U.S. GAAP. The accompanying consolidated financial statements include all the accounts of the Company and its wholly-owned subsidiary as of December 31, 2015 and 2014. All intercompany transactions and balances have been eliminated in consolidation.

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 to reflect the aforementioned stock split. The number of authorized shares of common stock remains at 50,000,000 shares and the number of authorized shares of preferred stock remains at 20,000,000 shares.

Use of Estimates

The preparation of consolidated 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 revenues and expenses during the reporting period. Significant estimates in these consolidated financial statements include valuation allowance on deferred taxes, effects of stock-based compensation and warrants, contingent liabilities, and the provision or benefit for income taxes. Due to the inherent uncertainty involved in making estimates, actual results reported in future periods may differ materially from those estimates.

Cash and Concentration of Credit Risk

The Company maintains its cash at a major financial institution with high credit quality and, at times, the balance in its cash deposits may exceed the Federal Deposit Insurance Corporation limits of $250,000. The Company has not experienced and does not anticipate any losses on deposits with commercial banks and financial institutions that exceed federally insured limits.

Deferred Offering Costs

Deferred offering costs consist primarily of direct incremental costs related to the Company's IPO. As of December 31, 2015, the Company had deferred offering costs of $438,061. There were no deferred offering costs as of December 31, 2014. Upon completion of the IPO, deferred offering costs will be offset against the proceeds of the IPO.

Patents

The Company holds an acquired patent related to research and development activities. The Company does not currently employ the research and development findings associated with this patent for any of its products and it is uncertain if the patent has an alternative future use, however, the Company intends to hold the asset indefinitely. Under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 730, "*Research and Development*," the costs related to this patent are expensed in the period incurred. (See Note 4, Related Party Transactions, Option to Purchase a Patent.)

Patent filing fees and prosecution costs relative to patent applications and patents filed by the Company are expensed as incurred. During the year ended December 31, 2015 and for the period from June 26, 2014 (inception) through December 31, 2014, the Company incurred $206,220 and $7,208, respectively, of costs related to patent applications which is included in "formation and operating costs" in the accompanying consolidated statements of operations.

Long-Lived Assets

Long-lived assets, including fixed assets and intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. In reviewing for impairment, the carrying value of such assets is compared to the estimated undiscounted future cash flows expected from the use of the assets and their eventual disposition. If such cash flows are not sufficient to support the asset's recorded value, an impairment charge is recognized to reduce the carrying value of the long-lived asset to its estimated fair value. The determination of future cash flows as well as the estimated fair value of long-lived assets involves significant estimates on the part of management. In order to estimate the fair value of a long-lived asset, the Company may engage a third party to assist with the valuation. If there is a material change in economic conditions or other circumstances influencing the estimate of future cash flows or fair value, the Company could be required to recognize impairment charges in the future.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability of fair value measurements, a three-tier fair value hierarchy which prioritizes the inputs used in the valuation methodologies, is 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 that are not active, or other inputs that are 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, 2015 and 2014, the carrying amounts of the Company's financial instruments, including cash, accounts payable and accrued expenses, approximate fair value due to the short-term nature of these instruments.

At December 31, 2015 and 2014, the Company does not have any assets or liabilities required to be measured at fair value in accordance with ASC Topic 820, *Fair Value Measurements.*

Income Taxes

The Company accounts for income taxes under ASC Topic 740,*Income Taxes* ("ASC 740"). ASC 740 requires the recognition of deferred tax assets and liabilities for both the expected impact of differences between the financial statements and tax basis of assets and liabilities and for the expected future tax

benefit to be derived from tax loss and tax credit carry-forwards. ASC 740 additionally requires a valuation allowance to be established when it is more likely than not that all or a portion of deferred tax assets will not be realized.

ASC 740 also clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. ASC 740 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company is required to file income tax returns in the United States (federal) and in various state and local jurisdictions. Based on the Company's evaluation, it has been concluded that there are no significant uncertain tax positions requiring recognition in the Company's consolidated financial statements. Since the Company was incorporated on June 26, 2014, the evaluation was performed for the 2015 and 2014 tax years, which are the only periods subject to examination. The Company believes that its income tax positions and deductions would be sustained on audit and does not anticipate any adjustments that would result in a material change to the financial positions reported as of December 31, 2015 and 2014.

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, 2015 and 2014 or during the year ended December 31, 2015 or for the period from June 26, 2014 (inception) through December 31, 2014. Management is currently unaware of any issues under review that could 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, 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. As of December 31, 2015 and 2014, potentially dilutive common shares consist of 9,560,296 and 10,856,371 warrants to purchase common stock, respectively.

The following is the computation of loss per share applicable to common stockholders for the periods indicated:

	Year ended December 31, 2015	June 26 (inception) to December 31, 2014
Net loss	$ (1,776,600)	$ (274,384)
Basic and diluted loss per share	$ (0.16)	$ (0.03)
Weighted average common shares outstanding:		
Basic and diluted	11,278,755	8,618,278

Research and Development Expenses

Research and development expenditures are charged to research and development expense as incurred. Research and development expense aggregated $489,327 for the year ended December 31, 2015 and $11,145 for the period from June 26, 2014 (inception) through December 31, 2014. Research and development costs include costs related to the Company's various contract research suppliers, engineering studies, supplies and outsourced testing and consulting as well as rental costs for access to certain facilities at one of the Company's contract research suppliers.

Stock-Based Compensation

Pursuant to ASC Topic 718, *Compensation — Stock Compensation* ("ASC 718"), the Company records stock-based compensation expense for all stock-based awards. Under ASC 718, the Company estimates the fair value of stock-based compensation using the Black-Scholes option pricing model. The fair value for awards that are expected to vest is then amortized on a straight-line basis over the requisite service period of the award, which is generally the option vesting term.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option valuation model. The assumptions used in the Black-Scholes valuation model are as follows:

- Grant price: the grant price of the issuances, with certain exceptions, is determined based on the estimated fair value of the shares at the date of grant.
- Risk-free interest rate: the risk free interest rate for periods within the contractual life of the option is based on the U.S. treasury yield in effect at the time of grant.
- Expected lives: as permitted by Staff Accounting Bulletin 107, due to the Company's insufficient history of option activity, the Company utilizes the simplified approach to estimate the options expected term, which represents the period of time that options granted are expected to be outstanding.
- Expected volatility: is determined based on average historical volatilities of comparable companies in the similar industry.
- Expected dividend yield: is based on current yield at the grant date or the average dividend yield over the historical period. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

Segment, and Geographical Concentration

The Company operates in one operating segment and therefore has one reporting segment. All of the Company's assets are located in the United States.

Reclassification

Certain previously reported amounts have been reclassified to conform to the presentation used in the consolidated financial statements as of and for the year ended December 31, 2015, including separately presenting accounts payable, accrued expenses and research and development costs.

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

The Company considers the applicability and impact of all Accounting Standards Updates ("ASU") issued by the FASB. ASU's not listed below were assessed and determined not to be applicable or are expected to have minimal impact on the Company's consolidated financial position and results of operations.

Accounting Standards Not Yet Adopted

In February 2016, FASB issued ASU 2016-02,*Leases.* The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a right-of-use ("ROU") asset and a lease liability on the balance sheet for all leases with terms longer 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 within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating 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 ASU 2016-02 will have on its consolidated financial statements.

In November 2015, FASB issued ASU 2015-17,*Income Taxes.* Current U.S. GAAP requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. To simplify the presentation of deferred income taxes, the amendments in this ASU require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in this ASU apply to all entities that present a classified statement of financial position. The new standard is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years with early adoption permitted. The implementation of this ASU is not expected to have a material impact on the Company's consolidated financial position or results of operations.

In April 2015, the FASB issued ASU 2015-03,*Simplifying the Presentation of Debt Issuance Costs.* ASU 2015-03 requires debt issuance costs to be presented in the balance sheet as a direct deduction from the associated debt liability. ASU 2015-03 is effective for interim and annual reporting periods beginning after December 15, 2015. The new guidance will be applied on a retrospective basis and early adoption is permitted. The Company does not expect the adoption of ASU 2015-03 to have a significant impact on the Company's consolidated results of operations, financial position or cash flows.

In August 2014, the FASB issued ASU No. 2014-15,*Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. Certain disclosures will be required if conditions give rise to substantial doubt about an entity's ability to continue as a going concern. ASU 2014-15 applies to all entities and is effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. The Company does not expect that the adoption of this standard will have a material effect on its consolidated financial statements.

In June 2014, the FASB issued ASU 2014-10,*Development Stage Entities (Topic 915)*: Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. ASU 2014-10 simplifies the accounting guidance by removing all incremental financial reporting requirements for development stage entities. The amendments related to the elimination of the inception-to-date information and other disclosure requirement of Topic 915 should be applied retrospectively and are effective for annual reporting periods beginning after December 15, 2014 and interim periods therein. Early adoption is permitted. The Company early adopted ASU 2014-10 effective on inception. Adoption of this standard had no impact on the Company's financial position, results of operations or cash flows; however, the presentation of the financial statements does not present the disclosures that are no longer required.

In May 2014, the FASB issued ASU No. 2014-09,*Revenue from Contracts with Customers*, which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or 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, and 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 ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). The Company is currently evaluating the impact ASU 2014-09 will have on its consolidated financial statements.

Note 3 — Accrued Expenses

Accrued expenses consisted of the following for the periods indicated:

	December 31, 2015	December 31, 2014
Chief Executive Officer contributed services deemed payable	$ 240,000	$ —
Bonus payable	124,583	—
Accrued professional fees	36,000	26,500
Accrued expenses	8,389	6,000
Accrued vacation payable	5,879	—
Total accrued expenses	$ 414,851	$32,500

Note 4 — Related Party Transactions

Option to Purchase a Patent

On September 21, 2014, the Company entered into an agreement which gives the Company the option to purchase United States Patent #US 8,622,976 issued January 7, 2014, “System and Methods for Infusion of Fluids Using Stored Potential Energy and a Variable Flow Resistor” (the “Patent”) from Pavillion Holdings Group LLC (“PHG”), a related party, for $1,000. PHG, a medical device holding company, was founded by our current Chief Executive Officer, our Vice Chairman and our Chief Medical Officer. The Company had up to one year to exercise this option and purchase the Patent for $10,000. The Company recognized the cost of the option in formation and operating costs in the accompanying consolidated statements of operations. In September 2015, the Company exercised this option and now owns the Patent along with associated patent applications.

HCFP LLC

Pursuant to a management services agreement with HCFP LLC, an affiliate of certain officers and directors of the Company, such entity agreed to make available to the Company, among other things, the services of the Company’s Former Chief Financial Officer (“Former CFO”), who was HCFP LLC’s Chief Financial Officer. This Agreement would automatically terminate if the Former CFO ceased serving as the Company’s Chief Financial Officer. The Former CFO resigned as the Company’s Chief Financial Officer on October 26, 2015 which terminated the management services agreement with HCFP LLC. The Company incurred no fees under this agreement during the year ended December 31, 2015 or the period from June 26, 2014 (inception) through December 31, 2014.

HCP Advisors LLC

Effective as of October 27, 2015, the Company entered into a three-year management services agreement with HCP/Advisors LLC, an affiliate of a director of the Company, which replaces the management services agreement with HCFP LLC. Pursuant to the HCP/Advisors agreement, such entity has agreed to provide the Company with certain management services, including without limitation

identifying potential corporate opportunities, providing certain financial and accounting resources, 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. The Company incurred $60,000 of fees under this agreement during the year ended December 31, 2015.

Pavilion Holdings Group LLC

Pursuant to the management services agreement with Pavilion Holdings Group LLC (the "Pavilion Agreement"), such entity will agree to make available to the Company the services of Michael J. Glennon and Brian J. deGuzman, each a member of Pavilion Holdings Group LLC, to serve as the Company's Vice Chairman and Chief Medical Officer, respectively. Pavilion Holdings Group LLC will also provide the Company with such other advisory and consulting services as reasonably requested by the Company, including but not limited to interfacing with regulatory consultants, designing and executing pre-clinical and clinical studies, participating in design process and recruiting additional resources, business development services, assisting with vendor selection and relationships, strategic relationships, sourcing innovative technologies and other corporate opportunities. The Company has agreed to pay Pavilion Holdings Group LLC a monthly fee of $20,000 for such services.

The Pavilion Agreement will commence upon consummation of the IPO for a term of one year and will be automatically renewed for successive one year periods; provided that either party may terminate the agreement at any time for any reason upon 30 days' prior written notice to the other party. In addition, the Pavilion Agreement will automatically terminate if Mr. Glennon or Dr. deGuzman ceases to serve as the Company's Vice Chairman and Chief Medical Officer, respectively.

Note 5 — Commitments and Contingencies

Compensation and Employment Agreements

The Company's Chief Executive Officer and its Former CFO, who are both stockholders of the Company, were not paid a salary from the Company from June 26, 2014 (inception) through October 26, 2015. The Company has recognized the value of their services, determined based on salaries of similar executives at similarly sized companies, in the accompanying consolidated statement of operations as contributed capital. For the year ended December 31, 2015 and for the period from June 26, 2014 (inception) through December 31, 2014, the Company charged $313,333 and $200,000, respectively, to "formation and operating costs" in the accompanying statements of operations.

Chief Executive Officer Employment Agreement

Effective November 1, 2014, the Company entered into an employment agreement with its Chief Executive Officer (the "CEO Employment Agreement") for a five-year term with a base salary of $240,000 per year, a guaranteed bonus beginning on January 1 of each year beginning on January 1, 2016 equal to 50% of his base salary. The Chief Executive Officer will also be eligible to earn annual performance bonuses meeting certain objectives as determined by the Board of Directors; provided, however, that the base salary shall be paid only upon, and subject to, the consummation of an initial public offering. 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 Chief Executive Officer with "good reason."

Effective November 1, 2015, the Company amended the employment agreement of its Chief Executive Officer, increasing his base salary from $240,000 to $295,000 per year commencing on November 1, 2015; provided, however, that the base salary from November 1, 2014 to October 31, 2015 of $240,000

("Contingent Salary") shall be paid only upon, and subject to, the consummation of an initial public offering. The Company has determined the likelihood of the IPO is probable, therefore, a liability has been recorded as of December 31, 2015 in the accompanying consolidated balance sheet for the Contingent Salary and guaranteed 50% bonus.

Chief Financial Officer Employment Agreement

Effective as of October 8, 2015, the Company entered into a two-year employment agreement with its new Chief Financial Officer, Richard Fitzgerald ("CFO Employment Agreement"). Richard Fitzgerald will receive a base salary of $275,000 per year and will be eligible to earn annual performance bonuses meeting certain objectives as determined by the Board of Directors. Upon the consummation of the IPO, he will also be granted an option to purchase 125,000 shares of the Company's common stock with an exercise price equal to $5.00 per share. 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. 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 Chief Executive Officer with "good reason."

Leases

Beginning on May 1, 2015, the Company rents access to a research and development facility in Massachusetts that provides for month-to-month rent of $1,000 per month. The landlord and the Company can cancel this rental arrangement at any time. Total rental expense under this arrangement for the year ended December 31, 2015 was $8,000.

The Company also leases space that serves as the Company's corporate office under a lease agreement entered in January 2016 which provides for two consecutive six month terms beginning on February 1, 2016 at the rate of $9,500 per month. The agreement may be canceled at the end of the initial six month term at the election of the Company and also provides for access to common area office facilities.

Note 6 — Provision for Income Taxes

Income tax (benefit) expense consists of the following for the year ended Decmber 31, 2015 and for the period from June 26, 2014 (inception) through December 31, 2014:

	Year ended December 31, 2015	Period from June 26, 2014 (inception) through December 31, 2014
Current:		
Federal, state and local	$ —	$ —
Deferred:		
Federal	(573,065)	(26,034)
State and local	(169,758)	(4,017)
	(742,823)	(30,051)
R&D credit carryforward	(20,674)	—
Less: Valuation allowance	763,497	30,051
	$ —	$ —

PAVMED INC. (F/K/A PAXMED INC.) AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

At December 31, 2015 and 2014, reconciliations of the federal statutory income tax rate to the effective income tax rates are as follows:

	December 31,	
	2015	2014
U.S. statutory rate	(35.0)%	(35.0)%
State income taxes (net of federal benefit)	(10.4)%	(5.8)%
Permanent differences	3.6%	8.5%
Tax credits	(1.2)%	(1.2)%
Valuation allowance	43.0%	33.5%
Effective income tax rate	0.0%	0.0%

At December 31, 2015 and 2014, the approximate tax effects of temporary differences which give rise to the net deferred tax assets are as follows:

	December 31,	
	2015	2014
Noncurrent deferred tax assets:		
Net operating loss	$ 568,721	$ 4,553
Deferred compensation	165,404	—
Section 195 deferral-start-up costs	38,749	25,498
Tax credit carryforwards	20,674	—
Valuation allowance	(793,548)	(30,051)
	$ —	$ —

The Company has federal and state net operating loss carryforwards at December 31, 2015 and 2014 of $1,243,538 and $18,181 expiring through 2035 and 2034, respectively, resulting in deferred tax assets of $568,721 and $4,553 respectively. Additionally the Company generated $20,674 of research and development tax credit carryforwards during the year ended December 31, 2015. ASC 740 requires a “more likely than not” criterion be applied when evaluating the realization of a deferred tax asset. Management does not expect that it is more likely than not that the Company will generate sufficient taxable income in future years to utilize the deferred tax assets. As such, full valuation allowances of $793,548 and $30,051 have been recorded against the net deferred tax assets.

The Company files income tax returns in the U.S. in federal and applicable state jurisdictions. The Company’s fiscal 2015 tax filings and its initial period of operations from June 26, 2014 (inception) through December 31, 2014 tax returns remain subject to examination by taxing authorities.

Note 7 — Stockholders’ Equity

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, 2015 and 2014, there are no shares of preferred stock issued or outstanding.

Common Stock

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

In connection with the organization of the Company, a total of 8,083,049 shares of the Company’s common stock and 8,710,182 warrants (“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 warrants are defined in the related subscription agreements.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

From June 26, 2014 through July 22, 2014, a total of 418,089 units were sold to the initial stockholders ("Initial Investors") for an aggregate purchase price of $75,000 less offering costs of $7,500. On November 4, 2014, the Company completed an additional private placement of 2,355,233 units raising $845,000 in gross offering proceeds less offering costs of $46,500. Each of the units referred to above consists of one share of common stock and one warrant ("Private Placement Warrants"). The terms and conditions of the Private Placement Warrants are defined in the related subscription agreements.

Note 8 — Warrants

The table below summarizes warrants outstanding and warrant activity during the year ended December 31, 2015 and for the period from June 26, 2014 (inception) through December 31, 2014:

	Warrants	Weighted-Average Exercise Price
Balance, June 26, 2014 (inception)	—	$ —
Granted	11,483,504	$ 0.90
Contributed back to the Company	(627,133)	$ 0.90
Balance, December 31, 2014	10,856,371	$ 0.90
Granted	97,554	$ 0.90
Exercised	(1,393,629)	$ 0.90
Balance, December 31, 2015	9,560,296	$ 0.90

The warrants outstanding at December 31, 2015 are immediately exercisable at $0.90, and have a weighted average remaining term of approximately 5.6 years. All of the warrants outstanding at December 31, 2015 contain an automatic conversion feature such that their terms will convert to warrant terms that are identical to any warrants issued in the IPO.

The Company initially issued 8,710,182 warrants in connection with the formation of the Company. An additional 418,089 and 2,355,233 warrants were issued in connection with the units sales made in June through July 2014 and November 2014, respectively. The Founders' Warrants and Private Placement Warrants are deemed to be equity instruments.

On October 14, 2014, certain Founders agreed to contribute 627,133 Founders' Warrants back to the Company at no cost. The Company accounted for the fair value of the contributed warrants as a charge directly to additional paid-in capital. The Company estimates that the fair value of the contributed Founders' Warrants is approximately $29,000 using the Black-Scholes option-pricing model with the following assumptions: fair value of the underlying common stock of $(0.90), dividend yield of 0.00%, expected volatility of 58.99%, risk-free rate of 2.52%, and expected term of 7 years.

In November 2014, the holders of the remaining Founders' Warrants entered into a sideletter agreement whereby the Company agrees as long as the warrants are held by the Founders that they may exercise such warrants on a cashless basis. The Company will not be required to net-cash settle the warrants.

The Company has agreed to use commercially reasonable efforts to register the Private Placement Warrants and common stock underlying the Private Placement Warrants in the IPO.

On August 31, 2015, the Company issued 97,554 warrants with an exercise price of $5.00 to an outside advisor in exchange for services. The Company estimated that the fair value of the warrants issued to the Company's advisor during August 2015 was approximately $272,357 using the Black-Scholes option-pricing model with the following assumptions: fair value of the underlying common stock of $5.00, dividend yield of 0.00%, expected volatility of 58.44%, risk-free rate of 2.33%, and expected term of 6 years.

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

Note 9 — 2014 Long-Term Incentive Equity Plan

In November 2014, the Company's Board of Directors and stockholders adopted the 2014 Long-Term Incentive Equity Plan ("the Stock Plan"). The 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 Stock Plan reserves 1,951,081 shares of common stock for issuance in accordance with the Stock Plan's terms.

All of the Company's officers, directors, employees and consultants, as well as those of its subsidiaries, are eligible to be granted awards under the Stock Plan. An incentive stock option may be granted under the Stock Plan only to a person who, at the time of the grant, is an employee of the Company or its subsidiaries. The types of awards that may be granted under the Stock Plan include stock options, stock appreciation rights, restricted stock and other stock-based awards subject to limitations under applicable law. No awards were granted under the Stock Plan during the year ended December 31, 2015 and for the period from June 26, 2014 (inception) through December 31, 2014. All awards will be subject to approval by the Company's Board of Directors.

Option to Purchase Shares

On April 9, 2015, the Company agreed to issue to each of Dr. Aklog, Mr. Glennon, Dr. deGuzman and the Former CFO an option to purchase 278,726 shares, 278,726 shares, 278,726 shares and 55,745 shares; to each of the five members of its Medical Advisory Board options to purchase 27,873 shares; and to each of non-executive directors options to purchase 97,554 shares upon consummation of the IPO. On October 8, 2015, the Company agreed to issue the Company's Chief Financial Officer, Mr. Fitzgerald, an option to purchase 125,000 shares on the same terms as contemplated in the April 9, 2015 commitments. The options will be issued under the Stock Plan, will be exercisable at the price the units are sold in the IPO and will vest in 36 monthly installments.

Note 10 — Selected Quarterly Financial Data (unaudited)

The following table contains quarterly financial information for the year ended December 31, 2015 and for the period from June 26, 2014 (inception) through December 31, 2014. The Company believes that the following information reflects 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 results for any future period.

	2015				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenues	$ —	$ —	$ —	$ —	$ —
Formation and operating costs	130,337	293,158	274,371	589,407	1,287,273
Research and development costs	16,000	67,450	264,532	141,345	489,327
Total operating expenses	146,337	360,608	538,903	730,752	1,776,600
Loss from operations	(146,337)	(360,608)	(538,903)	(730,752)	(1,776,600)
Net loss	(146,337)	(360,608)	(538,903)	(730,752)	(1,776,600)
Basic and diluted net loss per common share[(2)]	$ (0.01)	$ (0.03)	$ (0.05)	$ (0.06)	$ (0.16)

PAVMED INC. (F/K/A PAXMED INC.) AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

	2014				
	First Quarter[1]	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenues	$ —	$ —	$ —	$ —	$ —
Formation and operating costs	—	5,477	101,135	156,627	263,239
Research and development costs	—	—	—	11,145	11,145
Total operating expenses	—	5,477	101,135	167,772	274,384
Loss from operations	—	(5,477)	(101,135)	(167,772)	(274,384)
Net loss	—	(5,477)	(101,135)	(167,772)	(274,384)
Basic and diluted net loss per common share[2]	—	$ (0.00)	$ (0.01)	$ (0.02)	$ (0.03)

(1) Not applicable as the Company was formed and commenced operations on June 26, 2014. Accordingly, no operating activity to report.

(2) Basic and diluted net loss per share is computed independently for each quarter and year presented; as such the sum of the quarters may not equal the full year amounts.

Exhibit 31.1

CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER

I, Lishan Aklog, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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. 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

    c. 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.

Dated: April 11, 2016

/s/ Lishan Aklog, M.D.

Lishan Aklog, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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. 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

    c. 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.

Dated: April 11, 2016

/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 of PAVmed Inc. (the "Company") on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lishan Aklog, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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.

Dated: April 11, 2016

/s/ Lishan Aklog, M.D.

Lishan Aklog, 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 of PAVmed Inc. (the "Company") on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Richard F. Fitzgerald, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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.

Dated: April 11, 2016

/s/ Richard F. Fitzgerald

Richard F. Fitzgerald, Chief Financial Officer
(Principal Financial and Accounting Officer)