UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

OR

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

For the transition period from _____ to _____

Commission File Number: 001-37685

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

Delaware **(State or Other Jurisdiction of Incorporation or Organization)**	**47-1214177** **(IRS Employer Identification No.)**
One Grand Central Place **60 E. 42nd Street** **Suite 4600** **New York, NY 10165** **(Address of Principal Executive Offices)**	**10165** **(Zip Code)**

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

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

Title of each Class	Trading Symbol(s)	Name of each Exchange on which Registered
Common Stock, $0.001 par value per share	PAVM	The NASDAQ Stock Market LLC
Series Z Warrants, each to purchase one share of Common Stock	PAVMZ	The NASDAQ Stock Market LLC
Series W Warrants, each to purchase one share of Common Stock	PAVMW	The NASDAQ Stock Market LLC

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes [ ] No [X]

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period the registrant was required to submit such files). Yes [X] No [ ]

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
		Emerging growth company	[X]

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

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

As of June 30, 2019, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's voting stock held by non-affiliates was approximately $29.8 million, based on 26,107,832 shares of common stock held by non-affiliates and a last reported sales price per share of the registrant's common stock of $1.14 on such date.

As of April 10, 2020 there were 44,133,745 shares of the registrant's Common Stock, par value $0.001 per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2020 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K where indicated. Such definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the year ended December 31, 2019.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K of PAVmed Inc. ("we", "us", "our" or "PAVmed" or the "Company") contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K (this "Form 10-K"), including statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements are not guarantees of future performance and the Company's actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in Item 1A of Part I of this Form 10-K under the heading "Risk Factors," which are incorporated herein by reference.

Important factors that may affect our actual results include:

- our limited operating history;
- our financial performance, including our ability to generate revenue;
- ability of our products to achieve market acceptance;
- success in retaining or recruiting, or changes required in, our officers, key employees or directors;
- potential ability to obtain additional financing when and if needed;
- ability to protect our intellectual property;
- ability to complete strategic acquisitions;
- ability to manage growth and integrate acquired operations;
- potential liquidity and trading of our securities;
- regulatory or operational risks;
- cybersecurity risks;
- risks related to the COVID-19 pandemic;
- the impact of the material weakness identified by our management;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- the time during which we will be an Emerging Growth Company ("EGC") under the Jumpstart Our Business Startups Act of 2012, or JOBS Act.

In addition, our forward-looking statements do not reflect the potential impact of any future financings, acquisitions, mergers, dispositions, joint ventures or investments we may make.

We may not actually achieve the plans, intentions, and /or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. You should read this Annual Report on Form 10-K and the documents we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

PART I

Item 1. Business

Background and Overview

PAVmed is a highly-differentiated multi-product technology medical device company organized to advance a broad pipeline of innovative medical technologies from concept to commercialization, employing a business model focused on capital efficiency and speed to market. Since inception on June 26, 2014, the Company's activities have focused on advancing its lead products towards regulatory approval and commercialization, protecting its intellectual property, and building its corporate infrastructure and management team. The Company operates in one segment as a medical device company with four operating divisions which include GI Health, Minimally Invasive Interventions, Infusion Therapy, and Emerging Innovations. As resources permit, we will continue to explore internal and external innovations that fulfill our project selection criteria without limiting ourselves to any target specialty or condition. The Company has ongoing operations conducted in two active majority owned subsidiaries: Lucid Diagnostics, Inc. ("Lucid Diagnostics" or "Lucid") incorporated in May 2018 and Solys Diagnostics, Inc. ("Solys Diagnostics" or "Solys") incorporated in October 2019.

PAVmed and its subsidiaries have proprietary rights to the trademarks used herein, including, among others, PAVmed™, Lucid Diagnostics™, Caldus™, CarpX™, DisappEAR™, EsoCheck™, EsoGuard™, EsoCheck Cell Collection Device™ EsoCure Esophageal Ablation Device™ , NextCath™, NextFlo™, PortIO™, and "Innovating at the Speed of Life" ™. Solely as a matter of convenience, trademarks and trade names referred to herein may or may not be accompanied with the requisite marks of "™" or "®", however, the absence of such marks is not intended to indicate, in any way, PAVmed or its subsidiaries will not assert, to the fullest extent possible under applicable law, their respective rights to such trademarks and trade names.

Our multiple products are in various phases of development and regulatory clearances or approvals. EsoCheck has received 510(k) marketing clearance from the U.S. Food and Drug Administration ("FDA") as a generic esophageal cell collection device. EsoGuard has been established as a Laboratory Developed Test ("LDT") and was launched commercially in December 2019 after Clinical Laboratory Improvement Amendment ("CLIA") and College of American Pathologists ("CAP") accreditation of the test at Lucid's commercial diagnostic laboratory partner ResearchDx Inc. ("ResearchDx"), headquartered in Irvine, CA. Our other products in development have not yet received clearance or approval to be marketed or sold in the U.S. or elsewhere. We have been granted patents by the U.S. Patent and Trademark Office ("USPTO") for CarpX, PortIO, and Caldus and have acquired licenses to certain patents and intellectual property for DisappEAR from Tufts University and a group of academic centers, for EsoGuard and EsoCheck from Case Western Reserve University ("CWRU") and more recently for patents covering infrared technology to non-invasively detect glucose in tissue within the in-patient field of use from Liquid Sensing, Inc.

Our four operating divisions include:

- GI Health (EsoGuard Esophageal DNA Test, EsoCheck Esophageal Cell Collection Device, and EsoCure Esophageal Ablation Device with Caldus Technology);
- Minimally Invasive Interventions (CarpX Minimally Invasive Device for Carpal Tunnel Syndrome);
- Infusion Therapy (PortIO Implantable Intraosseous Vascular Access Device and NextFlo Highly Accurate Disposable Intravenous Infusion Set); and
- Emerging Innovations (non-invasive laser-based glucose monitoring, NextCath™ self-anchoring catheters, pediatric ear tubes and mechanical circulatory support).

A brief description of our key divisions and products is as follows:

GI Health

- *EsoGuard, EsoCheck, and EsoCure –*
  refers to a patented platform technology (EsoGuard and EsoCheck) licensed from CWRU to Lucid Diagnostics developed to provide an accurate, non-invasive, patient-friendly screening test for the early detection of adenocarcinoma of the esophagus ("EAC") and of Barrett's Esophagus ("BE"), including dysplasia, pre-cursors to EAC in patients with chronic heart burn or acid reflux, along with a technology (EsoCure) developed by PAVmed to treat BE. EsoGuard is a molecular diagnostic esophageal DNA test shown in a published human study to be highly accurate at detecting BE, as well as EAC. EsoCheck is a non-invasive cell collection device designed to sample cells from a targeted region of the esophagus in a five-minute office-based procedure, without the need for endoscopy. Both EsoGuard and EsoCheck are commercially available, as separately marketed products, for physicians to prescribe for U.S. patients. EsoCure is in development to provide an Esophageal Ablation Device using Caldus Technology to allow a clinician to treat dysplastic BE before it can progress to EAC, a highly lethal esophageal cancer, and to do so without the need for complex and expensive capital equipment.

Item 1. Business - Continued

Background and Overview - continued

Minimally Invasive Interventions

- *CarpX –*
  refers to a patented, single-use disposable, minimally invasive device designed to treat carpal tunnel syndrome while reducing recovery times. CarpX is a medical precision cutting device allowing a physician to relieve the compression on the median nerve without an open incision or the need for endoscopic or other imaging equipment. CarpX was resubmitted to the FDA for 510(k) premarket notification in March 2020 after successfully completing a human clinical safety study.

Infusion Therapy

- *PortIO –*
  refers to a novel, patented, implantable, intraosseous vascular medical 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 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. The absence of an intravascular component will likely result in a very low infection rate.

- *NextFlo –*
  refers to a patented, disposable, IV infusion set designed to eliminate the need for complex and expensive electronic infusion pumps for most of the estimated one million infusions of fluids, medications and other substances delivered each day in hospitals and outpatient settings in the United States. NextFlo is designed to deliver highly accurate gravity-driven infusions independent of the height of the IV bag. It maintains constant flow by incorporating a proprietary, passive, pressure-dependent variable flow-resistor consisting entirely of inexpensive, easy-to-manufacture disposable mechanical parts. NextFlo testing has demonstrated constant flow rates across a wide range of IV bag heights, with accuracy rates comparable to electronic infusion pumps.

Emerging Innovations

- refers to a diversified and expanding portfolio of innovative products designed to address unmet clinical needs across a broad range of clinical conditions. We are evaluating a number of these product opportunities and intellectual property covering a spectrum of clinical conditions, which have either been developed internally or have been presented to us by clinician innovators and academic medical centers, for consideration of a partnership to develop and commercialize these products. This collection of products includes, without limitation, initiatives in noninvasive glucose monitoring, mechanical circulatory support, self-anchoring catheters, and pediatric ear tubes. Furthermore, we are exploring other opportunities to grow our business and enhance shareholder value through the acquisition of pre-commercial or commercial stage products and/or companies with potential strategic corporate and commercial synergies.

Item 1. Business - Continued

Background and Overview - continued

GI Health (Gastroenterology – EsoGuard, EsoCheck, and EsoCure)

In May 2018, Lucid Diagnostics, a majority-owned subsidiary of PAVmed, entered into a patent license agreement with CWRU (the "CWRU License Agreement"), for the exclusive worldwide license of the intellectual property rights for two distinct proprietary technologies focused on the early detection and prevention of EAC, a highly lethal form of esophageal cancer.

The two patent-protected technologies licensed from CWRU are EsoGuard and EsoCheck:

- EsoGuard is a molecular diagnostic esophageal DNA test shown in a published human study to be highly accurate at detecting BE, as well as EAC. BE is a condition in which there are changes in the type of cells lining the esophagus, and which can occur with or without dysplasia (abnormal change in cells that occurs prior to cells becoming cancerous). Most individuals with BE are unaware that they have BE and thus are unaware of their risk of developing EAC, as well as available treatment options which are highly effective at preventing progression of disease. The estimated immediately addressable domestic market opportunity for EsoGuard is nearly $2 billion based on tens of millions of U.S. patients with gastroesophageal reflux disease ("GERD"), more commonly called acid reflux or chronic heartburn, who are BE screening candidates according to published American College of Gastroenterology ("ACG") guidelines.

- EsoCheck is a non-invasive cell collection device designed to sample cells from a targeted region of the esophagus in a five-minute office-based procedure, without the need for endoscopy. It consists of an easy to swallow capsule the size of a gelcap, containing a proprietary textured balloon used to collect a mucosal cell sample when inflated. When the balloon is deflated after cell collection, the proprietary and patent-protected Collect+Protect Technology retracts the balloon with its collected cells back into the capsule, where they are protected during the retrieval process. These sampled cells may then be subjected to any commercially available diagnostic test, including EsoGuard.

Additionally, PAVmed has recently added the EsoCure Esophageal Ablation Device with Caldus Technology to its commercial product development pipeline. EsoCure is a disposable single-use thermal balloon ablation catheter designed to advance through the working channel of a standard endoscope and allow the clinician to treat dysplastic BE before it can progress to highly lethal EAC and to do so without the need for complex and expensive capital equipment. It complements Lucid Diagnostics' portfolio of EsoGuard and EsoCheck products, which are designed to detect nondysplastic and dysplastic BE, as well as EAC itself. EsoCure incorporates PAVmed's patented Caldus Technology ("Caldus") which allows direct thermal tissue ablation using disposable single-use ablation devices. Once PAVmed completes its product development process including obtaining market clearance from the FDA, we intend to add EsoCure to our product offering being presented to the GI physician community by Lucid's contract sales force.

Hence, our first commercial products consist of the EsoCheck device for collecting esophageal cells and the EsoGuard DNA assay for testing cells for the presence of BE and EAC, with both products now commercially available to be prescribed by physicians for U.S. patients. Currently, each product is permitted to be distributed as a separate and distinct product offering. However, we are planning a human clinical trial, expected to be approximately 31 months in duration, in support of an FDA premarket approval ("PMA") application for the marketing of EsoCheck and EsoGuard in combination as a screening tool for the detection of BE. We also plan to develop and commercialize other products that use or enhance the same underlying technology or address the same disease states of the esophagus. We are also currently exploring commercial partnerships for the launch of EsoGuard outside the United States.

We believe the development and commercial availability of our EsoGuard diagnostic test is revolutionary, particularly when performed on samples collected by EsoCheck. Our molecular DNA assay has the potential to save many lives through early BE detection. We were affirmed in this belief in February 2020 when we received Breakthrough Device designation from the FDA for our EsoGuard Esophageal DNA Test on esophageal samples collected using its EsoCheck Cell Collection Device in a prevalent well-defined group of patients at elevated risk for esophageal dysplasia due to chronic GERD. The FDA Breakthrough Device Program was created to offer patients more timely access to breakthrough technologies which provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions by expediting their development, assessment and review through enhanced communications and more efficient and flexible clinical study design, including more favorable pre/post market data collection balance. Breakthrough Devices receive priority FDA review, and a bipartisan bill before Congress (H.R. 5333) seeks to require Medicare to temporarily cover all Breakthrough Devices for three years while determining permanent coverage. Additionally, the National Cancer Institute ("NCI") highlighted EsoGuard and EsoCheck as one of a handful of the year's significant advances in cancer prevention in the NCI's 2020 Annual Plan and Budget Proposal submitted to Congress.

GI Health - Gastroenterology – EsoGuard, EsoCheck, and EsoCure

Furthermore, we believe EsoGuard and EsoCheck (and later EsoCure, if and when it receives FDA 510(k) clearance) will revolutionize the frequency and manner that GI physicians interact with patients suffering from chronic acid reflux and other diseases of the esophagus for the following reasons:

- EsoGuard is the first and only DNA test designed to facilitate the diagnosis of BE and related precursors to highly lethal EAC. EsoGuard has been shown in a 408-patient human study published in *Science Translational Medicine* to be highly accurate at detecting BE, with and without dysplasia, as well as EAC, with greater than 90% sensitivity and specificity.

- EsoCheck is the only esophageal cell collection device capable of performing targeted sampling of esophageal cells in a minimally invasive way while also preventing the dilution and contamination of the cell samples as the catheter is withdrawn, thus allowing for the DNA test to pick up the low level signal of pre-cancerous changes against the background noise of other changes in non-targeted anatomic areas.

- The American College of Gastroenterology's guidelines recommend screening in millions of high-risk patients to detect and treat BE, with or without dysplasia, before it progresses to EAC. However, fewer than 10% actually undergo screening using the traditional invasive approach, upper endoscopy. Tragically, most patients diagnosed with EAC are neither aware of their underlying BE, nor that they missed the opportunity to undergo treatment which could have prevented progression to EAC had the BE been diagnosed earlier. As a result, over 80% die within five years of diagnosis. A modest increase in screening rates from 10-25% of high-risk GERD patients would prevent several thousand deaths per year from EAC. The use of EsoGuard on samples collected with EsoCheck has the potential to reverse this tragic situation and we believe could have as great an impact on esophageal cancer as widespread Pap screening has had in preventing deaths from cervical cancer.

Our EsoGuard Opportunity

The incidence of EAC, the most common cancer of the esophagus, has quadrupled over the past 30 years. Its prognosis remains dismal, with fewer than 20% of patients surviving at five years. We are pursuing the development of the EsoGuard technology to provide the more than 30 million diagnosed GERD patients a non-invasive, less costly test by which to detect BE so that patients identified with the condition may receive surveillance and medical therapies well known to be highly effective at preventing progression to esophageal cancer.

The primary risk factor for, and a presumed cause of BE is GERD, commonly known as chronic heartburn or acid reflux, wherein stomach acid refluxes into the esophagus. GERD affects 20-40% of Western adult populations, according to published epidemiological data. The repeated exposure to stomach acid can lead to specific metaplastic and dysplastic, *i.e.* pre-cancerous changes in the esophageal lining, a condition known as Barrett's Esophagus (which we refer to as BE).

BE is most diagnosed in the U.S. by the presence of so-called "salmon colored" mucosa visualized during upper endoscopy together with columnar epithelium (so-called intestinal metaplasia) seen on in biopsies taken from such an affected area. In BE, columnar epithelium replaces the stratified squamous epithelium which normally lines the distal esophagus (at the nexus of the stomach). This metaplastic epithelium is the initial manifestation of a progressive disease process, which, if unabated, continues through a dysplastic phase and ultimately into EAC. Due to the known risk for progression of BE toward EAC, current guidelines advise patients with nondysplastic BE to be enrolled in endoscopic surveillance programs in order to detect progression. Endoscopic surveillance includes extensive biopsy sampling, taken per the Seattle biopsy protocol. For nondysplastic BE, the American College of Gastroenterology recommends surveillance endoscopy at 3-5 year intervals. For patients with confirmed low grade dysplasia ("LGD") and without life-limiting comorbidity, endoscopic therapy is considered as the preferred treatment modality, although endoscopic surveillance every 12 months is an acceptable alternative. Patients with high grade dysplasia ("HGD") are to be managed with endoscopic therapy.

The only currently-validated approach to assess a patient for BE and EAC, and the current "gold standard", is white light esophagogastroduodenoscopy ("EGD," also commonly known as "upper endoscopy"), together with collection of multiple biopsy specimens from the potentially affected area in the distal esophagus. The procedure is invasive and expensive. In the U.S., EGD is almost always done under intravenous sedation in a specialized facility. It requires a patient to be fasting for several hours beforehand, to take a day off from work, and to be accompanied by a caregiver who also must miss work as a result. Multiple biopsies must be taken, and each must be read by a highly trained and specialized medical pathologist. Interpretation of these biopsies is highly subjective; for BE with LGD, pathological interpretation comes with an unacceptably low concordance rate between pathologists. The EGD procedure itself, the administration of anesthesia, and the procurement of biopsies, all carry medical risk. No screening alternative exists currently, and no device currently carries an FDA label indication to screen for any of these conditions. It is our belief that EsoGuard may become the widespread screening test to fulfill this unmet patient need similar to how pap smears and HPV testing have now become the widespread screening test to help eradicate cervical cancer.

Our EsoGuard Opportunity - continued

However, despite the well-accepted understanding that BE may progress to dysplasia and EAC, the clear guidance on the importance of BE surveillance and treatment, and the broad availability of EGD throughout the U.S., most cases of BE remain undiagnosed. Multiple studies demonstrate that more than 90% of patients who develop EAC never knew they had BE prior to their EAC diagnosis. A major opportunity for prevention of this cancer is being missed due to inadequate screening of at-risk populations. The major GI societies clearly define populations at high risk and advocate screening of such individuals, yet the vast majority go unscreened. It is estimated that more than 90% of high risk individuals for whom screening is currently indicated do not have it done. Put simply, nearly all EAC patients have evidence of BE but fewer than one in ten will have had the condition detected prior to their cancer diagnosis.

Dysplasia can be treated with ablation, but most patients are diagnosed with EAC at an advanced stage. EsoCheck and EsoGuard are designed to enhance screening and help clinicians catch BE and dysplasia while it's still early enough to be treated and eliminated. Enhancing screening, in this case, means providing better sampling of the esophagus as well as a highly accurate test to determine whether precursor conditions have occurred.

Nearly all patients diagnosed with EAC have evidence of BE, and it is accepted that BE is a precursor condition on a spectrum of progression that in certain individuals will culminate in EAC, but in the vast majority of those with EAC, no prior diagnosis of BE will have been made. If detected before the EAC esophagus cancer develops, Barrett's Esophagus can be successfully treated, usually with non-surgical approaches. Heartburn symptoms, commonly seen in patients with acid reflux with or without BE, can easily be treated with over-the counter medications, while a diagnosis of BE with LGD or HGD offers options for endoscopic management including radiofrequency ablation and local resection; these technologies have made LGD and HGD highly treatable with success rates of such therapies at greater than 90%.

Our EsoGuard and EsoCheck Solution

EsoCheck collects cells from the esophagus without the need for endoscopy in a non-invasive five-minute office-based procedure. Its proprietary and patent-protected Collect+Protect Technology protects collected samples from being diluted or contaminated during retrieval within an easy to swallow capsule the size of a gelcap. The capsule contains a proprietary textured balloon that when inflated inside the esophagus exposes ridges that have been shown to collect a greater amount of cellular material than predicate devices.

We have completed a survival porcine study that included side-by-side comparison testing between the EsoCheck Cell Collection Device and the Hobbs Medical Cytology Brush, a reference device included in our 510(k) submission to the FDA. The study was conducted under Good Laboratory Practices ("GLP") per the FDA's regulation 21 CFR Part 58.5 and the results submitted to the FDA as part of the EsoCheck 510(k) marketing application. One of the objectives of the study was to evaluate the performance of the EsoCheck Device and the Hobbs Medical Cytology Brush when used as indicated for cell collection in the esophagus in a clinically representative model. Specific evaluation included assessment of the adequacy of the sample of collected cells.

The study was performed utilizing four animals with two separate anatomic areas in each animal's esophagus sampled with the EsoCheck device, and two separate anatomic areas in each animal's esophagus sampled with the Hobbs Medical cytology brush to ensure that each cell sample was taken from a previously undisturbed area of the esophagus.

After collection of the esophageal cell samples, each cell collection device was placed in vials containing standard preservative solution. The vials were then delivered to a Clinical Laboratory Improvement Amendments ("CLIA") and College of American Pathologists ("CAP") certified laboratory for assessment of the cellular material. A pathologist with subspecialty board certification in gastrointestinal cytopathology reviewed the slides and cell counts were determined using standard methodology. Each slide was viewed under high-power and standard visual estimation techniques were used to determine the total number of cells sampled. The results showed an average number of cells greater than 25,000 for the EsoCheck device compared to an average number of cells greater than 11,000 for the Hobbs Medical Cytology Brush.

Once the targeted region of the esophagus is swabbed collecting cells on the balloon's surface, the Collect+Protect Technology pulls the collected cells into the capsule where they are then protected during the retrieval process. Avoiding sample dilution is a key feature of the device since capturing unnecessary cells decreases the ability to detect the needed signal. The sampled cells can then be sent onto a molecular laboratory to perform any commercially available diagnostic test.

The use of EsoGuard, on samples collected using EsoCheck, may offer an accurate, lower cost, non-invasive approach, that does not require endoscopy, to screen for BE and EAC. The use of EsoGuard, on samples collected using EsoCheck, is not intended as a replacement for EGD. Instead of replacing EGD, it is our vision that the use of EsoGuard, on samples collected using EsoCheck, may "enlarge the top of the funnel" of high risk individuals who get screened in the first place; those who test positive by EsoGuard will proceed to an EGD, whether as a confirmatory diagnostic procedure, a therapeutic ablation procedure, or both.

By focusing the use of these follow-up EGDs on patients with the highest pre-EGD likelihood of a positive finding, and by doing so more effectively and less expensively than the current risk stratification criteria allow, the use of EsoGuard, on samples collected using EsoCheck, may enable health care systems to allocate more effectively the resources they currently spend on performing EGDs.

EsoGuard and EsoCheck Development and Commercial Status

EsoCheck is commercially available under a substantial equivalence determination made by the FDA pursuant to a 510(k). On June 21, 2019, Lucid was notified by FDA that it may market EsoCheck, subject to the general controls provisions of the Food, Drug, and Cosmetic Act (the "FDCA"), as a cell collection device indicated for use in the collection and retrieval of surface cells of the esophagus in the general population of adults, 22 years of age and older.

EsoGuard is commercially available to be prescribed by physicians for patients in the United States as an LDT and has been reported in an article in *Science Translational Medicine* to have a high sensitivity and specificity for the detection of Barrett's Esophagus with and without dysplasia, as well as for EAC. LDT refers to a laboratory developed test and is a type of molecular diagnostic test that is designed, manufactured and used within a single laboratory which is also certified pursuant to the CLIA to support the marketing of the test.

EsoCheck (*i.e.*, by itself) may be used routinely by physicians to collect esophageal cells for various medical diagnostic purposes, including to diagnose or manage conditions such as Esophageal Candidiasis (a yeast infection of the esophagus which occurs in patients with compromised immune systems) and Eosinophilic Esophagitis (a common inflammatory condition of the esophagus) ("EoE"). EsoGuard (*i.e.*, also by itself) may be performed on cytology samples collected by a means other than EsoCheck (*e.g.*, via EGD. However, our present clinical development focus, and the subject of a recent IVD pre-submission meeting with the FDA, is on assessing the performance of the combined system (*i.e.*, the use of the EsoGuard assay on cells collected using EsoCheck) as a screening tool to detect BE, with and without dysplasia, and/or EAC, in individuals deemed to be at high risk for these conditions.

Eosinophilic Esophagitis

In March 2020, we entered into a clinical trial research agreement with the University of Pennsylvania ("Penn") for a clinical trial designed to evaluate whether Lucid's EsoCheck Esophageal Cell Collection Device with Collect+Protect™ Technology provides a less invasive, more efficient, and cost-effective alternative to endoscopic biopsies in the management of patients with EoE.

EoE is a rapidly emerging allergy-mediated inflammatory condition of the esophagus similar to and often associated with inflammatory bowel disease ("IBD"). Although underappreciated by the medical community and frequently confused with GERD, EoE has a prevalence comparable to IBD and exacts a significant burden on patients. It can lead to swallowing difficulties, esophageal scarring, food impaction and pain. Current treatment includes oral steroids and an elimination diet. Since inflammation can persist despite resolution of symptoms, treatment courses can be very difficult and costly for patients, requiring multiple and frequent invasive endoscopies with biopsies. To date efforts to replace endoscopy with a non-invasive diagnostic device have proven unsuccessful.

The Lucid-Penn agreement covers a research program entitled "*Pilot Study of EsoCheck Compared to Biopsies and Brush Cytology During Endoscopy for Evaluation of Eosinophilic Esophagitis*" (the "Study") led by principal investigator Gary W. Falk, M.D., M.S., AGAF. Dr. Falk is a professor of Gastroenterology, the clinical co-director of the Joint Center for Digestive, Liver and Pancreatic Medicine at the Perelman School of Medicine at the University of Pennsylvania, and the co-director of the Penn Medicine Esophageal and Swallowing Center at the Hospital of the University of Pennsylvania. He is also a Director of the International Society for Diseases of the Esophagus and Past President of the American Society of Gastrointestinal Endoscopy (ASGE).

The trial is a prospective cross-sectional pilot feasibility study of ten patients with suspected or established EoE scheduled for a clinically indicated upper endoscopy. The patients will undergo esophageal sampling using EsoCheck followed by endoscopy, including brushings and biopsies. The primary endpoint of the trial is the sensitivity and specificity of EsoCheck versus endoscopic biopsy in the assessment of EoE.

EsoGuard and EsoCheck Development and Commercial Status - continued

Barrett's Esophagus Screening Tool

We intend to seek FDA approval for the use of EsoGuard, on samples collected using EsoCheck, as an IVD device through a PMA submission. The combined system may offer an accurate, lower cost, non-invasive, approach to screen for BE with and without dysplasia, and for EAC, as compared with the current gold standard, namely diagnostic EGD plus biopsy. EsoCheck used for this purpose is performed as a five-minute office-based procedure without sedation. Samples collected are sent for laboratory analysis by EsoGuard and typically result in the issuance of a report of findings to the ordering physician, in under three weeks from the date of the test.

In October 2019, we had a pre-submission meeting with the FDA seeking FDA guidance on the clinical development plan we propose to conduct, consisting of a screening study and a case control study, in support of a future PMA submission to approve EsoCheck and EsoGuard as an IVD medical device. We expect to enroll our first patient in the early part of 2020.

In February 2020, we received Breakthrough Device designation from the FDA for its EsoGuard™ Esophageal DNA Test on esophageal samples collected using its EsoCheck Cell Collection Device in a prevalent well-defined group of patients at elevated risk for esophageal dysplasia due to chronic GERD. The FDA Breakthrough Device Program was created to offer patients more timely access to breakthrough technologies which "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions" by expediting their development, assessment and review through enhanced communications and more efficient and flexible clinical study design, including more favorable pre/post market data collection balance. Breakthrough Devices receive priority FDA review, and a bipartisan bill before Congress (H.R. 5333) seeks to require Medicare to temporarily cover all Breakthrough Devices for three years while determining permanent coverage.

EsoGuard Business Strategy

The EsoGuard technology is progressing through a two-phase regulatory and commercialization strategy which seeks to maximize the long-term commercial opportunity while providing near-term commercial milestones.

Near-Term Strategy

In June 2019, we received 510(k) marketing clearance for the EsoCheck cell collection device from the FDA, which determined that EsoCheck is substantially equivalent to legally marketed predicate devices for its indication for use, namely "the collection and retrieval of surface cells of the esophagus in the general population of adults, 22 years of age or older." We are also pursuing other indications for EsoCheck beyond its use to collect cells for the EsoGuard DNA test. We have engaged key advisors to begin utilizing EsoCheck in other common esophageal conditions such as Esophageal Candidiasis and EoE.

EsoGuard has been established as an LDT and was launched commercially in December 2019 after completing CLIA/CAP certification of the test at Lucid's commercial diagnostic laboratory partner ResearchDx, headquartered in Irvine, CA.

Laboratory Developed Tests

LDTs are clinical laboratory tests that are designed, manufactured and used within a single laboratory. The laboratories that furnish LDTs are subject to regulation under CLIA and state clinical laboratory licensure laws (where applicable). The FDA takes the position that LDTs meet the definition of a medical device under the FDCA. Historically, however, the FDA has exercised enforcement discretion with respect to most LDTs, and not actively enforced the regulatory requirements that otherwise apply to medical device manufacturers (*e.g.*, premarket review, Quality Systems Regulation, adverse event reporting, establishment registration, device listing). The FDA has traditionally chosen to exercise enforcement discretion because LDTs were limited in number, were relatively simple tests, and were typically used to diagnose rare disease and uncommon conditions.

In October 2014, the FDA published two draft guidance documents describing a proposed risk-based framework under which the FDA proposed to end enforcement discretion and begin regulating LDTs as medical devices. The FDA's draft framework proposed, among other things, premarket review for higher-risk LDTs, such as those that have the same intended use as FDA-approved companion diagnostic currently on the market. In November 2015, the FDA issued a report citing evidence for the need for additional regulation of LDTs and stated the FDA is continuing to work to finalize the 2014 draft guidance. However, in November 2016, the FDA announced that it did not intend to finalize the draft guidance at that time. In January 2017, the FDA issued a Discussion Paper on LDTs, which confirmed it did not intend to finalize the draft guidance at that time to allow more time for public discussion and time for the congressional authorizing committees to develop a legislative solution. Various legislative proposals that would give FDA express authority to regulate LDTs have been proposed since that time, but the chances of any specific proposal being enacted remain unclear at this time. It is also unclear at this time if or when the FDA may end enforcement discretion for LDTs, and the FDA may decide to regulate certain LDTs on a case-by-case basis at any time. Action by the FDA to actively regulate our LDT may materially impact our ability to develop and commercialize EsoGuard as planned.

Reimbursement Strategy

Successful commercialization of our EsoGuard test depends, in large part, on our receipt of adequate reimbursement from government insurance plans, including Medicare and Medicaid, managed care organizations and private insurance plans. We are in the process of seeking a Local Coverage Determination ("LCD") from Palmetto GBA ("Palmetto"), the Medicare Administrative Contractor ("MAC") that coordinates coverage for molecular diagnostic tests and will subsequently seek private payer health insurance coverage for patients. As of yet, no payer has adopted a positive coverage policy for EsoGuard. Until such time, we will need to obtain reimbursement from payers on a case-by-case basis.

At the end of March 2019, we submitted an application for a Proprietary Laboratory Analysis ("PLA") code for EsoGuard to the American Medical Association (the "AMA)." The AMA assigned EsoGuard PLA code 0114U "Gastroenterology (Barrett's esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus" effective October 1, 2019.

The Clinical Laboratory Fee Schedule ("CLFS") has not yet set the Center for Medicare and Medicaid Services ("CMS") reimbursement rate for EsoGuard or EsoCheck, and neither have any other third-party payers approved reimbursement or set a reimbursement rate for our products. In December 2019, CMS posted the Final Determinations for new and revised billing codes for laboratory services under the Medicare CLFS. Under the Final Determinations, Medicare payment for the EsoGuard test will be set by the regional MACs under the "gapfill" process. Under this process, the MACs will consider test charges, resources, rates paid by other payers, rates paid for similar tests, and other factors. CMS will take the regional rates set by MACs in early 2020 and determine a preliminary CLFS rate for 2021 at the median of the MAC rates. This preliminary rate will be subject to comments before being finalized later in 2020. The final gapfill amount will apply for the period January 1, 2021 through December 31, 2023.

Commercial third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new healthcare products. As a result, there is uncertainty surrounding whether EsoGuard or EsoCheck, or any other product or service we develop, will be eligible for coverage by third-party payers or, if eligible for coverage, what the reimbursement rates will be. Reimbursement of esophageal cancer screening by a third-party payer may depend on a number of factors, including a payer's determination that tests using our technologies are: sensitive and specific for esophageal cancer and pre-cancer; not experimental or investigational; approved or recommended by the major guidelines organizations; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost-effective.

Medicare

For EsoGuard, Medicare reimbursement is critical. CMS relies on a network of MACs to process provider claims for reimbursement, including claims for diagnostic tests. Where appropriate, MACs draft and finalize LCDs that describe the circumstances under which an item or service that is not included in the CLFS will (or will not) be covered. Almost all EsoGuard claims will be processed by the MAC for California, Noridian Healthcare Solutions ("Noridian"). Noridian participates in the Molecular Diagnostic Services ("MolDX") Program coordinated by Palmetto. Under the MolDX Program, Palmetto reviews a detailed dossier of information describing the performance characteristics of molecular diagnostic tests (*i.e.*, data describing the test's analytical validity, clinical validity, and clinical utility) and, working collaboratively with other MAC medical directors, decides whether to cover a test. We will need to work with the MolDX Program to obtain a favorable final LCD before Noridian will pay claims for EsoGuard.

LDTs that are covered by Medicare are generally reimbursed under the Medicare CLFS. From time to time, Congress has revised the Medicare statute, including how CMS establishes CLFS payment rates. The payment amounts established under the Medicare fee schedules (such as the CLFS) are important because they will determine the amount of reimbursement for a diagnostic under Medicare, and those payment amounts are also often used as a basis for payment amounts set by other governmental and private third-party payers. For example, state Medicaid programs are prohibited from paying more than the CLFS rate for clinical laboratory services furnished to Medicaid recipients.

Private Third-Party Payers

In addition to seeking Medicare coverage and reimbursement, we will seek coverage and reimbursement from private payers such as health insurance companies and HMOs. Private payers generally will determine whether to approve an LDT for reimbursement based on the published results demonstrating the analytical validity, clinical validity, and clinical utility of the test.

Reimbursement rates paid by private third-party payers can vary based on whether the provider is considered to be an "in-network" provider, a participating provider, a covered provider, an "out-of-network" provider or a non-participating provider. These definitions can vary among payers. An in-network provider usually has a contract with the payer or benefits provider. This contract governs, among other things, service-level agreements and reimbursement rates. In certain instances, an insurance company may negotiate an in-network rate for our testing. An in-network provider may have rates that are lower per test than those that are out-of-network, and that rate can vary widely. Rates vary based on the payer, the testing type and often the specifics of the patient's insurance plan. If a laboratory agrees to contract as an in-network provider, it generally expects to receive quicker payment and access to additional covered patients. However, it is likely that we will initially be considered an "out-of-network" or non-participating provider by payers who cover the vast majority of patients until we can negotiate contracts with the payers. Our out-of-network claims may be subject to certain "surprise billing" restrictions enacted by state legislatures and/or currently under consideration in the U.S. Congress.

We cannot predict whether, or under what circumstances, payers will cover and pay for our tests. Full or partial denial of coverage by payers, or reimbursement at inadequate levels, would have a material adverse impact on our business and on market acceptance of our tests.

We are pursuing a variety of strategies to maximize commercial payer coverage for EsoGuard, including developing cost effectiveness data to provide to payers to make the case for EsoGuard reimbursement. We will focus our efforts on large national and regional insurers and health plans that have affiliated health systems.

When there is a private or governmental third-party payer coverage policy in place, we will bill the payer through our contract laboratory service provider (and the patient for cost-sharing, where applicable). Our efforts in obtaining reimbursement based on individual claims, including pursuing appeals or reconsiderations of claims denials, could take a substantial amount of time, and bills may not be paid for many months, if at all. Furthermore, if a third-party payer denies coverage after final appeal, payment may not be received at all. Where there is no coverage policy in place, we will pursue reimbursement on a case-by-case basis.

Longer-Term Strategy

Our longer-term strategy is to secure a specific indication, based on published guidelines, for BE screening in certain at-risk populations using EsoGuard on samples collected with EsoCheck. This requires having the EsoGuard screening system cleared or approved by the FDA as an IVD device, a process which is progressing in close collaboration with our medical and regulatory advisors, including the former Director, Office of In Vitro Diagnostics and Radiological Health, FDA Center for Devices and Radiological Health. An FDA pre-submission package outlining Lucid-sponsored clinical studies to be performed in support of this indication has been submitted and a pre-submission meeting held with the FDA on October 9, 2019 to discuss its clinical data requirements for a premarket submission to approve EsoGuard as an IVD medical device. As part of advancing this longer-term strategy, PAVmed hired David F. Wurtman, M.D., in February 2019 to act as, and spend substantially all of his time as, Lucid's Chief Medical Officer. In June 2019, PAVmed hired Randy Brown, to act as and spend substantially all of his time as Lucid's Chief Operating Officer. Mr. Brown, who recently served as the director of clinical operations of a large multinational medical device company, is overseeing clinical planning of these upcoming clinical trials sponsored by Lucid, as well as operations of the EsoGuard LDT. In September 2019, we entered into an agreement with a clinical research organization ("CRO") in connection with EsoGuard clinical trials. The CRO will assist us with conducting two concurrent clinical trials, an EsoGuard screening study and an EsoGuard case control study. The term of the agreement with the CRO runs from the September 2019 to the conclusion of the respective clinical trials, which is expected not to exceed 31 months. The agreement may be cancelled with sixty days written notice, without an early termination fee. We enrolled our first patient in the clinical trials in February 2020.

The screening study will enroll GERD patients without a prior diagnosis of BE or EAC who satisfy ACG BE screening guidelines. The case control study will enroll patients with a previous diagnosis of non-dysplastic BE, dysplastic BE (both low and high-grade) or EAC. In both studies, EsoGuard will be compared to the gold standard of endoscopy with biopsies. In February 2020, EsoGuard has received Breakthrough Device designation from the FDA for its EsoGuard Esophageal DNA Test on esophageal samples collected using its EsoCheck Cell Collection Device in a prevalent well-defined group of patients at elevated risk for esophageal dysplasia due to chronic GERD.

FDA Breakthrough Device

The U.S. Food and Drug Administration "Breakthrough Device" designation relates to the FDA's Breakthrough Device Program that was created to offer patients more timely access to breakthrough technologies which provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions by expediting their development, assessment and review through enhanced communications and more efficient and flexible clinical study design, including more favorable pre- and post-market data collection. Breakthrough Devices receive priority FDA review, and a bipartisan bill before Congress (H.R. 5333) seeks to require Medicare to temporarily cover all Breakthrough Devices for three years while determining permanent coverage.

In-Vitro Diagnostics

IVDs are regulated by the FDA as medical devices. Medical devices marketed in the United States are subject to the regulatory controls under the FDCA and regulations adopted by the FDA. Some requirements, known as premarket requirements, apply to medical devices before they are marketed, and other requirements, known as post-market requirements, apply to medical devices after they are marketed.

The particular premarket requirements that must be met to market a medical device in the United States will depend on the classification of the device under FDA regulations. Medical devices are categorized into one of three classes, based on the degree of risk they present. Devices that pose the lowest risk are designated as Class I devices; devices that pose moderate risk are designated as Class II devices and are subject to general controls and special controls; and the devices that pose the highest risk are designated as Class III devices and are subject to general controls and premarket approval.

A premarket submission to the FDA will be required for some Class I devices, most Class II devices; and all Class III devices. Most Class I and some Class II devices are exempt from premarket submission requirements. Some Class I and most Class II devices may be marketed after a 510(k) clearance, while a more extensive PMA is required to market Class III devices.

Unless the FDA begins enforcing the medical device requirements with respect to LDTs (either generally or with respect to our specific test), or Congress enacts legislation that explicitly gives FDA the authority to regulate LDTs, EsoGuard (as a stand-alone product) will not be subject to FDA requirements, including (without limitation) the requirements for FDA premarket review and post-market controls. Since the EsoGuard test is being performed in a clinical laboratory, the laboratory will be subject to CLIA requirements, as well as the laboratory requirements in the state in which the laboratory is located (if applicable). Insofar as the laboratory accepts specimens from patients nationwide, the laboratory will be required to obtain an out-of-state laboratory license from regulators in New York, California, Pennsylvania, Maryland, and Rhode Island. Moreover, before we can begin offering our LDT to patients in New York, we must obtain test-specific approval from the state.

Complying with the FDA's requirements for medical devices can be expensive, time consuming, and may subject us to significant or unanticipated delays. If we are required to obtain premarket clearance or approval to perform or continue performing EsoGuard tests, or otherwise become subject to FDA regulation (e.g., via an act of Congress), we cannot assure you that we will be able to obtain such clearance or approval or comply with such regulations. Even if we obtain regulatory clearance or approval where required, such authorization may not be for an intended use that we believe to be commercially attractive or critical to the commercial success of our tests. As a result, the application of FDA oversight to our tests could materially and adversely affect our business, financial condition, and results of operations.

However, in parallel to our efforts to commercialize EsoGuard as an LDT, we are engaging with the FDA to explore the possibility of performing EsoGuard on cell samples collected using EsoCheck as an IVD. The IVD path seeks to secure a specific Barrett's Esophagus screening indication for EsoGuard and EsoCheck as an FDA-cleared device in high-risk GERD patients as defined by published society guidelines. This will allow EsoGuard and EsoCheck to be broadly marketed together as a single diagnostic tool to screen patients for BE. It requires a premarket submission to the FDA supported by strong clinical data demonstrating that EsoGuard performed on samples collected with EsoCheck is sufficiently sensitive and specific to serve as a widespread screening tool in high-risk GERD patients recommended for screening. We have provided a pre-submission document to the FDA outlining our clinical plan and have held a pre-submission meeting with the FDA on October 9, 2019 to review the proposed clinical plan to meet the above endpoints in an effort to secure EsoGuard IVD FDA clearance as a medical device once the clinical study is completed. The EsoGuard screening tool also has received a "Breakthrough Device" designation, which will facilitate the process of seeking premarket approval.

CWRU License Agreement

In May 2018, PAVmed incorporated Lucid Diagnostics and caused Lucid to issue a total of 10.0 million founders shares of its common stock for a purchase price of $0.001 per share, including: the issue of 8,187,499 founders shares to PAVmed; 943,464 founders shares to CWRU; and 289,679 founders shares to each of the three individual physician inventors of the of the intellectual property and proprietary technologies underlying the CWRU License Agreement.

In May 2018, Lucid entered into the CWRU License Agreement. Under the terms of the CWRU License Agreement, we acquired an exclusive worldwide right to use the intellectual property rights to the EsoGuard and EsoCheck technology for the detection of changes in the esophagus. CWRU retains the right to grant licenses to the EsoCheck and EsoGuard technology for other non-overlapping uses.

The CWRU License Agreement required Lucid to pay an initial license fee to CWRU of approximately $273,000. The initial license fee consisted of an initial payment of $50,000, followed by quarterly payments of $50,000 until such fee is paid-in-full, provided, however, the commencement of the quarterly payments is subject to the Company consummation of a bona fide financing with an unrelated third-party in excess of $500,000. As of December 31, 2019 and 2018, respectively, the balance of the initial license fee of $273,000 remains unpaid.

The CWRU License Agreement also provides for potential payments upon the achievement of certain product development and regulatory clearance milestones. In this regard, upon FDA clearance on June 21, 2019 of the EsoCheck device, Lucid incurred a $75,000 milestone payment. The CWRU License Agreement also provides for two additional milestone obligations with a payment of $100,000 due within 30 days upon the first commercial sale of a licensed product and a payment of $200,000 due upon a PMA submission to the FDA related to a licensed product.

The Company will be required to pay CWRU a royalty of 5% on net sales of less than $100,000,000 per contract year and 8% for net sales greater than $100,000,000 per contract year, with the following minimum annual royalty payments:

- $50,000 per contract year beginning January 1 following the first anniversary of first commercial product sale;
- $150,000 per year for each year after the first year net sales of a licensed product exceed $25 million;
- $300,000 per year for each year after the first year net sales of a licensed product exceed $50 million;
- $600,000 per year for each year after the first year net sales of a licensed product exceed $100 million;
- Minimum annual royalty amounts are adjusted by the percentage change in the CPI-W Consumer Price Index.

Under the CWRU License Agreement, Lucid is responsible for the costs of CWRU in preparing, filing and prosecuting any patents related to the EsoGuard and EsoCheck technology (subject to a provision for cost sharing in the event CWRU grants other non-overlapping licenses to the technology). CWRU agreed to apply for patent coverage, at Lucid's expense, in any country requested by Lucid, to the extent such protection is reasonably attainable. CWRU also may apply for patent, copyright or trademark rights to the EsoGuard and EsoCheck technology in other countries, at its option, and Lucid will have no rights under any the patents in such countries unless Lucid reimburses CWRU for its expenses. In the event of any actual or threatened infringement of any patent in the field of use covered by the License Agreement, Lucid will have the first right to commence an action against the infringer. Lucid also will have the right to defend against any claims that the EsoGuard and EsoCheck technology infringes on the intellectual property rights of a third party.

The CWRU License Agreement provides for Lucid to indemnify CWRU and certain related parties for any claims relating to product liability or similar claims involving acts or omissions by Lucid in connection with the EsoGuard technology and the development, use or sale of products based on such technology, or relating to Lucid's gross negligence or willful misconduct, or relating to our breach of the CWRU License Agreement, unless, in any case, such claim results from the gross negligence or willful misconduct of CWRU.

The CWRU License Agreement terminates upon the expiration of certain related patents, or on May 12, 2038 in countries where no such patents exist, or upon expiration of any exclusive marketing rights that have been granted by the FDA or other U.S. government agency, whichever comes later. The key EsoGuard U.S. patents begin to expire in August 2024, however, Lucid is pursuing applications of the clinical utility to extend the patent protection with more recently filed families of cases that have a twenty year term and will be set to expire in the mid to late 2030's once they are issued. It is noteworthy that the accuracy confidence of the EsoGuard assay has only been tested with cells collected using the EsoCheck Collect + Protect technology. The key EsoCheck device U.S. patents begin to expire in December 2034. In the event that Lucid defaults in the payment of any amount when due under the License Agreement, and such amount is not paid within 30 days of notice of nonpayment, CWRU may terminate the exclusivity of the license or terminate the CWRU License Agreement in full. In addition, either party may terminate the CWRU License Agreement upon the other party's default in the performance of its obligations under the License Agreement, subject to certain grace periods. Upon expiration of the CWRU License Agreement in the ordinary course, we expect to continue selling products using the EsoGuard and EsoCheck technology, as CWRU's proprietary intellectual property rights in the technology also will have expired.

EsoGuard Sales and Marketing

We currently expect to commercialize the EsoCheck and EsoGuard products through a network of independent U.S. sales representative and/or inventory-stocking medical distributors. To do so, we rely on having a high gross margin on our products, although there can be no assurance that we will be able to achieve such margins. A high gross margin allows us to properly incentivize our independent sales reps and distributors, which in turn allows us to attract the top independent reps and 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 the EsoCheck and EsoGuard products if it is in our long-term interests. We may also choose to enter into distribution agreements with one or more larger strategic partners whereby we retain full responsibility for the manufacturing of the EsoCheck and EsoGuard products but outsource a substantial portion or all of our 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.

EsoGuard Clinical Laboratory and EsoCheck Manufacturing

EsoGuard will be marketed as an LDT, which is a clinical laboratory test that is designed, manufactured and used within a single laboratory. The laboratories that furnish LDTs are subject to regulation under CLIA and state clinical laboratory licensure laws (where applicable). We will depend on third parties as the clinical laboratories for our LDTs. Although we relied on the central reference laboratory in Cleveland, Ohio, to complete our initial EsoGuard LDT validation process, as part of our longer term commercialization strategy, we have established an outsourced contract relationship with ResearchDx, a state-of-the-art, highly automated contract diagnostic organization in Irvine, California that is certified pursuant to federal CLIA requirements to perform key portions of the assay to support the marketing of the EsoGuard LDT. ResearchDx will have the capacity to process and report on the volume of expected patient samples using EsoGuard for the foreseeable future. We completed the EsoGuard LDT validation process at ResearchDx in December 2019, making the LDT test available for physicians to prescribe for patients.

We currently have no plans to use in-house facilities to manufacture the EsoCheck device, because the fixed overhead costs and limited flexibility involved in owning manufacturing facilities are not consistent with our business strategy. The diagnostic medical device industry, including many of its largest players, depends heavily on contract manufacturers operating in the United States and abroad. Diagnostic 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 and service providers, 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 and service providers to establish and manage the EsoCheck and EsoGuard products' supply chain, dual sourcing whenever possible. We expect to help them design and build the EsoCheck and EsoGuard 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 the EsoCheck and EsoGuard 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.

EsoGuard and EsoCheck Intellectual Property

Our GI Health business will depend on proprietary medical device and diagnostic technologies, including the EsoCheck and EsoGuard technology licensed by us. 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 GI Health business. The EsoCheck and EsoGuard technology is protected by patents in the United States and internationally, and our policy is to continue to aggressively file patent applications, both independently and in collaboration with CWRU, as appropriate, to protect this technology and other proprietary technologies of ours relating to our GI Health business, including inventions and improvements to inventions. Under the CWRU License Agreement, CWRU has agreed to apply for patent coverage, at our expense, in any country requested by us, to the extent such protection is reasonably attainable. 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 Canada, the European Union 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 USPTO in granting a patent.

We intend to continuously reassess and fine-tune our intellectual property strategy in order to fortify the position of our GI Health business 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 in our GI Health business. We intend to protect our proprietary rights through a variety of methods, including confidentiality agreements and/or proprietary information agreements with suppliers, employees, consultants, independent contractors and other entities who may have access to proprietary information. We will generally require employees to assign patents and other intellectual property to us as a condition of employment with us. All of our consulting agreements will pre-emptively assign to us all new and improved intellectual property that arise during the term of the agreement.

The License Agreement with CWRU terminates upon the expiration of certain related patents, or on May 12, 2038 in countries where no such patents exist, or upon expiration of any exclusive marketing rights that have been granted by the FDA or other U.S. government agency, whichever comes later. The key EsoGuard U.S. patents begin to expire in August 2024, however, the company is pursuing applications of the clinical utility to extend the patent protection with more recently filed families of cases that have a twenty year term and will be set to expire in the mid to late 2030's once they are issued. It is noteworthy that the accuracy confidence of the EsoGuard assay has only been tested with cells collected using the EsoCheck Collect + Protect technology. The key EsoCheck device U.S. patents begin to expire in December 2034. In the event that we default in the payment of any amount when due under the License Agreement, and such amount is not paid within 30 days of notice of nonpayment, CWRU may terminate the exclusivity of the license or terminate the License Agreement in full. In addition, either party may terminate the License Agreement upon the other party's default in the performance of its obligations under the License Agreement, subject to certain grace periods. Upon expiration of the License Agreement in the ordinary course, we expect to continue selling products using the EsoGuard and EsoCheck technology, as CWRU's proprietary intellectual property rights in the technology also will have expired.

EsoGuard and EsoCheck Competition

The U.S. market for esophageal cancer (*i.e.*, EAC) and pre-cancer (*i.e.*, BE, with or without dysplasia) screening is large, consisting of more than 30 million at-risk individuals over the age of 50. Given the large market for pre-cancer screening, we likely will face numerous competitors, some of which possess significantly greater financial and other resources and development capabilities than us. Our EsoGuard test faces competition from procedure-based detection technologies such as upper endoscopy, and other screening technologies such as pill-based imaging solutions like PillCam Eso, cleared by the FDA in November 2004, and transnasal esophagoscopy, a flexible tube with a miniature camera that is inserted into the nose and advanced through the esophagus into the upper portion of the stomach. Our EsoCheck device faces competition from other manufactures with devices designed to collect cell samples from targeted regions of the esophagus. For example, Cytosponge is a small mesh sponge within a soluble gelatin capsule that dissolves in the stomach and then is pulled thru the targeted region brushing the lining of the esophagus and then later retrieved, although, unlike EsoCheck, it is unprotected from contamination. Interpace Diagnostics (Nasdaq: IDXG), NeoGenomics (Nasdaq: NEO) and Cernostics (private) are developing progression type test for known patients with BE aimed at assessing or predicting the likely development of EAC. Our competitors may also be developing additional methods of detecting esophageal cancer and pre-cancer that have not yet been announced.

Accordingly, the market for our GI Health products is highly competitive and is characterized by extensive research and clinical efforts and rapid technological change. In order to compete effectively, EsoGuard and EsoCheck will have to achieve market acceptance, receive adequate insurance coverage and reimbursement, be cost effective and be simultaneously safe and effective. We believe that the principal competitive factors in our markets are:

- diagnostic accuracy and the quality of outcomes for medical conditions;
- acceptance by physicians 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.

Most of our existing and potential competitors have substantially greater financial, marketing, sales, distribution, manufacturing and technological resources. We may be unable to compete effectively against our competitors either because their products and services are superior or more cost efficient, or because of they have access to greater resources than us. These competitors may have greater name recognition than we do. Many of these competitors have obtained all desirable FDA or other regulatory approvals, and superior patent protection, for their products. Certain of our competitors have already commercialized their products, and others may commercialize their products in advance of our products. In addition, our competitors may make technical advances that render our products obsolete. We may be unable to respond to such technical advances.

Notwithstanding that the market for BE and EAC screening is highly competitive, we believe that EsoCheck, currently cleared by the FDA pursuant to a 510(k), and EsoGuard, the first and only DNA-based non-invasive BE screening LDT test on the market today, compare favorably to other available products and services. When used in combination after achieving FDA approval as an IVD medical device through the PMA process, the use of EsoGuard, on samples collected using EsoCheck, may offer an accurate, lower cost, non-invasive approach, that does not require endoscopy, to screen for BE and EAC. The test may be performed in five minutes, without sedation, in an outpatient ambulatory setting such as a primary care or family practice physician’s office or a freestanding diagnostic facility.

EsoGuard and EsoCheck Specific Government Regulation

HIPAA and Other Privacy Laws

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HIPAA") established comprehensive protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or "Covered Entities": health plans, healthcare clearinghouses, and healthcare providers that conduct certain healthcare transactions electronically. Covered Entities and their business associates must have in place administrative, physical, and technical standards to guard against the misuse of individually identifiable health information. We perform activities that may implicate HIPAA, such as providing clinical laboratory testing services and entering into specific kinds of relationships with Covered Entities and business associates of Covered Entities. Penalties for violations of HIPAA include civil money and criminal penalties.

Our activities must also comply with other applicable privacy laws, which impose restrictions on the access, use and disclosure of personal information. More state and international privacy laws are being adopted. Many state laws are not preempted by HIPAA because they are more stringent or are broader in scope than HIPAA. Beginning in 2020 we will also need to comply with the California Consumer Privacy Act of 2018, which protects personal information other than health information covered by HIPAA. In the E.U., the General Data Protection Regulation ("GDPR") took effect in May 2018 and imposes increasingly stringent data protection and privacy rules. All of these laws may impact our business and may change periodically, which could have an effect on our business operations if compliance becomes substantially costlier than under current requirements. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain patient samples and associated patient information could significantly impact our business and our future business plans.

Self-Referral Law

The federal "self-referral" law, commonly referred to as the "Stark" law, provides that physicians who, personally or through a family member, have ownership interests in or compensation arrangements with a laboratory are prohibited from making a referral to that laboratory for laboratory tests reimbursable by Medicare, and also prohibits laboratories from submitting a claim for Medicare payments for laboratory tests referred by physicians who, personally or through a family member, have ownership interests in or compensation arrangements with the testing laboratory. The Stark law contains a number of specific exceptions which, if met, permit physicians who have ownership or compensation arrangements with a testing laboratory to make referrals to that laboratory and permit the laboratory to submit claims for Medicare payments for laboratory tests performed pursuant to such referrals. We are subject to comparable state laws, some of which apply to all payers regardless of source of payment, and do not contain identical exceptions to the Stark law.

Specimen Transportation

Our commercialization activities for EsoGuard subject us to regulations of the Department of Transportation, the United States Postal Service, and the Centers for Disease Control and Prevention that apply to the surface and air transportation of clinical laboratory specimens.

Environmental

The cost of compliance with federal, state and local provisions related to the protection of the environment has had no material effect on our GI Health business. There were no material capital expenditures for environmental control facilities in the years ended December 31, 2018 and 2019, and there are no material expenditures planned for such purposes for the year ended December 31, 2020.

Minimally Invasive Interventions

CarpX - Percutaneous Device to Treat Carpal Tunnel Syndrome

The Market

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 2.5% of U.S. adults, or approximately five million individuals, have CTS and about 600,000 surgical procedures are performed annually for CTS. According to the Centers for Disease Control and Prevention, CTS accounts for two million office visits per year. Of the CTS patients that are candidates for surgery, an estimated 1.5 million CTS patients continue to suffer in silence rather than undergoing traditional invasive surgery due to concerns over the prolonged recovery time associated with an open incision. 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 are invasive and must be performed in a surgical operating room. Endoscopic approaches are less invasive, but are more technically challenging, more expensive and have been associated with higher complication rates. These approaches still require a surgical incision and some surgical dissection before the endoscope is passed into the carpal tunnel. Two less-invasive devices are currently on the market. One device attempts to use transillumination to guide blind passage of a protected knife and the other passes a saw-like device blindly or by ultrasound guidance. Technical limitations have hindered market acceptance of these devices.

Our Solution

We have developed CarpX as a patented, single-use disposable, minimally invasive medical device designed as a precision cutting tool to treat carpal tunnel syndrome while reducing recovery times. We believe our device will allow the physician to relieve the compression on the median nerve without an open incision or the need for endoscopic or other imaging equipment. To use our device, the operator first advances a guidewire through the carpal tunnel under the ligament. Our device is then advanced over the wire and positioned in the carpal tunnel under ultrasonic and/or fluoroscopic guidance. When the balloon is inflated it creates tension in the ligament positioning the cutting electrodes underneath it and creates space within the tunnel, providing anatomic separation between the target ligament and critical structures such as the median nerve. Radiofrequency energy is briefly delivered to the electrodes, rapidly cutting the ligament and relieving the pressure on the nerve. We believe our device will be significantly less invasive than existing treatments. We also believe it will allow for more extensive lateral dissection within the tunnel and more reliable division of the ligament, resulting in lower recurrence rates than some of the endoscopic approaches. The USPTO has issued U.S. Patent 10,335,189 which covers the technology underlying PAVmed's CarpX minimally invasive device developed to treat carpal tunnel syndrome. The patent, assigned to PAVmed at its founding, lists Lishan Aklog, M.D., PAVmed's Chairman and Chief Executive Officer, and Brian J. deGuzman, M.D., its Chief Medical Officer, as inventors. We have advanced, in partnership with our design and contract manufacturing partners, our CarpX product from concept to working prototypes, completed successful benchtop and cadaver testing confirming the device consistently cuts the transverse carpal ligament, as well as commercial design and development, and performed pre-submission verification and validation testing.

Minimally Invasive Interventions

CarpX - Percutaneous Device to Treat Carpal Tunnel Syndrome - continued

Regulatory History

On November 2017, we filed with the FDA a premarket notification submission for CarpX under section 510(k) of the FDCA using a commercially available carpel tunnel release device as a predicate.

In July 2018, the FDA received our response to its requests-for-information regarding non-clinical support for our 510(k) premarket notification submission. Our response to the FDA included results from an animal study, which documented the device's bipolar electrode design results in minimal spread of thermal energy – less than one-millimeter thermal injury by pathologic analysis – and no increase in tissue temperatures except directly over the cutting electrodes. Our response also included additional physician usability testing, wherein each of the hand surgeons successfully performed the CarpX procedure multiple times in cadavers.

In August 2018 we were notified by the lead FDA branch reviewing the 510(k) premarket notification submission it had not reached a consensus with the consulting branch within the review period allotted under the FDA's rules and regulations. Accordingly, the lead branch recommended we take the appropriate steps to extend the review process through resubmission of the 510(k) premarket notification.

In January 2019, following an in-person pre-submission meeting, the FDA recommended clinical testing to definitively document CarpX procedural safety in humans and indicated data from a properly structured clinical study outside of the U.S. would be acceptable, precluding the need to engage in the time-consuming FDA Investigational Device Exemption (IDE) process required for U.S. studies. We offered to amend our previously planned first-in-human ("FIH") clinical trial in New Zealand to meet this clinical testing recommendation and postponed the initiation of the amended study until study parameters were finalized with the FDA. We reached a consensus with the FDA on the parameters of the CarpX FIH safety study, including both pre-operative and post-operative electrodiagnostic testing to document device safety. The CarpX FIH safety study was designed as a single-arm, two-center, two-surgeon, 20-patient study of the CarpX procedure in carpal tunnel syndrome patients, with a device safety primary endpoint defined as the absence of certain serious device-related adverse events over a limited 90-day follow-up period.

By August 2019, all 20 patients of its FIH 510(k) clinical safety study underwent successful CarpX procedures.

In December 2019, PAVmed personnel and the local clinical investigators in New Zealand completed an on-site review of the study data concluding that the device appeared to meet the study's primary effectiveness and safety endpoints. The remaining tasks required before a resubmission could occur included finalization of the clinical reports, including customary overreads of the diagnostic test results by a U.S. physician. Following the completion of the overreads, the 510(k) application was compiled with the requisite compendium of clinical data and submitted to the FDA.

In March 2020, we announced the FDA acknowledged receipt of a 510(k) premarket notification submission for our CarpX minimally invasive carpal tunnel device. This re-submission incorporates data from the FIH clinical safety study described above, in which all patients met the study's pre-specified safety and effectiveness endpoints. The final report noted that twenty carpal tunnel syndrome patients in New Zealand underwent successful CarpX minimally invasive carpal tunnel release. All patients met the study's pre-specified effectiveness endpoint – clinical device technical success defined as the ability of CarpX to perform complete division of the transverse carpal ligament as assessed by post-procedural endoscopic inspection of the transverse carpal ligament after treatment. Two-week and 90-day post-operative follow-up rates were 100% and 95%, respectively, exceeding the target 80% rate recommended by the FDA. The only loss to follow-up was a patient who was documented to be "back to normal" with resolution of symptoms at six weeks but opted not to return to the study site because he was traveling a significant distance away and was overall very satisfied with the procedure's outcome.

All patients who completed follow-up met the study's pre-specified primary safety endpoint – device safety defined as no serious adverse event probably or definitely related to the device resulting in significant morbidity through 90-day follow-up. Patients underwent additional pre-specified outcome assessments at baseline and during post-operative follow-up, using well-established, standardized and validated measures to assess patient satisfaction, as well as changes in symptoms, motor and sensory function and neurophysiological parameters following carpal tunnel release. These outcome assessments included the Global Satisfaction Questionnaire, QuickDASH and Boston Carpal Tunnel Syndrome (BCTQ) Questionnaires, Ten Test and Semmes-Weinstein Monofilament sensory tests, Grip and Pinch Strength motor function tests, as well as nerve conduction and electromyographic studies. The excellent results of these pre-specified outcome assessments following CarpX minimally invasive carpal tunnel release were similar to, or better than, expected results following traditional open surgery.

Additional observations from the study strongly support CarpX's clinical and commercial potential. Surgeons were able to achieve the same anatomic result as traditional open surgery using a minimally invasive approach. Endoscopic visualization showed that CarpX cut the ligament cleanly and precisely, without evidence of thermal spread beyond the target tissue cut line. Procedure times fell after a short learning curve, indicating that CarpX minimally invasive carpal tunnel release can be performed in the same or less time as traditional open surgery. The final set of procedures were performed through 5-10 mm keyhole incisions, with no incision crossing the base of the palm, an area known to be problematic for healing, resulting in delayed recovery and persistent pain after traditional open surgery. The surgeons also observed that the CarpX balloon appeared to create more space within the carpal tunnel than traditional carpal tunnel release, which could favorably impact long-term outcomes.

CarpX Sales and Marketing

Once we obtain market clearance from the FDA, we expect to commercialize our products through a network of independent U.S. sales representatives and/or inventory-stocking medical distributors together with our in-house sales management and marketing teams. Our focus on high-margin products, including CarpX, 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.

Item 1. Business - Continued

Background and Overview - continued

Infusion Therapy – PortIO and NextFlo

PortIO – Implantable Intraosseous Vascular Access Device

The Market

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

Current Devices and Their Limitations

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

Our Solution

The intraosseous route provides a means for infusing fluids, medications and other substances directly into the bone marrow cavity which communicates with the central venous circulation via nutrient and emissary veins. This route is well established, having been used for decades in a variety of settings including trauma, especially military trauma, and pediatric emergencies. It has been shown to be bioequivalent to the intravenous route. Complication rates are low and there are few contraindications. Recently, physicians have expanded the use of the intraosseous route to non-emergent clinical scenarios. Currently available intraosseous devices pass through the skin into the bone and are therefore limited to short term use. We have developed a novel, implantable intraosseous vascular access device which does not require accessing the central venous system and does not have an indwelling intravascular component. It is designed to be highly resistant to occlusion and, we believe, may not require regular flushing. It features simplified, near-percutaneous insertion and removal, without the need for surgical dissection or radiographic confirmation. It provides a near limitless number of potential access sites and can be used in patients with chronic total occlusion of their central veins. We believe the absence of an intravascular component will result in a very low infection rate.

Our PortIO implantable intraosseous vascular access device is being developed for up to seven days of continuous use, as a means for infusing fluids, medications and other substances directly into the bone marrow cavity and from there into the central venous circulation.

We have advanced, in partnership with our design and contract manufacturing partners, our PortIO product from concept to working prototypes, benchtop, animal, and cadaver testing, commercial design and development, verification and validation testing. We are pursuing an FDA clearance for use in patients with a need for vascular access up to seven days, under *de novo* classification of section 513(f)2 of the FDCA. The broader “seven days” clearance is being pursued in discussion with FDA following our previous initial submission to the FDA for a 510(k) premarket notification for use in patients only requiring 24-hour emergency type vascular access. The GLP animal study requested by the FDA has been completed along with supplementary cadaver and animal studies. This data was submitted to the FDA as part of a pre-submission filing that included an in-person meeting on January 8, 2020 to define a likely small human clinical safety study through the *de novo* pathway. Based on encouraging animal data, we are also planning a long-term (60-day implant duration) FIH clinical study in dialysis patients or those with poor venous access in Colombia, South America and intend to fulfill the likely FDA request for human clinical data with an “outside-of-United States” clinical safety study in Auckland, New Zealand. Of significance toward our belief of PortIO will one day become the answer to solve many of the current drawbacks intravenous access devices regularly encounter, our supplemental animal testing has demonstrated maintenance-free patency over a six-month implant duration.

NextFlo – Highly-Accurate Disposable Infusion System

The Market

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

Current Devices and Their Limitations

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

Our Solution

We have developed a highly-accurate infusion system with variable flow resistors. We acquired U.S. Patent 8,622,976 issued January 7, 2014 and associated U.S. and international patent applications, "*System and Methods for Infusion of Fluids Using Stored Potential Energy and a Variable Flow Resistor*". We have built on the principles underlying this patent and developed a new concept whereby the variable resistor does not have to be mechanically linked to the infusion drive mechanism. This simplifies the design and expands the range of potential follow-on products. We have performed extensive computer simulation, built protypes, and conducted benchtop testing on various embodiments and have demonstrated highly-accurate flow rates across a wide range of driving pressures.

Our NextFlo product has been developed as a highly accurate, disposable intravenous ("IV") infusion set. NextFlo maintains constant flow by incorporating a proprietary, passive, pressure-dependent variable flow-resistor consisting entirely of inexpensive, easy-to-manufacture disposable mechanical parts. We believe this technology will permit hospitals to return to gravity-driven infusions and eliminate expensive and troublesome electronic pumps for most of the over one million infusions of fluids, medications and other substances delivered each day in hospitals and outpatient settings in the United States.

The NextFlo disposable IV infusion set has achieved a key milestone in its quest to eliminate the need for complex and expensive electronic infusion pumps. NextFlo testing has now repeatedly demonstrated it can achieve constant flow rates across a wide range of IV bag heights, with accuracy rates comparable to electronic infusion pumps. Deloitte Consulting LLP has completed a comprehensive market research and strategic analysis of NextFlo demonstrating a very large addressable market and recommended PAVmed seek a long-term strategic partnership or acquisition. The global professional services firm Alvarez and Marsal has been running a formal M&A process for NextFlo targeting strategic and financial partners. The process is active with ongoing discussion with multiple parties.

Emerging Innovations

We are evaluating a number of product opportunities and intellectual properties covering a spectrum of clinical conditions, which have either been developed internally or have been presented to us by clinician innovators and academic medical centers, for consideration of a partnership to develop and commercialize these products. Additionally, we are exploring other opportunities to grow our business and enhance shareholder value through the acquisition of pre-commercial or commercial stage products and /or companies with potential strategic corporate and commercial synergies. The emerging innovation products that we presently believe are furthest along the development timeline are as follows:

DisappEAR

PAVmed's DisappEAR pediatric ear tubes, manufactured from a proprietary aqueous silk technology licensed from Tufts University and two Harvard teaching hospitals, seeks to revolutionize the care of the estimated one million children who undergo bilateral ear tube placement each year to treat complex or recurrent middle ear infections or fluid collections, by eliminating the need for a second procedure as well as the standard difficult-to-administer post-operative ear drop regimen. An eight-month animal study of DisappEAR has been completed with excellent results. The ear tubes appear to possess unexpected surfactant properties which would provide several unique benefits over traditional plastic tubes, including enhanced flow of fluids in and out of the tube and potential intrinsic antimicrobial properties. A six-month GLP animal study has been completed and the Company is in active discussions with a large strategic partner to produce commercial-scale aqueous silk to support a future FDA 510(k) submission and commercialization.

Noninvasive Glucose Monitoring

In October 2019, PAVmed incorporated Solys Diagnostics Inc. ("Solys") and caused Solys to issue 8.3 million shares of its common stock to PAVmed and also to immediately enter into a license agreement with Liquid Sensing, Inc., a subsidiary of Airware, Inc., each an unrelated-third-party, in exchange for 1.5 million shares of Solys common stock issued to Airware, Inc., and 200,000 shares of Solys common stock issued to a unrelated-third-party consultant. Airware Inc. equity interests have certain anti-dilution rights under limited circumstances and 810,810 shares of Solys common stock issued to Airware Inc. are subject to certain milestone vesting restrictions. PAVmed Inc. and Airware Inc. have entered into a shareholder's agreement which, among other customary terms, limits certain transfers of their respective ownership interests in Solys.

The exclusive worldwide licensing agreement with Liquid Sensing, Inc. grants to Solys a license for six issued and one pending U.S. patents covering a proprietary nondispersive infrared laser technology for the non-invasive detection of glucose and other substances such as electrolytes in tissue within the inpatient (*e.g.*, hospital) field of use. Pursuant to the licensing agreement, Solys will immediately advance the technology toward an established accuracy milestone for blood glucose monitoring within the licensed field of use. Upon achievement of the accuracy milestone, it is expected Solys will then pursue a full regulatory and development plan while also seeking to maximize the value of this proprietary technology with potential strategic partners or acquirers in the blood glucose monitoring market. If commercialized by Solys, Liquid Sensing Inc. has the right to collect future royalties on revenues related to the product developed for commercial use. Liquid Sensing Inc. has granted a 15 percent equity interest in its company to PAVmed with a portion of the shares issued being subject to certain performance vesting restrictions.

FlexMo – Extracorporeal Membrane Oxygenation (ECMO) Cannula

We are developing a next generation Extracorporeal Membrane Oxygenation ("ECMO") cannula to overcome current limitations and challenges related to cannula positioning and vascular access. ECMO is a treatment that uses a pump to circulate blood through an artificial lung back into the bloodstream during heart or lung failure or compromise. ECMO is used when the lungs cannot provide enough oxygen to the body or cannot get rid of carbon dioxide, or the heart cannot pump enough blood to the body. Clinicians have multiple choices in terms of cannula placement depending on the patient condition and traditionally two access sites are necessary to complete the circuit. Many of these configurations require precision placement of the cannula to ensure oxygenated blood is correctly circulated through the patient's arterial system. The addition of these advanced and alternative tailored placements of ECMO cannula will allow clinicians to serve a greater patient population and increases likelihood of procedural success.

FlexMo's proposed embodiment will expand opportunities across all clinical spectrums by allowing the reinfusion into any anatomic location, including Right Atrium, Right Ventricle, Pulmonary Artery, Left Atrium and the Aorta. With the advent of more portable and readily available ECMO technology, the use of ECMO has increased for every clinical indication and usage will continue to rise. Further development of FlexMo is subject to availability of additional financial resources. Once this product is commercialized, we believe it will garner a premium pricing and support increased use of ECMO through simplified procedural steps and enhanced vascular access pathways.

NextCath - Self-Anchoring Short-Term Catheters

A wide variety of short-term catheters are used in clinical practice to infuse fluids, medications or other substances into a vein or other structures, to monitor physiologic parameters and to drain visceral organs or cavities. Currently marketed short-term catheters are not self-anchoring, they have been traditionally anchored to the skin with simple tape or some other adhesive incorporated into the sterile dressing. We are developing self-anchoring short-term catheters which do not require suturing, traditional anchoring techniques or costly add-on catheter securement devices. We are initially focusing on interventional radiology catheters which are less commoditized and result in significantly greater risk when dislodged. Our self-anchoring technique, however, is applicable to most, if not all, short-term catheters. The self-anchoring mechanism is integral to the catheter. It allows insertion with standard techniques and the use of simple clear sterile dressings. It allows the hub of the catheter to be flat and the tubing to come out eccentrically, or parallel to the skin, improving patient comfort and catheter management. We have filed a nonprovisional patent application, engaged design and contract manufacturing firms with experience in extrusions which have completed initial design work on the first product in the NextCath product line, and completed head-to-head testing of retention forces, comparing our working prototype to several competing products, which has validated our approach and advanced the commercial design and development process focusing on optimizing the self-anchoring helical portion as well as cost of materials and manufacturing processes. Further development of NextCath is subject to availability of additional financial resources. Once this product is commercialized, we believe it will garner premium pricing based on fewer complications and reduced overall costs.

Additional Products

We are evaluating a number of product opportunities and intellectual property covering a spectrum of clinical conditions, which have been presented to us by clinician innovators and academic medical centers, for consideration of a partnership to develop and commercialize these products; we are also exploring opportunities to partner with larger medical device companies to commercialize our lead products as they move towards regulatory clearance and commercialization. In this regard, we remain actively engaged with our full-service regulatory consulting partner and who is working closely with our contract design, engineering and manufacturing partners as our products advance towards regulatory submission, clearance, and commercialization.

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

Our product pipeline is dynamic, and we adjust our development and commercialization plans based on real-time progress, changes in market conditions, commercial opportunity and availability of resources.

Recent Events

Product Development Events

In June 2019, Lucid, PAVmed's majority owned subsidiary, received FDA 510(k) marketing clearance for EsoCheck as a generic esophageal cell collection device. See "—GI Health— EsoGuard and EsoCheck Development and Commercial Status".

In October 2019, Solys Diagnostics, PAVmed's majority owned subsidiary, entered into a license agreement with Liquid Sensing, Inc., a subsidiary of Airware, Inc., granting Solys a license for six issued and one pending U.S. patents covering a nondispersive infrared laser proprietary technology for the non-invasively detection of glucose and other substances such as electrolytes in tissue within the inpatient (*e.g.*, hospital) field of use. See "—Emerging Innovations—Noninvasive Glucose Monitoring."

In December 2019, Lucid, PAVmed's majority owned subsidiary completed CLIA/CAP certification for EsoGuard Esophageal DNA Test as an LDT at Lucid's commercial diagnostic laboratory partner, ResearchDx. See "—GI Health— EsoGuard Clinical Laboratory and EsoCheck Manufacturing."

In January 2020, an FDA pre-submission in-person meeting was held to review PortIO's GLP animal study and to define a small human clinical safety study to support FDA approval through the *de novo* pathway. See "—Infusion Therapy—PortIO."

In February 2020, Lucid, PAVmed's majority owned subsidiary, received Breakthrough Device designation from the FDA for EsoGuard Esophageal DNA Test on esophageal samples collected using its EsoCheck Cell Collection Device. See "—GI Health—EsoGuard Business Strategy."

In February 2020, the first patient was enrolled in Lucid's IVD clinical trial for EsoGuard Esophageal DNA Test on esophageal samples collected using its EsoCheck Cell Collection Device. See "—GI Health—EsoGuard Business Strategy."

In March 2020, we announced the FDA acknowledged receipt of a 510(k) premarket notification submission for the Company's CarpX minimally invasive carpal tunnel device, which incorporates data from the Company's successful first-in-human CarpX clinical safety study. See "—Minimally Invasive Interventions—CarpX."

Item 1. Business - Continued

Background and Overview - continued

Recent Events

Financing Transactions

In April, May and June 2019, we raised approximately $5.4 million, net, from three registered direct offerings of 5,480,000 shares of our common stock pursuant to our previously filed effective shelf registration statement on Form S-3 (File No. 333-220549).

In November 2019, we consummated the sale of a Senior Secured Convertible Notes in a private placement with a $14.0 million aggregate face value principle, referred to herein as the "November 2019 Senior Convertible Notes".

The November 2019 Senior Convertible Notes were further sub-divided into a Series A and Series B, each having a face value principal of $7.0 million, with each referred to as the "Series A November 2019 Senior Convertible Notes" and the " Series B November 2019 Senior Convertible Notes". The Series A and Series B November 2019 Senior Convertible Notes each provide for the payment of a $700,000 lender fee, with such lender fee deducted from the proceeds when funded by the investors, and additionally, we are obligated to pay a financial advisory fee to the placement agent of 6.5% of the cash proceeds upon their receipt.

With respect to the Series A November 2019 Senior Convertible Notes, the investors delivered to us cash proceeds of $6.3 million on November 4, 2019, after deducting $0.7 million of lender fee, and we incurred total offering costs of $550,254, including a $409,500 advisory fee paid to the placement agent.

Subsequent to December 31, 2019, with respect to the Series B November 2019 Senior Convertible Note, the investors, at their election under the prepayment provisions, delivered to the Company cash proceeds of $6.3 million on March 30, 2020 after deducting $0.7 million of lender fees, and we paid an advisory fee of $409,500 to the placement agent.

In connection with the November 2019 Senior Convertible Notes, a registration statement on Form S-3 was filed with the SEC in December 2019, which has not yet been declared effective, for the common stock underlying the Series A November 2019 Senior Convertible Note.

Other Events

The Series B Convertible Preferred Stock provides for dividends at a rate of 8% per annum based on the $3.00 per share stated value of the Series B Convertible Preferred Stock, with such dividends compounded quarterly, accumulate, and are payable in arrears upon being declared by the Company's board of directors. The Company's board of directors declared a Series B Convertible Preferred Stock dividend payment of earned but unpaid dividends as of December 31, 2019, payable as of January 1, 2020, of an aggregate of $69,493, with such dividend payment settled by the issue of an additional 23,182 shares of Series B Convertible Preferred Stock in accordance with the Series B Certificate of Designation.

Background and Overview - continued

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 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 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 our products must 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.

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 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 our product is safe and substantially equivalent to FDA-cleared predicates. The FDA's costlier and more prolonged PMA pathway requires us to demonstrate our product is safe and effective through randomized clinical studies. A product which is eligible for the 510(k) pathway will require substantially less capital and time than one that requires full PMA clearance. With all our products we are very aggressive about identifying what we believe are the quickest paths to regulatory clearance, paying very careful attention to selection of the best predicates and references as well as careful attention to precisely crafting the primary indications for use language. Although we favor products eligible for the FDA's 510(k) pathway, with or without clinical safety studies, we may also pursue PMA pathway products with large addressable markets, or in the case of one of our lead products, PortIO™, pursue classification under section 513(f)(2) of the FDCA, also referred to as *de novo* classification, which could be more rigorous than the 510(k) pathway, but generally require substantially less time and resources than a PMA pathway. We have a variety of options to commercialize such products more efficiently by initially, or even exclusively, targeting European or emerging markets which have shorter, less costly regulatory pathways for such projects. We also attempt to identify narrower applications and indications with lower regulatory hurdles 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 such a move will enhance our ability to execute on our strategy. As we grow, we expect to maintain a lean management infrastructure while expanding our bandwidth primarily with skilled project managers.

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

Research and development expenses are recognized in the period they are incurred and consist principally of internal and external expenses incurred for the research and development of our products. We incurred approximately $15.7 million in cumulative research and development expenses from June 26, 2014 (inception) through December 31, 2019, inclusive of approximately $6.6 million and $4.3 million in each of the years ended December 31, 2019 and 2018, respectively. We plan to increase our research and development expenses for the foreseeable future as we continue development of our products. Our only product to obtain regulatory approval to date is EsoCheck, which has received 510(k) marketing clearance from the FDA as a generic esophageal cell collection device. EsoGuard has been established as an LDT that does not require regulatory approval and was launched commercially in December 2019 after completing CLIA/CAP certification of the test at Lucid's commercial diagnostic laboratory partner ResearchDx, headquartered in Irvine, CA. Our current research and development activities are focused principally on obtaining FDA approval and clearance and initializing commercialization of the other lead products in our product portfolio pipeline, such as EsoGuard IVD, CarpX and PortIO, while advancing DisappEAR and NextFlo through development. The research and development activities on the other portfolio products is commensurate with available sufficient capital resources.

Our Implementation Strategy

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

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

It is our belief, despite these efforts, only a small fraction of the potential pool of intellectual capital (i*e*. the universe of individual clinicians with innovative product ideas) is participating in medical device innovation. These clinicians rarely engage in the process for a variety of reasons, including the belief 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 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 put us in strong position to partner with innovative clinicians and academic medical centers focusing on medical device innovation. We have developed a collaboration model focused on licensing technologies for development and commercialization. Since our founding, we have been contacted by clinicians and centers inquiring about opportunities to work with us on developing and commercializing their ideas and technologies. In November 2016, we signed a definitive licensing agreement with a group of leading academic institutions, including Tufts University and two Harvard Medical School teaching hospitals – Massachusetts Eye and Ear Infirmary and Massachusetts General Hospital. The agreement provides us with an exclusive worldwide license to develop and commercialize antibiotic-eluting resorbable ear tubes based on a proprietary aqueous silk technology conceived and developed at these institutions, a product we have initially referred to as DisappEAR. More recently, in May 2018, we licensed technologies from Case Western Reserve University for EsoGuard and EsoCheck. Within the twelve to eighteen months following the grant date of the license, Lucid Diagnostics, our majority owned subsidiary, achieved FDA 510(k) market clearance for EsoCheck and launched EsoGuard as an LDT at our contract laboratory in California. Typical in-license products, once commercialized, provided for the licensor institution to receive royalties based on revenue, and/or milestone payments, potentially including a portion of certain additional proceeds from the sale or sublicensing of the technology to a third party.

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

Approach to Sales and Marketing

We generally expect to commercialize our products through a network of independent U.S. medical representatives and/or inventory-stocking 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 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. We currently have applied for or own 72 patents across 10 families of products. Patent protection and other proprietary rights are thus essential to our business. Our policy is to aggressively file patent applications to protect our proprietary technologies including inventions and improvements to inventions. We seek patent protection, as appropriate, on:

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

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

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

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

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

Approach to Health Insurance 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.

A product's reimbursement profile, both in the U.S. and internationally, is an important component of the product'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. For those products that have high strategic value, but with less defined reimbursement, we have engaged reimbursement experts and support from industry associations to accelerate the acquisition of satisfactory reimbursement levels.

Competition for New Medical Device Innovation

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 the principal competitive factors in our markets are:

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

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

Government Regulation

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

Healthcare Reform

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

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

As an example of Healthcare legislation volatility, the Affordable Care Act imposed, among other things, a new federal excise tax on the sale of certain medical devices. The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law on Dec. 18, 2015, included a two-year moratorium on the medical device excise tax imposed by Internal Revenue Code section 4191. Because of the moratorium, the medical device excise tax did not apply to sales of taxable medical devices during the period beginning on January 1, 2016 and ending on December 31, 2017. The moratorium expired on Dec. 31, 2017. On January 22, 2018 as part of a stop gap spending bill, President Trump signed into law a moratorium for an additional two years retroactive to January 1, 2018. The tax was scheduled to go into effect until January 1, 2020. On December 20, 2019, the U.S. President signed into law a federal spending package that permanently repealed the 2.3% medical excise tax.

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

Item 1. Business - Continued

Background and Overview - continued

Our Business Model - continued

Government Regulation - continued

FDA Regulation

Generally, products we develop must be cleared by the FDA before they are 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 FDCA and/or the Public Health Service Act, as well as by other regulatory bodies. FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, recordkeeping, market clearance or approval, advertising and promotion, import and export, marketing and sales, and distribution of medical devices and products.

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

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

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

To request marketing authorization by means of a 510(k) clearance, we must submit a pre-market notification demonstrating 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 would constitute a significant change in intended use, requires a new 510(k) clearance or, if the device would no longer be substantially equivalent, would require PMA, or possibly, a de novo pathway under section 513(f)2 of the FDCA. In addition, any additional claims the Company wished to make at a later date may require a PMA. If the FDA determines the product does not qualify for 510(k) clearance, they will issue a Not Substantially Equivalent letter, at which point the Company must submit and the FDA must approve a PMA or issue premarket clearance using the de novo before marketing can begin.

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

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

During the review of a 510(k) submission, the FDA may request more information or additional studies and may decide 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.

Item 1. Business - Continued

Background and Overview - continued

Our Business Model - continued

Government Regulation - continued

FDA Regulation - continued

FDA Regulations will continue to change and evolve including the 2016-21st Century Cures Act which mandated the creation and revision of policies and processes intended to speed patient access to new medical devices and codifying into law the FDA's expedited review program for breakthrough devices for which EsoGuard was so designated. In 2017, the Food and Drug Administration Reauthorization Act (FDARA) which included improvements to premarket review times and investments in strategic initiatives like the National Evaluation System for health Technology (NEST) and patient input and decoupling accessory classification from classification of the parent device. We must continue to be aware of these changes that possibly impact our development and commercialization work. The Company has a network of professionals with extensive experience in these matters that advise us on both the pre-approval/clearance requirements as well as the post market surveillance compliance obligations.

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 it is safe to test the device on humans and 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 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 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 FDCA. 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 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 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 any of our products are sold in a foreign country, we may be subject to similar foreign laws, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Physician Payment Sunshine Act

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

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

Federal Anti-Kickback Statute

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

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

The Foreign Corrupt Practices Act

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

International Regulation

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

European Union

The European Union or EU will require a CE mark certification or approval in order to market our products in the various countries of the European Union or other countries outside the United States. To obtain CE mark certification of our products, we will be required to work with an accredited European notified body organization to determine the appropriate documents required to support certification in accordance with existing medical device directive. The predictability of the length of time and cost associated with such a CE mark may vary or may include lengthy clinical trials to support such a marking. Once the CE mark is obtained, we may market our product in the countries of the EU. The new European Medical Device Regulation (EU MDR 2017/745) goes into effect on May 26, 2020. The EU MDR imposes strict new requirements on medical device companies marketing their products in Europe. As such, many device companies have been scrambling to renew existing CE certificates granted under the Medical Devices Directive (MDD 93/42/EEC). Notified Bodies are now focused on their current customers and those customers' current devices making it virtually impossible to submit a new MDD application before May 2020.

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.

Item 1. Business - Continued

Background and Overview - continued

Employees

Currently, we have fifteen full-time compensated employees, including our Chairman of the Board of Directors and Chief Executive Officer ("CEO"), our President and Chief Financial Officer ("CFO"), and our Chief Medical Officer ("CMO"). Our non-employee Vice Chairman is currently not a compensated employee of the Company, but is a compensated member of our board of directors. No employees are covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Corporate History

We were incorporated on June 26, 2014 in the State of Delaware, under the name PAXmed Inc. On April 19, 2015, we changed our name to PAVmed Inc.

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

Our founders include three accomplished medical device entrepreneurs: Lishan Aklog M.D., Michael J. Glennon, and Brian J. deGuzman, M.D. In 2007, they founded Pavilion Holdings Group ("PHG"), a medical device holding company with a vision to create innovative single-product medical device companies using an outsourced business model focused on capital efficiency and speed to market. Two years later PHG formed Pavilion Medical Innovations ("PMI"), a venture-backed medical device incubator. Between 2008 and 2013, PHG and PMI founded four distinct, single-product medical device companies, three of which commercialized products and one of which was acquired, each as discussed below.

Vortex Medical Inc., founded in 2008 with $3.5 million in capital, created the AngioVac system, designed to remove large volume clots and other undesirable intravascular material without the need for open surgery. It received its initial FDA clearance 16 months after the company was founded. AngioVac was commercially launched in 2009 and the first AngioVac procedure was performed at Harvard's Brigham and Women's Hospital later the same year. 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 did not require any additional capital beyond original $3.5 million raised.

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

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

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

Available Information

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

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

Item 1A, Risk Factors

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

Risks Related to Financial Position and Capital Resources

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

We have incurred net losses since our inception.

To date, since our inception in June 2014, we have financed our operations principally through issuances of common stock, preferred stock, warrants, and debt, in both private placements and underwritten public offerings of our 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 our operating expenses will continue to increase as we continue to build our commercial infrastructure, develop, enhance and commercialize new products and incur additional operational and reporting costs associated with being a public company. As a result, we expect to continue to incur operating losses for the foreseeable future.

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

In our December 31, 2019 consolidated financial statements, we have concluded and stated our recurring losses from operations, recurring cash flows used in operations, accumulated deficit, and the requirement to raise additional capital to support our operating and capital expenditures, raise substantial doubt regarding our ability to continue as a going concern. Correspondingly, our independent registered public accounting firm's report on our consolidated financial statements also includes an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. Our plans to address this going concern risk include, pursuing additional offerings of debt and/or equity securities. The consolidated financial statements do not include any adjustments might result from our inability to consummate such offerings or our ability to continue as a going concern. Moreover, there is no assurance if we consummate additional offerings, we will raise sufficient proceeds in such offerings to pay our financial obligations as they become due. These factors raise substantial doubt about our ability to continue as a going concern.

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

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

- continue our research and development;
- pursue clinical trials;
- protect our intellectual property rights or defend, in litigation or otherwise, any claims 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;
- achieve market acceptance of our products;
- establish and expand our sales, marketing and distribution capabilities; and
- invest in businesses, products and technologies, although we currently have no commitments or agreements relating to do so.

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 we would otherwise seek to market. We also may have to reduce marketing, customer support or other resources devoted to our products.

Risks Associated with Our Business

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

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

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

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

- respond to new technologies or technical standards;
- react to changing customer requirements and expectations;
- acquire other companies to gain new technologies or products 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 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. To date, only our EsoCheck and EsoGuard products have reached the marketing stage. 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 these products will be successful. If we are not successful in bringing one or more products to market, whether because we fail to address marketplace demand, fail to develop viable technologies or otherwise, we may not generate any revenues and our results of operations could be seriously harmed.

Our products may never achieve market acceptance.

To date, we have not generated any revenues. Our ability to generate revenues from product sales and to achieve profitability will depend upon our ability to successfully commercialize our products. Because we only recently began to market our first 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.

Risks Associated with Our Business - continued

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 reimbursement will be available for any product 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 we successfully develop.

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

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

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

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

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

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

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

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

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

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

Risks Associated with Our Business - continued

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.

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

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

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

Risks Associated with Our Business - continued

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

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

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

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

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

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

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

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

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

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

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

Risks Associated with Our Business - continued

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 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.

Risks Associated with Our Business - continued

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 Associated with Our Business - continued

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

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

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

Our business may be adversely affected by health epidemics, including the recent coronavirus outbreak.

In December 2019, an outbreak of a novel strain of coronavirus ("COVID-19") originated in Wuhan, China and has since spread to a number of other countries, including the U.S. On March 11, 2020, the World Health Organization characterized COVID-19 as a pandemic.

COVID-19 may have an adverse impact on our operations, supply chains and distribution systems or those of our contractors of our laboratory partner, and increase our expenses, including as a result of impacts associated with preventive and precautionary measures that are being taken, such restrictions on travel, quarantine polices and social distancing. For example, the ability of our employees or those of our contractors or laboratory partner to work may be adversely affected. In addition, the spread of COVID-19 has disrupted the United States' healthcare and healthcare regulatory systems which could divert healthcare resources away from, or materially delay FDA approval with respect to our products. Furthermore, our clinical trials may be affected by the COVID-19 outbreak. Site initiation and patient enrollment may be delayed, for example, due to prioritization of hospital resources toward the COVID-19 outbreak, travel restrictions imposed by governments, and the inability to access sites for initiation and monitoring. COVID-19 also may have an adverse impact on the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our product candidates, if approved, and impact our operating results. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which health epidemics such as COVID-19 could adversely impact our business. Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change.

Risks Associated with Our Business - continued

Failure in our information technology or storage systems could significantly disrupt our operations and our research and development efforts, which could adversely impact our revenues, as well as our research, development and commercialization efforts.

Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our information technology ("IT") systems that support our operations and our research and development efforts, and those IT systems within the control of our contract manufacturers and contract laboratories. The integrity and protection of our own data, and that of our customers and employees, is critical to our business. The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve. IT systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, and the precautionary measures taken by our contract parties, sustained or repeated system failures that interrupt our ability to generate and maintain data, could adversely affect our ability to operate our business. Furthermore, any breach in our IT systems could lead to the unauthorized access, disclosure and use of non-public information, including protected health information, which is protected by HIPAA and other laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and damage to our reputation.

System upgrades, enhancements and replacements, as well as new systems, are required from time to time, and require significant expenditures and allocation of valuable employee resources. Delays in integration or disruptions to our business from implementation of these new or upgraded systems could have a material adverse impact on our financial condition and operating results. There can be no assurance that our process of improving existing systems, developing new systems to support our expanding operations, integrating new systems, protecting confidential patient information, and improving service levels will not be delayed or that additional systems issues will not arise in the future. Failure to adequately protect and maintain the integrity of our information systems issues and data may result in a material adverse effect on our financial position, results of operations and cash flows.

Risks Related to Government Regulation

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.

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

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

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

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

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

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

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

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

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

In the U.S., there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that could result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the PPACA, was enacted in 2010. The PPACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The PPACA, among other things, 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. For instance, in December 2019, the 2.3% tax on sales of medical devices was repealed. At this time, it remains unclear whether there will be any changes made to the PPACA, whether to certain provisions or its entirety. We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

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

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

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

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

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

Risks Associated with Our Business - continued

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 Our Business - continued

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

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

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

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

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

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

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

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

Risks Associated with Our Business - continued

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

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

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

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

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

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

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

Risks Associated with Our Business - continued

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

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

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

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

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

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

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

Risks Associated with Our Business - continued

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

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

For example, as discussed above, certain of the Company's planned product candidates may fall under the regulatory purview of various centers at the FDA and in other countries by similar health and regulatory authorities. Each medical device that the Company wishes to market in the U.S. must first receive either 510(k) clearance or premarket approval from the FDA unless an exemption applies. Either process can be lengthy and expensive. The FDA's 510(k) clearance process may take from three to twelve months, or longer, and may or may not require human clinical data. The premarket approval process is much costlier and lengthier. It may take from eleven months to three years, or even longer, and will likely require significant supporting human clinical data. Delays in obtaining regulatory clearance or approval could adversely affect the Company's revenues and profitability. Although the Company has obtained 510(k) clearance for EsoCheck, this clearance may be subject to revocation if post-marketing data demonstrates safety issues or lack of effectiveness. Similar clearance processes may apply in foreign countries. Further, more stringent regulatory requirements or safety and quality standards may be issued in the future with an adverse effect on the Company's business.

In addition, the formulation, manufacturing, packaging, labeling, distribution, importation, sale and storage of the Company's and its subsidiaries' products are subject to extensive regulation by various federal agencies, including, but not limited to, the FDA, the FTC, State Attorneys General in the United States, the Ministry of Health, Labor and Welfare in Japan, as well as by various other federal, state, local and international regulatory authorities in the countries in which its products are manufactured, distributed or sold. If the Company or its manufacturers fail to comply with those regulations, the Company and its subsidiaries could become subject to significant penalties or claims, which could harm its results of operations or its ability to conduct its business. In addition, the adoption of new regulations or changes in the interpretations of existing regulations may result in significant compliance costs or discontinuation of product sales and may impair the marketing of its products, resulting in significant loss of net sales. The Company's failure to comply with federal or state regulations, or with regulations in foreign markets that cover its product claims and advertising, including direct claims and advertising by the Company or its subsidiaries, may result in enforcement actions and imposition of penalties or otherwise harm the distribution and sale of its products. Further, the Company and its subsidiaries' businesses are subject to laws governing our accounting, tax and import and export activities. Failure to comply with these requirements could result in legal and/or financial consequences that might adversely affect its sales and profitability.

Risks Associated with Ownership of Our Common Stock

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

Our certificate of incorporation authorizes the issuance of up to 100,000,000 shares of common stock, par value $.001 per share, and 20,000,000 shares of preferred stock, par value $.001 per share. In addition, pursuant to the November 2019 SPA, we are required to seek stockholder approval to increase the number of shares of our common stock we are authorized to issue to 150,000,000 shares. 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.

Risks Associated with Ownership of Our Common Stock - continued

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

As of December 31, 2019, we had an aggregate of $8.7 million of indebtedness, which was secured by substantially all of our assets. In addition, we may incur additional debt in the future. Our indebtedness could have important consequences on our business. To the extent new debt and/or new credit sources are added to our existing debt, the related risks for us could intensify. In particular, it could:

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

In addition, the agreements governing our indebtedness contain (and any agreements governing our future indebtedness may contain) financial and other restrictive covenants which may potentially be subject to factors beyond our control and negatively affect our ability to comply.

Despite our right to pay the interest and principal balance of our existing indebtedness by issuing shares of our common stock, we may be required to repay such indebtedness in cash, if we do not meet certain customary equity conditions (including minimum price and volume thresholds) or in certain other circumstances. For example, we may be required to repay the outstanding principal balance and accrued but unpaid interest, along with a premium, upon the occurrence of certain changes of control or an event of default. We also may be required to repay any future indebtedness incurred by us in cash. In such event, we may not be able to generate sufficient cash to service our existing indebtedness, or any future indebtedness incurred by us, as cash payments become due.

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

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

As of December 31, 2019, our management and their affiliates collectively own approximately 14% 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.

Risks Associated with Ownership of Our Common Stock - continued

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

On October 10, 2019, we were not in compliance with the market value of listed securities ("MVLS") standard of the continued listing standards for Nasdaq Capital Market companies. Although on January 10, 2020, the Nasdaq Staff notified us that we had regained compliance, there can be no assurance that we will be able to continue to meet the MVLS or any of the other Nasdaq Capital Market listing standards. If we are unable to maintain compliance with the MVLS standard and all other listing standard, our common stock may no longer be listed on the Nasdaq Capital Market or another national securities exchange and the liquidity and market price of our common stock may be adversely affected.

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

We are unable to predict whether an active trading market for our common stock will be sustained. If an active market is not sustained for any reason, it may be difficult for you to sell your securities at the time you wish to sell them, at a price that is attractive to you, or at all.

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

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

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

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

Risks Associated with Ownership of Our Common Stock - continued

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

As of December 31, 2019, we had outstanding: (i) employee stock options to purchase 5,203,529 shares of our common stock at a weighted average exercise price of $2.68 per share; (ii) warrants to purchase 17,196,857 shares of our common stock at a weighted average exercise price of $1.68 per share; (iii) unit purchase options to purchase 53,000 units at an exercise price of $5.50 per unit, with each unit consisting of one share of our common stock and one warrant, and each warrant entitling the holder to purchase one share of our common stock at an exercise price of $1.60 per share; (iv) Series B preferred stock convertible into 1,158,209 shares of our common stock; (v) the November 2019 Senior Convertible Notes, which were convertible into 8,750,000 shares of our common stock (assuming the November 2019 Senior Convertible Notes were converted in full on such date at the initial fixed conversion price of $1.60 per share); and (vi) the December 2018 Senior Convertible Note (as defined below), which was convertible in to 31,250 shares of our common stock (assuming the December 2018 Senior Convertible Note was converted in full on such date at the initial fixed conversion price of $1.60 per share). As of December 31, 2019, we also have 2,548,406 shares reserved for issuance, but not subject to outstanding awards, under our long-term incentive equity plan, and 167,228 shares reserved for issuance under our employee stock purchase plan.

Furthermore, accrued and unpaid interest and installments of principal under the 2019 Convertible Notes and the 2018 Convertible Notes are due on bi-monthly payment dates as prescribed therein, and are payable at our option in shares of our common stock, subject to the satisfaction of customary equity conditions (including minimum price and volume thresholds). The number of shares of common stock to be issued under these notes may be substantially greater than the estimate set forth in the preceding paragraph, if the interest and the installments of principal are paid in shares of our common stock, because in such cases the number of shares issued will be determined based on the then current market price, but in any event not more than fixed conversion price per share or less than a floor price specified in the notes. We cannot predict the market price of our common stock at any future date, and therefore, we are unable to accurately forecast or predict the total amount of shares that ultimately may be issued under these notes. In addition, the number of shares issued under these notes may be substantially greater if we voluntarily lower the conversion price, which we are permitted to do pursuant to the terms thereof.

The issuance of these shares will dilute our other equity holders, which could cause the price of our common stock to decline.

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.

Risks Associated with Ownership of Our Common Stock - continued

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

We are an "emerging growth company," as defined in the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, December 31, 2021, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period under the JOBS Act.

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

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, the other rules and regulations of the Securities and Exchange Commission, or SEC, and the rules and regulations of Nasdaq or any other national securities exchange on which our securities are then trading. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and Nasdaq have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel devote a substantial amount of time to these compliance initiatives. These rules and regulations result in significant legal and financial compliance costs and make some activities more time-consuming and costlier.

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

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors if 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.

We identified a material weakness in our internal control over financial reporting. If we are unable to remediate the material weakness, or if we experience additional material weaknesses in the future, our business may be harmed.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for evaluating and reporting on the effectiveness of our system of internal control. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with U.S. GAAP. As a public company, we are required to comply with the Sarbanes-Oxley Act and other rules that govern public companies. In particular, we are required to certify our compliance with Section 404 of the Sarbanes-Oxley Act, which requires us to furnish annually a report by management on the effectiveness of our internal control over financial reporting.

Management performed an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2019 and concluded that our internal control over financial reporting was not effective as of December 31, 2019 due to the material weakness related to the level of precision of our control environment. Specifically, we did not maintain a properly designed control environment that identified key control risk areas with an appropriate level of precision in order to conclude on the operating effectiveness of our disclosure controls and procedures. We have taken and continue to take remedial steps to improve our internal control over financial reporting. For further discussion of the material weakness identified and our remedial efforts, see Item 9A.

Remediation efforts place a significant burden on management and add increased pressure to our financial resources and processes. If we are unable to successfully remediate our existing material weakness or any additional material weaknesses in our internal control over financial reporting that may be identified in the future in a timely manner, the accuracy and timing of our financial reporting may be adversely affected; our liquidity, our access to capital markets, the perceptions of our creditworthiness may be adversely affected; we may be unable to maintain or regain compliance with applicable securities laws, the listing requirements of the Nasdaq Stock Market; we may be subject to regulatory investigations and penalties; investors may lose confidence in our financial reporting; our reputation may be harmed; and our stock price may decline.

Risks Associated with Ownership of Our Common Stock - continued

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Property

Our principal corporate offices, located at One Grand Central Place, 60 East 42nd Street, Suite 4600, New York, NY 10165, are currently leased on a month-to-month basis, with such lease agreement able to be cancelled with three months written notice. We also have short-term leases for limited office space in each of Pennsylvania and Massachusetts. At this time, we consider the leased office space to be commensurate with our current operations. Notwithstanding, we may obtain additional space as warranted by our business operations.

Item 3. Legal Proceedings

In the ordinary course of our business, particularly as we begin commercialization of our products, we may be subject to certain other legal actions and claims, including product liability, consumer, commercial, tax and governmental matters, which may arise from time to time. Except as otherwise noted herein, we do not believe we are currently a party to any other pending legal proceedings. Notwithstanding, legal proceedings are subject-to inherent uncertainties, and an unfavorable outcome could include monetary damages, and excessive verdicts can result from litigation, and as such, could result in a material adverse impact on our business, financial position, results of operations, and /or cash flows. Additionally, although we have specific insurance for certain potential risks, we may in the future incur judgments or enter into settlements of claims which may have a material adverse impact on our business, financial position, results of operations, and /or cash flows.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market for Common Equity

Our common stock is traded on the Nasdaq Capital Market under the symbol "PAVM." Our Series Z Warrants and Series W Warrants are also traded on the Nasdaq Capital Market under the symbols "PAVMZ" and "PAVMW," respectively.

Holders

As of March 31, 2020, there were 44,133,745 shares of our common stock outstanding. Our shares of common stock are held by 25 holders of record and we believe our shares of common stock are held by more than 3,000 beneficial owners.

Dividends

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

The Series B Convertible Preferred Stock provides for dividends at a rate of 8% per annum based on the $3.00 per share stated value of the Series B Convertible Preferred Stock, with such dividends compounded quarterly, accumulate, and are payable in arrears upon being declared by the Company's board of directors. The Series B Convertible Preferred Stock dividends from April 1, 2018 through October 1, 2021 are payable-in-kind ("PIK") in additional shares of Series B Convertible Preferred Stock. The dividends may be settled after October 1, 2021, at the option of the Company, through any combination of the issuance of additional Series B Convertible Preferred Stock, shares of common stock, and /or cash payment.

Through December 31, 2019, the Company's board of directors had declared Series B Convertible Preferred Stock dividend payments of an aggregate of $647,518, with such dividend payment settled by the issue of an additional 215,966 shares of Series B Convertible Preferred Stock in accordance with the applicable certificate of designations. Subsequent to December 31, 2019, in January 2020, the Company's board of directors declared a Series B Convertible Preferred Stock dividend payment of earned but unpaid dividends as of December 31, 2019, payable as of January 1, 2020, of $69,492, with such dividend payment settled by the issue of an additional 23,182 shares of Series B Convertible Preferred Stock in accordance with the applicable certificate of designations.

Recent Sales of Unregistered Securities

Except as previously disclosed in our current reports on Form 8-K and quarterly reports on Form 10-Q, we did not sell any unregistered securities or repurchase any of our securities during the fiscal year ended December 31, 2019.

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our consolidated financial condition and results of operations should be read together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements involving risks and uncertainties and should be read together with the "Forward-Looking Statements" and "Risk Factors" sections of this Annual Report on Form 10-K for a discussion of important factors which could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Unless the context otherwise requires, references herein to "we", "us", and "our", and to the "Company" or "PAVmed" are to PAVmed Inc. and its subsidiaries.

Overview

PAVmed is a highly differentiated multi-product technology medical device company organized to advance a broad pipeline of innovative medical technologies from concept to commercialization, employing a business model focused on capital efficiency and speed to market. Since inception on June 26, 2014, the Company's activities have focused on advancing the lead products towards regulatory approval and commercialization, protecting its intellectual property, and building its corporate infrastructure and management team. The Company operates in one segment as a medical device company and recently aligned its product offerings into four general groupings intended to become future operating divisions of the Company which include GI Health, Minimally Invasive Interventions, Infusion Therapy, and Emerging Innovations. As resources permit, we will continue to explore internal and external innovations that fulfill our project selection criteria without limiting ourselves to any target specialty or condition. In addition to the PAVmed, the parent company, we have substantive daily operations conducted in two majority owned subsidiaries: Lucid Diagnostics, incorporated in May 2018 and Solys Diagnostics, incorporated in October 2019.

Our multiple products are in various phases of development and regulatory clearance or approval. EsoCheck has received 510(k) marketing clearance from the FDA as a generic esophageal cell collection device. EsoGuard has been established as a LDT and was ready for commercial launch in December 2019 after completing CLIA/CAP certification of the test at Lucid's commercial diagnostic laboratory partner ResearchDx, headquartered in Irvine, CA. Our other products in development have not yet received clearance or approval to be marketed or sold in the U.S. or elsewhere. We have been granted patents by the USPTO for CarpX, PortIO, and Caldus and have acquired licenses to certain patents and intellectual property for DisappEAR from Tufts University and a group of academic centers, for EsoGuard and EsoCheck from CWRU and more recently for patents covering infrared technology to non-invasively detect glucose in tissue within the in-patient field of use from Liquid Sensing, Inc.

Our product groupings for each of the four operating divisions include:

- GI Health (EsoGuard Esophageal DNA Test, EsoCheck Esophageal Cell Collection Device, and EsoCure Esophageal Ablation Device with Caldus Technology);
- Minimally Invasive Interventions (CarpX Minimally Invasive Device for Carpal Tunnel Syndrome);
- Infusion Therapy (PortIO Implantable Intraosseous Vascular Access Device and NextFlo Highly Accurate Disposable Intravenous Infusion Set); and
- Emerging Innovations (non-invasive laser-based glucose monitoring, NextCath™ self-anchoring catheters, pediatric ear tubes and mechanical circulatory support).

From inception through December 31, 2019, our operational efforts have been almost exclusively devoted to medical innovation, product development, testing, clinical studies, patent writing, regulatory acceptance, insurance reimbursement and more recently toward planning and pre-market activities (e.g. trade shows and industry conferences) to sustain a substantive market introduction in 2020 for EsoCheck, our first FDA cleared device, and our EsoGuard LDT assay.

EsoCheck is commercially available under a substantial equivalence determination made by the FDA pursuant to a 510(k). On June 21, 2019, Lucid was notified by FDA that it may market EsoCheck, subject to the general controls provisions of the FDCA, as a cell collection device indicated for use in the collection and retrieval of surface cells of the esophagus in the general population of adults, 22 years of age and older.

EsoGuard is commercially available to be prescribed by physicians for patients in the United States as an LDT and has been reported in an article in *Science Translational Medicine* to have a high sensitivity and specificity for the detection of BE with and without dysplasia, as well as for EAC. LDT refers to a laboratory developed test and is a type of molecular diagnostic test that is designed, manufactured and used within a single laboratory which is also certified pursuant to the CLIA to support the marketing of the test.

EsoCheck (*i.e.*, by itself) may be used routinely by physicians to collect esophageal cells for various medical diagnostic purposes, including to diagnose or manage conditions such as Esophageal Candidiasis (a yeast infection of the esophagus which occurs in patients with compromised immune systems) and Eosinophilic Esophagitis (a common inflammatory condition of the esophagus). EsoGuard (*i.e.*, also by itself) may be performed on cytology samples collected by a means other than EsoCheck *e.g.*, via EGD. However, our present clinical development focus, and the subject of a recent IVD pre-submission meeting with the FDA, is on assessing the performance of the combined system (*i.e.*, the use of the EsoGuard assay on cells collected using EsoCheck) to detect BE, with and without dysplasia, and/or EAC, in individuals deemed to be at high risk for these conditions.

Overview - continued

Other Products – Continuing development and regulatory clearances

As mentioned above, many of our other products are in various phases of development and regulatory clearances or approvals and incurred substantive amount of management effort and/or costs to date and will require more of the same in the upcoming year, include:

- CarpX – A March 2020, 510(k) application is currently has been accepted for review by the FDA after completion in December 2019 of a first-in-human clinical study. Once we obtain market clearance from the FDA, we expect to commercialize our products to U.S. hand surgeons through a network of independent sales representatives and/or inventory-stocking medical distributors together with our in-house sales management and marketing teams.

- PortIO - We are pursuing an FDA clearance for use in patients with a need for vascular access up to seven days, under *de novo* classification of section 513(f)2 of the FDCA. The broader "seven days" clearance is being pursued in discussion with FDA following our previous initial submission to the FDA for a 510(k). The GLP animal study requested by the FDA has been completed along with supplementary cadaver and animal studies. This data was submitted to the FDA as part of a pre-submission filing that included an in-person meeting on January 8, 2020 to define a likely small human clinical safety study through the *de novo* pathway. Based on encouraging animal data, we are also planning a long-term (60-day implant duration) FIH clinical study in dialysis patients or those with poor venous access in Colombia, South America and intend to fulfill the likely FDA request for human clinical data with an "outside-of-United States" ("OUS") clinical safety study in Auckland, New Zealand. Of significance toward our belief of PortIO will one day become the answer to solve many of the current drawbacks intravenous access devices regularly encounter, our supplemental animal testing has demonstrated maintenance-free patency over a six-month implant duration.

- NextFlo - The NextFlo disposable IV infusion set has completed key milestones in its quest to eliminate the need for complex and expensive electronic infusion pumps for most of the estimated one million infusions of fluids, medications and other substances delivered each day in hospitals and outpatient settings in the United States. NextFlo maintains constant flow by incorporating a proprietary, passive, pressure-dependent variable flow-resistor consisting entirely of inexpensive, easy-to-manufacture disposable mechanical parts. NextFlo testing has now repeatedly demonstrated it can achieve constant flow rates across a wide range of IV bag heights, with accuracy rates comparable to electronic infusion pumps. Deloitte Consulting LLP has completed a comprehensive market research and strategic analysis of NextFlo demonstrating a very large addressable market and recommended PAVmed seek a long-term strategic partnership or acquisition. The global professional services firm Alvarez and Marsal has been running a formal M&A process for NextFlo targeting strategic and financial partners. The process is active with ongoing discussion with multiple parties.

- DisappEAR - These are pediatric ear tubes, manufactured from a proprietary aqueous silk technology licensed from Tufts University and two Harvard teaching hospitals, that seek to revolutionize the care of the estimated one million children who undergo bilateral ear tube placement each year to treat complex or recurrent middle ear infections or fluid collections, by eliminating the need for a second procedure as well as the standard difficult-to-administer post-operative ear drop regimen. An eight-month animal study of DisappEAR has been completed with excellent results. The ear tubes appear to possess unexpected surfactant properties which would provide several unique benefits over traditional plastic tubes, including enhanced flow of fluids in and out of the tube and potential intrinsic antimicrobial properties. A six-month GLP animal study has been completed and the Company is in active discussions with a large strategic partner to produce commercial-scale aqueous silk to support a future FDA 510(k) submission and commercialization.

- Solys Diagnostics (Noninvasive Glucose Monitoring) - In October 2019, PAVmed formed Solys Diagnostics with authorization to issue 50 million shares of its common stock, par value $0.001 per share and 20 million shares of its preferred stock, par value $0.001 per share. Concurrent with its formation, Solys Diagnostics issued 8.3 million shares of its common stock to PAVmed and also immediately acquired a license agreement from Liquid Sensing, Inc., a subsidiary of Airware, Inc., each an unrelated-third-party, in exchange for 1.5 million shares of Solys Diagnostics common stock issued to Airware, Inc., and 200,000 shares of Solys Diagnostics common shares issued to a unrelated-third-party consultant. Airware Inc. equity interests have certain anti-dilution rights under limited circumstances and 810,810 shares of Solys Diagnostics common stock issued to Airware Inc. are subject to certain milestone vesting restrictions. The exclusive worldwide licensing agreement acquired from Liquid Sensing, Inc. is for its six issued and one pending U.S. patents covering a proprietary nondispersive infrared (NDIR) laser technology for the non-invasive detection of glucose and other substances such as electrolytes in tissue within the inpatient (e.g. hospital) field of use. Pursuant to the licensing agreement, Solys Diagnostics will immediately advance the technology toward an established accuracy milestone for blood glucose monitoring within the licensed field of use. Upon achievement of the accuracy milestone, it is expected Solys Diagnostics will then pursue a full regulatory and development plan while also seeking to maximize the value of this proprietary technology with potential strategic partners or acquirers in the blood glucose monitoring market. If commercialized by Solys Diagnostics, Liquid Sensing Inc. has the right to collect future royalties on revenues related to the product developed for commercial use. Liquid Sensing Inc. has granted a 15 percent equity interest in its company to PAVmed with a portion of the shares issued being subject to certain performance vesting restrictions.

Overview - continued

Financing

In April, May and June 2019, we raised approximately $5.4 million, net, from three registered direct offerings of 5,480,000 shares of our common stock pursuant to our previously filed effective shelf registration statement on Form S-3 (File No. 333-220549).

In November 2019, we consummated the sale of a Senior Secured Convertible Notes in a private placement with a $14.0 million aggregate face value principal, referred to herein as the "November 2019 Senior Convertible Notes".

The November 2019 Senior Convertible Notes were further sub-divided into a Series A and Series B, each having a face value principal of $7.0 million, with each referred to as the "Series A November 2019 Senior Convertible Note" and the "Series B November 2019 Senior Convertible Note". The Series A and Series B November 2019 Senior Convertible Notes each provide for the payment of a $700,000 lender fee, with such lender fee deducted from the cash proceeds when funded by the investors, and additionally, we are obligated to pay a financial advisory fee to the placement agent fee of 6.5% of the cash proceeds upon their receipt.

With respect to the Series A November 2019 Senior Convertible Note, the investors delivered to us cash proceeds of $6.3 million on November 4, 2019, after deducting $0.7 million of lender fees, and we incurred total offering costs of $550,254, including a $409,500 advisory fee paid to the placement agent.

Subsequent to December 31, 2019, with respect to the Series B November 2019 Senior Convertible Note, the investors, at their election under the prepayment provisions, delivered to us cash proceeds of $6.3 million on March 30, 2020, after deducting $0.7 million of lender fees, and we paid an advisory fee of $409,500 to the placement agent.

A registration statement on Form S-3 was filed with the SEC in December 2019, which has not yet been declared effective, for the common stock underlying the Series A November 2019 Senior Convertible Note.

Financial Results of Operations

Revenue

To date, we have not generated any revenues from product sales. Our ability to generate product revenue and become profitable depends upon our ability to successfully complete the development and initiate the commercialization of our products.

General and administrative expenses

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

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

Research and development expenses

Research and development expenses are recognized in the period they are incurred and consist principally of internal and external expenses incurred for the research and development of our products and include:

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

We plan to incur research and development expenses for the foreseeable future as we continue the development of our products. Our current research and development activities are focused principally on obtaining FDA clearance and initializing commercialization of the lead products in our pipeline including CarpX, EsoGuard, and EsoCheck, along with advancing our DisappEAR, NextFlo, and noninvasive glucose monitoring products through their respective development phase, with research and development activities on our other portfolio products commensurate with available capital resources. These planned research and development activities include the following:

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

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

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

Financial Results of Operations - continued

General and administrative expense

	December 31,			
	2019	**2018**	**$ Change**	**% Change**
Compensation & related personnel costs	$ 2,191,409	$ 1,791,775	$ 399,634	22%
Stock-based compensation	1,162,370	948,143	$ 214,227	23%
Outside professional services	3,066,441	2,593,282	$ 473,159	18%
Facility related costs	276,314	152,904	$ 123,410	81%
Board related costs	271,250	247,917	$ 23,333	9%
Other operating costs	697,181	576,185	$ 120,996	21%
Total general and administrative expenses	$ 7,664,965	$ 6,310,206	$ 1,354,759	21%

General and administrative expenses incurred in the year ended December 31, 2019 were $7,664,965, an increase of $1,354,759 as compared to $6,310,206 incurred for corresponding prior year period. The increased general and administrative expenses for the current year period is principally due to increased expenses related to compensation and related personnel costs of $399,634, stock based compensation of $214,227, outside professional services of $473,159, facility related costs of $123,410, board related costs of $23,333 and other operating costs of $120,996.

The increased compensation and related personnel costs expense in the year ended December 31, 2019 as compared to the corresponding prior year period, resulted from higher salary and benefit expense related to the hiring of additional personnel, annual salary increases, and higher accrued bonus expense, inclusive of increases in each of the guaranteed bonus under the Chief Executive Officer ("CEO") employment agreement and discretionary bonus payments to the CEO and other employees.

The stock-based compensation expense classified as general and administrative expense, which includes stock options and restricted stock granted to both employees and non-employees, of $1,162,370 incurred during the year ended December 31, 2019, increased $214,227 as compared to the corresponding prior year period, principally resulting from increased stock-based compensation expense resulting from stock options granted to employees in 2019.

The outside professional services expense of $3,066,441 incurred during the year ended December 31, 2019 as compared to the corresponding prior year period, increased by $473,159, principally resulting from increased expenses of: $380,720 related to intellectual property matters, $234,566 related to investor and public relations, $183,622 related to marketing expenses, and $29,598 associated with professional fees for legal, accounting, auditing, tax, valuations, and information technology; partially offset by decreased expenses of: $105,348 related to regulatory matters. Additionally, outside professional services expenses decreased $250,000 in the current period as compared with the corresponding prior period with respect to consulting agreements with entities and /or individuals affiliated with certain of our officers and /or former directors. In this regard, $0 and $250,000 of expense was incurred in the year ended December 31, 2019 and 2018, respectively, with respect to the HCP/Advisors consulting agreement.

The increase in facility related costs of $123,410 in the year ended December 31, 2019 as compared to the corresponding prior year period, principally resulted from increased computer and internet expense, postage and delivery expense and rent expense associated with our corporate offices.

The board of director related costs of $271,250 for the year ended December 31, 2019 increased by $23,333 as compared to the corresponding prior year period, principally resulting from increase in expenses related to board of director fees.

The increased other operating expenses in the year ended December 31, 2019 as compared to the prior year period, principally resulted from higher director and officer insurance premiums, worker compensation insurance expense, and travel and related costs.

Financial Results of Operations - continued

Research and development expenses

	December 31,			
	2019	**2018**	**$ Change**	**% Change**
Compensation & related personnel costs	$ 1,657,668	$ 755,759	$ 901,909	119%
Stock-based compensation	408,282	280,556	127,726	46%
Outside professional services	4,421,531	2,920,812	1,500,719	51%
Patent license fees	-	272,553	(272,553)	(100%)
Milestone	75,000	-	75,000	
Regulatory filing fees	-	10,953	(10,953)	(100%)
Other	67,849	12,366	55,483	449%
Total research and development expenses	$ 6,630,330	$ 4,252,999	$ 2,377,331	56%

Research and development expenses incurred for the year ended December 31, 2019 totaled $6,630,330, an increase of $2,377,331 as compared to $4,252,999 incurred for the corresponding prior year period. The increase in research and development expenses resulted from the milestone costs of $75,000 incurred with respect to the CWRU License Agreement and increased expenses of: $901,908 related to compensation and related personnel costs, $127,726 related to stock-based compensation, $1,500,720 of increased expenses incurred for outside professional services, and $55,483 of increased other operating costs; partially offset by decreased expenses of: patent license fees $272,553 with respect to the CWRU License Agreement, and regulatory filing fees of $10,953.

The increased compensation and related personnel costs expense of $901,909 in the year ended December 31, 2019 as compared to the corresponding prior year period, resulted from higher salary expense related to additional personnel, as well as annual salary increases, increased accrued bonus expense related to higher discretionary employee bonus payments, and accrued expense related to employee relocation costs, for which there was no comparative amount in the prior year period.

The outside professional services of $4,421,531 in the year ended December 31, 2019 is an increase of $1,500,720 as compared to the corresponding prior year period. The increased outside professional services research and development expense principally resulted from our emphasis of current research and development activities being focused principally on completion of on-going efforts to obtain FDA clearance and initializing commercialization of each of the CarpX, EsoGuard, EsoCheck and PortIO products, and to continue to advance the development of the DisappEAR and the NextFlo products, as discussed above under "Overview".

There were no regulatory filing fees for the year ended December 31, 2019. The regulatory filing fee of $10,953 in the year ended December 31, 2018 was with respect to the submission to the FDA of a 510(k) premarket notification for the EsoCheck.

The increased other operating expenses in the year ended December 31, 2019 as compared to the corresponding prior year period, principally resulted from higher compensation insurance expense, and travel and related costs.

Financial Results of Operations - continued

Other Income and Expense

Interest Expense – Senior Secured Convertible Note - November 4, 2019 - Series B.

The Senior Secured Convertible Notes issued November 4, 2019 are comprised of a Series A and Series B - each with a face value principal of $7.0 million - "Series A" and /or "Series B" "November 2019 Senior Convertible Note". The investors delivered to the Company cash proceeds of $6.3 million on November 4, 2019, after deducting $0.7 million of lender fees. Subsequent to December 31, 2019, with respect to the Series B November 2019 Senior Convertible Note, the investors delivered to the Company cash proceeds of $6.3 million on March 30, 2020, after deducting $0.7 million of lender fees.

The Series A and Series B November 2019 Senior Convertible Notes have a stated interest rate of 7.875% per annum, to the extent the investor has funded the cash proceeds of each such respective note. During the period November 4, 2019 to March 29, 2020, when the Series B November 2019 Senior Convertible Note was not funded by the investors, the Company will incur interest expense of 3.0% per annum on the $7.0 million face value principal of the Series B November 2019 Senior Convertible Note.

The (cash) payment of 3.0% interest on the $7.0 million face value principal of the (unfunded) Series B November 2019 Senior Convertible Note, as such interest is discussed above, resulted in the recognition of $32,667 during the period November 4, 2019 through December 31, 2019, with such interest expense included in other income (expense) in the accompanying consolidated statement of operations.

See our accompanying consolidated financial statements Note 12,*Debt*, for further information regarding the Senior Secured Convertible Notes issued November 4, 2019 - Series A and Series B.

Interest Expense - Senior Secured Note issued July 3, 2017 (Scopia Holdings LLC)

The Senior Secured Note, previously issued in July 2017 by us to Scopia Holdings LLC ("Scopia Note") had an annual interest rate of 15.0%, with interest payable semi-annually in arrears on June 30 and December 30 of each calendar year, commencing December 30, 2017 ("15% interest expense"). At our sole discretion, we were able to defer payment of up to 50% of each of the semi-annual 15% interest expense payable, with such deferred amount added to the outstanding interest-bearing principal balance of the Scopia Note. In this regard, the Scopia Note principal balance was $5,780,116 at December 27, 2018

On December 27, 2018, concurrent with the issue of the December 2018 Senior Convertible Note (as defined below), we repaid-in-full the previously issued Scopia Note, inclusive of the total outstanding principal payable and the accrued but unpaid interest expense payable as of December 27, 2018, with such repayment comprised of a $5.0 million cash payment and the issue of 600,000 shares of common stock of the Company. The Scopia Note repayment was executed under a Notice of Prepayment agreement dated December 27, 2018.

The Scopia Note total interest expense of $ $2,392,447, for the year ended December 31, 2018, and was comprised of $786,145 resulting from the 15% interest expense and $1,606,302 resulting from the amortization of Scopia Note debt discount. The Scopia Note remaining unamortized debt discount was $1,637,972 as of December 27, 2018 the date of extinguishment. There was no interest expense on the Scopia Note in 2019.

See our accompanying consolidated financial statements Note 12,*Debt*, for further information regarding the Scopia Note.

Financial Results of Operations - continued

Other Income and Expense - continued

Change in Fair Value – Senior Secured Convertible Notes

Fair Value Option Election

The November 2019 Senior Convertible Notes (Series A and Series B) and the December 2018 Senior Convertible Note are each a debt financial instrument host containing embedded features and /or options which would otherwise be required to be bifurcated from the debt-host and recognized as separate derivative liabilities subject to initial and subsequent periodic estimated fair value measurements under ASC 815, *Derivatives and Hedging* ("ASC-815").

Notwithstanding, ASC 825, *Financial Instruments* ("ASC-825"), under ASC 825-10-15-4 provides for the "fair value option" ("FVO") election, to the extent not otherwise prohibited by ASC 825-10-15-5, to be afforded to financial instruments, wherein the financial instrument is initially measured at its issue-date estimated fair value and subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. As such, the November 2019 Senior Convertible Notes, with respect to the Series A of such note, was initially measured at its November 4, 2019 issue-date estimated fair value and then subsequently remeasured at estimated fair value on a recurring basis at each subsequent reporting period date. (As well, the Series B of such note will be initially measured at its issue-date estimated fair value and then subsequently remeasured at estimated fair value on a recurring basis at each subsequent reporting period date. For accounting purposes, the Series B November 2019 Senior Convertible Note issue date is deemed to be the prepayment date of the promissory notes issued by the investors in payment for such Series B notes, or March 30, 2020.) As provided for by ASC 825-10-50-30(b), the estimated fair value adjustment is presented as a single line item within other income (expense) in the accompanying consolidated statement of operations.

Senior Secured Convertible Notes Issued November 4, 2019

As noted above, the November 2019 Senior Convertible Notes are comprised of Series A and Series B notes, each with a face value principal of $7.0 million.

With respect to the Series A November 2019 Senior Convertible Note, on November 4, 2019, the investors delivered to the Company cash proceeds of $6.3 million, after deducting $0.7 million of lender fees (which were recognized as a current period expense on such date), and we incurred total offering costs of $550,254, including a $409,500 advisory fee paid to the placement agent, with such offering costs recognized as an expense in other income (expense).

The Series A November 2019 Senior Convertible Note fair value adjustment totaled $475,250 and was recognized as current period income in the year ended December 31, 2019 (as no portion of such fair value adjustments resulted from instrument-specific credit risk of such note as of such dates), and was inclusive of the fair value adjustment on the November 4, 2019 issue date and the fair value adjustment as of December 31, 2019.

Senior Secured Convertible Note Issued December 27, 2018

On December 27, 2018, the Company consummated the sale of a Senior Secured Convertible Note in a private placement with a $7.75 million face value principal, referred to herein as the "December 2018 Senior Convertible Note".

On the December 27, 2018 closing date of the December 2018 Senior Convertible Note, the investor delivered to the Company cash proceeds were $7.0 million, after deducting $0.750 million of lender fees (which were recognized as a current period expense on the closing date), and the Company incurred total offering costs of $614,940, inclusive of the payment of $455,000 placement agent fee and legal fees, with such offering costs recognized as an expense in other income (expense) in the accompanying consolidated statement of operations.

The December 2018 Senior Convertible Note fair value adjustments of $333,849 and $153,000 in the years ended December 31, 2019 and 2018, respectively, were recognized as a current period income in the respective accompanying consolidated statement of operations (as no portion of such fair value adjustments resulted from instrument-specific credit risk of such note as of such dates).

The estimated fair value of the Series A November 2019 Senior Convertible Notes as of their November 4, 2019 issue date and as of December 31, 2019, was computed using a Monte Carlo simulation of the present value of its cash flows using a synthetic credit rating analysis and a required rate of return; and, the estimated fair value of the December 2018 Senior Convertible Note as of December 31, 2019 and 2018, were computed using a combination of the present value of its cash flows using a synthetic credit rating analysis' required rate of return and the Black-Scholes option pricing model, using the Company's common stock price, the Company's dividend yield, the risk-free rates based on U.S. Treasury security yields, estimated volatility in the value of the Company's common stock, and the respective unit purchase options' and warrants' exercise price.

See our accompanying consolidated financial statements Note 11,*Financial Instruments Fair Value Measurements*, and Note 12,*Debt*, for further information regarding the fair value option election, the change in fair value recognized as other income (expense), and the Series A November 2019 Senior Convertible Notes and the December 2018 Senior Secured Convertible Note.

Financial Results of Operations - continued

Other Income and Expense - continued

Debt Extinguishment – Senior Secured Convertible Note Issued December 27, 2018

During the year ended December 31, 2019, aggregate principal repayments of $6,058,000 on the December 2018 Convertible Note and corresponding non-installment payments of $199,847 were settled by the issue of a total of 7,773,110 shares of common stock of the Company with a fair value of $8,089,163, resulting in a debt extinguishment loss in the year ended December 31, 2019 of $1,831,316. There were no such issue of shares of common stock of the Company with respect to the December 2018 Senior Convertible Note in the prior year ended December 31, 2018.

The fair value of the shares of common stock of the Company issued was measured as the respective issue date quoted closing price per share of the common stock of the Company.

See our accompanying consolidated financial statements Note 12,*Debt*, for further information regarding the debt extinguishment loss with respect to the issue of shares of our common stock in connection with the Senior Secured Convertible Note issued December 27, 2018 .

Debt Extinguishment - Senior Secured Note issued July 3, 2017

We recognized as other income (expense), a debt extinguishment loss of $1.4 million resulting from the difference between a $5.5 million debt reacquisition price and a $4.1 million debt carrying value, net, of the Scopia Note as of December 27, 2018 debt repayment date.

See our accompanying consolidated financial statements Note 12,*Debt*, for further information regarding the Scopia Note.

Financial Results of Operations - continued

Other Income and Expense - continued

Modification Expense - Series Z Warrant Agreement Amendment - June 1, 2018

The Series Z Warrant is a common stock purchase warrant with an exercise price initially of $3.00 per share through May 31, 2018, and then $1.60 per share effective June 1, 2018, wherein, on May 15, 2018, the Company's board of directors approved a reduction to the Series Z Warrant exercise price to $1.60 per share, effective June 1, 2018.

The Series Z Warrant exercise price adjustment to $1.60 per share from $3.00 per share, resulted in the recognition of a modification expense under the analogous guidance with respect to stock option modification under FASB ASC 718, wherein an exchange of warrants is deemed to be a modification of the initial warrant agreement by the replacement with a revised warrant agreement, requiring the incremental estimated fair value, measured as the difference between the estimated fair value immediately after the modification as compared to the estimated fair value immediately before the modification, to the extent an increase, recognized as a modification expense.

In this regard, the Series Z Warrant June 1, 2018 exercise price adjustment resulted in the recognition on such date of a current period modification expense of $1,140,995 included in other income (expense) in the consolidated statement of operations, with a corresponding increase to additional paid-in capital in the consolidated balance sheet, as the Series Z Warrants are equity classified.

Additionally, the Series Z Warrants issued in both the March 15, 2018 Series A and Series A-1 Exchange Offer and the April 5, 2018 Series W Warrants Exchange Offer, each as discussed below, were issued under the original Series Z Warrant Agreement. The Company's board of directors approved Amendment No. 1 to the original Series Z Warrant Agreement, which was embodied in an Amended and Restated Series Z Warrant Agreement, dated June 8, 2018, referred to as the "Amended Series Z Warrant Agreement". The amendment to the original Series Z Warrant Agreement was evaluated under the analogous guidance with respect to stock option modification under FASB ASC 718 as discussed above but did not result in the recognition of a modification expense as there was no incremental estimated fair value.

Financial Results of Operations - continued

Other Income and Expense - continued

Overview - "Series A and Series A-1 Exchange Offer" - March 15, 2018 Exchange Date

The "Series A and Series A-1 Exchange Offer", completed on March 15, 2018, was offered to and accepted by all holders of both the Series A Convertible Preferred Stock and Series A Warrants, and the Series A-1 Convertible Preferred Stock and Series A-1 Warrants, wherein shares of Series B Convertible Preferred Stock were issued-upon-exchange of shares of each of Series A and Series A-1 Convertible Preferred Stock and Series Z Warrants were issued-upon-exchange of each of Series A and Series A-1 Warrants - referred to as the "Series A and Series A-1 Exchange Offer" and the "March 15, 2018 Exchange Date".

The Series Z Warrants issued-upon-exchange of Series A-1 Warrants in the Series A and Series A-1 Exchange Offer, as such exchange offer is discussed above, resulted in the recognition of a modification expense under the analogous guidance with respect to stock option modification under FASB ASC 718, as described above with respect to the Series Z Warrant Agreement Amendment.

In this regard, the March 15, 2018 Exchange Date estimated fair value of $895,478 of the equity-classified 1,399,185 Series Z Warrants issued-upon-exchange as compared to the estimated fair value of $545,682 of the equity-classified 279,837 Series A-1 Warrants extinguished-upon-exchange, resulted in incremental estimated fair value of $349,796, which was recognized on such exchange date as a current period modification expense in other income (expense) in the consolidated statement of operations, with a corresponding increase to additional paid in capital, as the Series Z Warrants are equity classified.

Financial Results of Operations - continued

Other Income and Expense - continued

Modification Expense - Series W Warrants Exchange Offer - April 5, 2018 '

A total of 5,075,849 Series Z Warrants were issued-upon-exchange of 10,151,682 Series W Warrants, in an exchange offer transaction referred to as the "Series W Warrants Exchange Offer" and the "April 5, 2018 Exchange Date". The Series W Warrant Exchange Offer, resulted in the recognition of a modification expense on the April 5, 2018 Exchange Date, under the analogous guidance with respect to stock option modification under FASB ASC 718, as described above with respect to the Amended Series Z Warrant Agreement. In this regard, the April 5, 2018 Exchange Date estimated fair value of $3,304,377 of the 5,075,849 Series Z Warrants issued-upon-exchange as compared of the estimated fair value of $2,537,921 of the 10,151,682 Series W Warrants extinguished-upon-exchange, resulted in incremental estimated fair value of $766,456, which was recognized on such exchange date as a current period modification expense in other income (expense) in the consolidated statement of operations, with a corresponding increase to additional paid in capital, as the Series Z Warrants are equity classified.

Financial Results of Operations - continued

Other Income and Expense - continued

Change in Fair Value - Derivative Liability - Series A Warrants Derivative Liability and Series A Convertible Preferred Stock Conversion Option

The Series A Warrants derivative liability and the Series A-1 Convertible Preferred Stock conversion option derivative liability were each initially measured at fair value at the time of issuance and subsequently remeasured at estimated fair value on a recurring basis at each reporting period date, with changes in estimated fair value of each respective derivative liability recognized as other income or expense.

As of the March 15, 2018 Exchange Date of the Series A and Series A-1 Exchange Offer each of the corresponding Series A Warrants derivative liability and the Series A Convertible Preferred Stock conversion option derivative liability were each fully extinguished-upon-exchange as of the March 15, 2018 Exchange Date. Accordingly, there was no recognition of income or expense related to the change in estimated fair value of each such derivative liability after the March 15, 2018 Exchange Date.

In this regard, as of the March 15, 2018 Exchange Date, the change in the estimated fair value of each respective derivative liability resulted in the recognition of income of $64,913 with respect to the Series A Convertible Preferred Stock conversion option derivative liability, and the recognition of a net expense of $96,480 with respect to the Series A Warrants derivative liability.

Financial Results of Operations - continued

Income Taxes

We account for income taxes using the asset and liability method, as required by FASB ASC Topic 740,*Income Taxes*, ("ASC 740"). Current tax liabilities or receivables are recognized for the amount of estimated income tax payable and/or refundable for the current year. Deferred tax assets and deferred tax liabilities are recognized for estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, along with net operating loss and tax credit carryforwards.

Deferred tax assets and deferred tax liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled, Changes in deferred tax assets and deferred tax liabilities are recorded in the provision for income taxes.

Under ASC 740, a "more-likely-than-not" criterion is applied when assessing the estimated realization of deferred tax assets through their utilization to reduce future taxable income, or with respect to a deferred tax asset for tax credit carryforward, to reduce future tax expense. A valuation allowance is established, when necessary, to reduce deferred tax assets, net of deferred tax liabilities, when the assessment indicated it is more-likely-than-not, the full or partial amount of the net deferred tax asset will not be realized. As a result of the evaluation of the positive and negative evidence bearing upon the estimated realizability of net deferred tax assets, and based on a history of operating losses, it is more-likely-than-not the deferred tax assets will not be realized, and therefore a valuation allowance reserve equal to the full amount of the deferred tax assets, net of deferred tax liabilities, has been recognized as a charge to income tax expense as of December 31, 2019 and 2018.

We have total estimated federal and state NOL carryforwards of approximately $40.0 and $27.4 million as of December 31, 2019 and 2018, respectively, which are available to reduce future taxable income and begin to expire in 2035. We have total estimated research and development ("R&D") tax credit carryforward of $0.4 million as of December 31, 2019, with the R&D tax credit carryforward available to reduce future tax expense and begin to expire in 2035.

See our consolidated financial statements Note 6,*Income Taxes*, for additional information with respect to our income tax provision, deferred tax assets, and deferred tax liabilities.

Liquidity and Capital Resources

Overview - Financing

Issue of Common Stock - Registered Offerings

In the year ended December 31, 2019, a total of 5,480,000 shares of common stock of the Company were issued in registered offerings, under common stock share subscription agreements entered into with individual investors, resulting in total proceeds of $5,480,000, before placement agent fees and legal fees of $101,098.

Issue of Common Stock - Conversions - Senior Secured Convertible Note - Issued December 27, 2018

On December 27, 2018, we issued the December 2018 Senior Secured Convertible Note with a face value principal of $7.75 million, a stated interest rate of 7.875% per annum, and a contractual maturity date of December 31, 2020. At the election of the Holder, the December 2018 Senior Convertible Note may be converted into shares of our common stock. As of December 31, 2019, the December 2018 Senior Convertible Note face value principal was approximately $1.7 million, as result of approximately $6.1 million face value principal repayments, as discussed below.

The December 2018 Senior Convertible Note proceeds were $7.0 million after payment of $750,000 of lender fees. We incurred total offering costs of $614,940, inclusive of the payment of a $455,000 placement agent fee and legal fees, with such offering costs recognized as a current period expense on December 27, 2018.

In the year ended December 31, 2019, with respect to the December 2018 Senior Convertible Note, aggregate principal repayments of $6,085,000, respectively, and $199,847 of corresponding non-installment payments, respectively, were settled by the issue of 7,773,110, shares of common stock of the Company, respectively, resulting in a debt extinguishment loss in the year ended December 31, 2019, of $1,831,317, respectively.

Liquidity and Capital Resources - continued

Overview - Financing- continued

Senior Secured Convertible Notes Issued November 2019

In a private placement, on November 3, 2019, we entered into a Securities Purchase Agreement ("SPA") with two institutional investors ("Investors", "Lender", and /or "Holders"), and pursuant to the SPA, on November 4, 2019, we consummated the sale of Senior Secured Convertible Notes with a $14.0 million aggregate face value principal, referred to as the "November 2019 Senior Convertible Notes". At the election of the holder, the November 2019 Senior Convertible Notes may be converted into shares of common stock of the Company.

The November 2019 Senior Convertible Notes were further sub-divided into a Series A and a Series B, each having a face value principal of $7.0 million, each referred to as the "Series A November 2019 Senior Convertible Note" and the "Series B November 2019 Senior Convertible Note". The Series A and Series B November 2019 Senior Convertible Notes each provide for the payment of a $700,000 lender fee, with such lender fee deducted from the cash proceeds when funded by the investors, and additionally, we are obligated to pay a financial advisory fee to the placement agent of 6.5% of the cash proceeds upon their receipt.

With respect to the Series A November 2019 Senior Convertible Note, on November 4, 2019, the investors delivered to us cash proceeds of $6.3 million, after deducting $0.7 million of lender fees, and we incurred total offering costs of $550,254, including a $409,500 advisory fee paid to the placement agent.

Subsequent to December 31, 2019, with respect to the Series B November 2019 Senior Convertible Note, on March 30, 2020, the investors, at their election under the prepayment provisions, delivered to us cash proceeds of $6.3 million, after deducting $0.7 million of lender fees and we paid an advisory fee of $409,500 to the placement agent.

In the year ended December 31, 2019, $85,750 of non-installment payments with respect to the Series A November 2019 Senior Convertible Note were paid in cash.

A bi-monthly principal repayment and corresponding interest payment is due on the Series A and Series B November 2019 Senior Convertible Notes commencing March 30, 2020, and then on each of the successive 15th day of the month and the last trading day of the month, and on the maturity date. On each bi-monthly date, we are required to settle an installment amount, consisting of a principal repayment totaling $378,380 together with interest thereon, which shall be satisfied in shares of our common stock, subject to customary equity conditions (including minimum price and volume thresholds), at 100% of the installment amount, or otherwise (or at our election, in whole or in part) in cash at 115% of the installment amount.

Under the November 2019 Senior Secured Convertible Notes, we are subject to certain customary affirmative and negative covenants regarding the incurrence of indebtedness, the existence of liens, the repayment of indebtedness, the payment of cash in respect of dividends, distributions or redemptions, and the transfer of assets, among other matters, We also are subject to a financial covenant requiring that we have an unrestricted cash balance of at least $2.0 million at each quarterly balance sheet date. The Company was in compliance with the financial covenant as of December 31, 2019.

Liquidity and Capital Resources - continued

Overview - Financing- continued

Summary of Financing in the year ended December 31, 2018

* During 2018, we raised approximately $15.5 million of net proceeds, comprised of $20.5 million of gross proceeds, less $5.0 million used to repay debt ahead of the contractual maturity date, including:

  In January 2018, we raised $4.3 million of net cash proceeds in an underwritten public offering of 2,649,818 shares of our common stock pursuant to our previously filed effective shelf registration statement on SEC Form S-3 - File No. 333-220549.

  In June 2018, we raised approximately $9.2 million of net cash proceeds from an Equity Subscription Rights Offering ("ESRO") pursuant to our previously filed effective registration statement on SEC Form S-1 - File No. 333-222581, wherein, 9.0 million units were issued comprised of a corresponding number of shares of our common stock and Series Z Warrants exercisable to purchase 9.0 million shares of our common stock at an exercise price of $1.60 per share.

  In December 2018, we raised approximately $7.0 million of net cash proceeds, after payment of $750,000 of lender fees, from the issue of the December 2018 Senior Convertible Note, with a face value principal of $7.75 million, to an institutional investor.

  Promptly after the consummation of the issue of the December 2018 Senior Convertible Note, we repaid in full the outstanding principal balance and all accrued but unpaid interest expense as of December 27, 2018 on the Scopia Note, with such repayment consisting of a cash payment of $5.0 million the issue of 600,000 shares of our common stock.

* Additionally during 2018, we also completed exchange offers of private securities and a tender offer of public warrants, including:

  In March 2018, in an exchange offer captioned the "Series A and Series A-1 Exchange Offer", we issued a total of 975,568 shares of Series B Convertible Preferred Stock for all of the issued and outstanding shares of each of the Series A Convertible Preferred Stock and the Series A-1 Convertible Preferred Stock, and we issued a total of 2,739,190 Series Z Warrants for all of the issued and outstanding of each of the Series A Warrants and the Series A-1 Warrants.

  In April 2018, in an exchange offer captioned the "Series W Warrant Exchange Offer", we completed a Tender Offer whereby 96.4% of the then outstanding publicly traded Series W Warrants, or 10,151,682 Series W Warrants, were exchanged for 5,075, 849 Series Z Warrants.

  The Series Z Warrants are publicly traded on the NASDAQ Capital Market under the symbol PAVMZ, and each Series Z Warrant may be exercised to purchase a share of our common stock, initially at $3.00 per share through May 31, 2018, then $1.60 per share effective June 1, 2018, as a result of our board of directors approval on May 15, 2018 of such exercise price adjustment.

Liquidity and Capital Resources - continued

Overview - Financing- continued

Summary of Financing in the year ended December 31, 2018 - continued

Senior Secured Convertible Note Issued December 27, 2018

In a private placement transaction with an institutional investor on December 27, 2018, we entered into a Securities Purchase Agreement under which we issued the December 2018 Senior Convertible Note, having a contractual maturity date of December 31, 2020, a face value principal of $7.75 million, and a stated interest rate of 7.875% per annum. At the election of the holder, the December 2018 Senior Convertible Note may be converted into shares of common stock of the Company, as discussed below.

The December 2018 Senior Convertible Note proceeds were $7.0 million after deducting $0.750 million of lender fees (which were recognized as a current period expense on such date), and we incurred an additional total offering costs of $614,940, inclusive of $455,000 placement agent fee, with such offering costs recognized as an expense in other income (expense) in the accompanying consolidated statement of operations.

On December 27, 2018, concurrent with the issue of the December 2018 Senior Convertible Note, we repaid-in-full the previously issued Scopia Note inclusive of the total outstanding principal payable and the accrued but unpaid interest expense payable as of December 27, 2018, with such repayment comprised of a $5.0 million cash payment and the issue of 600,000 shares of common stock of the Company.

The December 2018 Senior Convertible Note requires bi-monthly payments, with such payments due and payable on each of the 15th calendar day of each month and the Last Trading Day of each month, with the first bi-monthly payment date of January 15, 2019 and the last bi-monthly payment date of December 31, 2020. The bi-monthly payments have two components: a bi-monthly "Installment Repayment" which commences June 28, 2019 through December 31, 2020, and a bi-monthly "Non-Installment Payment" which commences January 15, 2019 through the December 31, 2020. The bi-monthly Installment Repayments are prescribed and the bi-monthly Non-Installment Repayments are a function of the remaining Senior Convertible Note face value principal outstanding.

Liquidity and Capital Resources - continued

Overview - Financing- continued

Equity Subscription Rights Offering - "ESRO" - June 12, 2018

Our ESRO, closed on June 12, 2018, resulted in approximately $10.4 million of gross cash proceeds, before approximately $1.0 million of commissions and fees to the dealer-managers, and approximately $0.2 million of offering costs incurred by the Company, upon the issue on June 12, 2018 of 9.0 million common stock units, comprised of one share of common stock of the Company and one Series Z Warrant, as noted above.

Issue of Common Stock - Underwritten Public Offering - January 2018

In January 2018, we conducted an underwritten public offering, under our previously filed and effective shelf registration statement on Form S-3 (File No. 333-220549) wherein we issued a total of 2,649,818 shares of our common stock resulting in cash proceeds, net of the underwriter's discount, of approximately $4.4 million before offering costs of approximately $0.1 million.

Series A and Series A-1 Exchange Offer - March 15, 2018

On the March 15, 2018 Exchange Date of the "Series A and Series A-1 Exchange Offer", a total of 975,568 shares of Series B Convertible Preferred Stock were issued, including 499,334 shares of Series B Convertible Preferred Stock issued-upon-exchange of 249,667 shares of Series A Convertible Preferred Stock and 476,234 shares of Series B Convertible Preferred Stock issued-upon-exchange of 357,259 shares of Series A-1 Convertible Preferred Stock; and, a total of 2,739,190 Series Z Warrants were issued, including 1,340,005 Series Z Warrants issued-upon-exchange of 268,001 Series A Warrants and 1,399,185 Series Z Warrants issued-upon-exchange of 279,837 Series A-1 Warrants.

Consequently, as of the March 15, 2018 Exchange Date, there were no issued and outstanding shares of Series A Convertible Preferred Stock and Series A Warrants, nor any issued and outstanding shares of Series A-1 Convertible Preferred Stock and Series A-1 Warrants, as each were fully exchanged for shares of Series B Convertible Preferred Stock and Series Z Warrants, respectively. Additionally, each of the Series A Warrants derivative liability and the Series A-1 Convertible Preferred Stock conversion option derivative liability were fully extinguished-upon-exchange as of the March 15, 2018 Exchange Date.

Liquidity and Capital Resources - continued

Overview - Financing- continued

Summary of Financing in the year ended December 31, 2018 - continued

Series W Warrants Offer-to-Exercise- February 8, 2018

On January 11, 2018, we filed with the SEC a Tender Offer Statement on Schedule TO offering Series W Warrants holders a temporary exercise price of $2.00 per share, with such offer having an expiry of February 8, 2018 - referred to as the "Series W Warrants Offer-to-Exercise". As of the February 8, 2018 expiry date, a total of 34,345 Series W Warrants were exercised at the temporary exercise of $2.00 per share, resulting in $68,690 of cash proceeds, before offering costs of $50,520.

Note and Security Purchase Agreement with Scopia Holdings LLC

On December 27, 2018, concurrent with the issue of the Senior Convertible Note issued on December 27, 2018, as discussed above, we repaid-in-full the previously issued Senior Secured Note between us and Scopia Holdings LLC, inclusive of the total outstanding principal payable and the accrued but unpaid interest expense payable as of December 27, 2018, with such repayment comprised of a $5.0 million cash payment and the issue to Scopia Holdings LLC of 600,000 shares of our common stock.

Liquidity and Capital Resources - continued

Going Concern

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

We are an early stage and emerging growth company and are subject-to the corresponding risk of such companies. Since inception we have not generated any revenues and have incurred losses and negative cash flows from operating activities. We do not expect to generate positive cash flows from operating activities in the near future until we complete the development process and regulatory approvals of our products, and thereafter begin to commercialize and achieve substantial marketplace acceptance of our products.

We have incurred a net loss attributable to PAVmed Inc. common stockholders of approximately $16.7 million and net cash flows used in operating activities of approximately $13.4 million for the year ended December 31, 2019. As of December 31, 2019, we have negative working capital of approximately $5.3 million, with such working capital inclusive of approximately $8.1 million of the Senior Secured Convertible Notes classified as a current liability and approximately $6.2 million of cash.

We anticipate incurring operating losses and do not expect to generate positive cash flows from operating activities, if any, for the next several years as we complete the development of our products, file for and request regulatory approvals and clearances of such products, and begin to commercially market such products. These factors raise substantial doubt about our ability to continue as a going concern within one year after the date our consolidated financial statements are issued.

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

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

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

Liquidity and Capital Resources - continued

Cash flows and liquidity

The cash flow sources and uses for operating, investing, and financing activities, for each period presented is as follows:

	Year Ended December 31,	
	2019	**2018**
Net cash flows (used in) or provided by:		
Operating activities	$ (13,357,271)	$ (8,787,907)
Investing activities	(27,203)	(26,609)
Financing activities	11,381,586	15,501,613
Net increase (decrease) in cash	(2,002,888)	6,687,097
Cash, beginning of period	8,222,119	1,535,022
Cash, end of period	$ 6,219,231	$ 8,222,119

Operating Activities

Net cash flows (used in) or provided by operating activities was $13,357,271 and $8,787,907 in the year ended December 31, 2019 and 2018, respectively, consisting of: a net loss - before noncontrolling interest of $17,268,131 and $18,172,822, respectively, with non-cash adjustments totaling, $3,901,860 and $9,384,915 to reconcile the net loss - before noncontrolling interest to net cash used in operating activities, inclusive of $3,974,794 and $8,038,595 of non-cash items, respectively, and, $(63,934) and $1,346,320 of a net change in operating assets and liabilities, respectively, as follows:

	Year Ended December 31,	
	2019	**2018**
Non-Cash Adjustments		
Depreciation expense	$ 14,226	$ 9,790
Stock-based compensation	1,570,652	1,228,699
Interest expense added to principal of Senior Secured Note	-	591,574
Interest expense - amortization of discount - Senior Secured Note		1,606,302
Debt extinguishment - Senior Secured Note	-	1,408,296
Debt extinguishment - Senior Convertible Note	1,831,317	-
Change in fair value - Senior Secured Convertible Note	558,599	903,000
Modification expense - Series Z Warrants - June 1, 2018	-	1,140,995
Modification expense - Series A-1 Warrant - October 18, 2017	-	-
Series A and Series A-1 Exchange Offer - March 15, 2018	-	349,796
Series W Warrants Exchange Offer - April 5, 2018	-	766,456
Unit Purchase Options Exchange Offer - August 22, 2018	-	2,120
Loss on issuance of Preferred Stock Units	-	-
Change in fair value - Series A Warrants derivative liability	-	96,480
Change in fair value - Series A Convertible Preferred Stock conversion option derivative liability	-	(64,913)
Sub-Total: non-cash adjustments, net	$ 3,974,794	$ 8,038,595
Change in Operating Assets and Liabilities		
Prepaid expenses and other current assets	$ (90,244)	$ (149,573)
Accounts payable	613,283	872,111
Accrued expenses and other current liabilities	56,027	623,782
Other Assets - Non-Current	(643,000)	-
Sub-Total: Change in operating assets and liabilities, net	$ (63,934)	$ 1,346,320

Liquidity and Capital Resources - continued

Cash flows and liquidity - continued

Investing Activities

Net cash flows used in investing activities was $27,203 and $26,209 in the year ended December 31, 2019 and 2018, respectively, related to the purchases of research and development and office equipment.

Financing Activities

Net cash flows provided by financing activities in the year ended December 31, 2019 totaled $11,381,586, principally comprised of: proceeds from issuance of common stock, issuance of Senior Convertible Note, and employee stock purchase plan of $5,480,000, $6,300,000 and $67,436, respectively, partially offset by: the payment of offer costs of $101,098, lender fees attributable to the Senior Convertible Note of $85,750, and a payment for the issuance of Senior Convertible Note – non-installment of $279,002.

Net cash flows provided by financing activities in the year ended December 31, 2018 totaled $15,501,613, principally comprised of: proceeds of $7,000,000, net of lender fees of 750,000, from the issue of a Senior Secured Convertible Note with a face value principal of $7,750,000; a payment of $5,000,000 with respect to the repayment of the previously issued Senior Secured Note (between us and Scopia Holdings LLC), with such payment concurrent with the Senior Convertible Note issued on December 27, 2018; proceeds of $9,437,000, offset by the payment of $225,674 of related incurred offering costs, from the "June 12, 2018 Equity Subscription Rights Offering"; and proceeds of $4,388,099, offset by the payment of $113,438 of related incurred offering costs, from the issue of common stock of the Company in an underwritten public offering in January 2018. Other financing activities during the year ended December 31, 2018 include: a total of $20,913 of net proceeds from the exercise of Series W Warrants and Series S Warrants; proceeds of $1,812 resulting from the issue of shares of common stock of Lucid Diagnostics Inc., a majority-owned subsidiary of the Company; and, the payment of $7,099 of Series A Convertible Preferred Stock dividends. See our consolidated financial statements Note 13, *Preferred Stock,* for a further discussion of the Series A Convertible Preferred Stock dividend cash payment.

Critical Accounting Policies and Significant Judgments and Estimates

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions affecting the reported amounts of assets, liabilities, and equity, along with the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the corresponding periods. In accordance with U.S. GAAP, we base our estimates on historical experience and on various other assumptions we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in our consolidated financial notes, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expense

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

Financial Instruments and Fair Value Measurements

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

Level 1	Level 1 Valuations based on quoted prices for identical assets and liabilities in active markets.
Level 2	Level 2 Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets which are not active, or other inputs observable or can be corroborated by observable market data.
Level 3	Level 3 Valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

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

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

Critical Accounting Policies and Significant Judgments and Estimates - continued

The Company accounts for the issued and outstanding Senior Convertible Notes under the "FVO election" of ASC 825,*Financial Instruments*, as discussed below. The Senior Secured Convertible Notes issued November 4, 2019 (Series A and Series B) and the Senior Secured Convertible Note issued December 27, 2018, are each a debt financial instrument host containing embedded features and /or options which would otherwise be required to be bifurcated from the debt host and recognized as separate derivative liabilities subject to initial and subsequent periodic estimated fair value measurements under ASC 815.

Notwithstanding, ASC 825-10-15-4 provides for the "fair value option ("FVO"), to the extent not otherwise prohibited by ASC 825-10-15-5, to be afforded to financial instruments, wherein the financial instrument is initially measured at its issue-date estimated fair value and subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. Further, the estimated fair value adjustment, as required by ASC 825-10-45-5, is recognized as a component of other comprehensive income ("OCI") with respect to the portion of the fair value adjustment attributed to a change in the instrument-specific credit risk, with the remaining amount of the fair value adjustment recognized as other income (expense) in the consolidated statement of operations. With respect to the Company, the "other income (expense) component" of the Senior Convertible Note fair value adjustment is presented in a single line in the consolidated statement of operations, as provided for by ASC 825-10-50-30(b). See Note 11, *Financial Instruments Fair Value Measurements*, and Note 12, *Debt*, for a further discussion of such FVO election and the Senior Secured Convertible Debt.

In addition to the Senior Secured Convertible Notes noted above, the Series A and Series A-1 Exchange Offer on March 15, 2018, and the Series A Exchange Offer on November 17, 2017, each as discussed above, the other issue-date and /or date-of-occurrence non-recurring estimated fair values include: the Series W Warrants Exchange Offer on April 5, 2018, the Series Z Warrant exercise price adjustment on June 1, 2018, and the UPO Exchange Offer on August 22, 2018; along with the Series A Preferred Stock Units private placement during the three months ended March 31, 2017, the Senior Secured Note and Series S Warrants issued in connection with the Note and Security Purchase Agreement between the Company and Scopia Holdings LLC on July 3, 2017; the Series A-1 Preferred Stock Units private placement on August 4, 2017; the Series A-1 Warrants Agreement Amendment No. 1 on October 18, 2017, and the conversion of shares of Series A Convertible Preferred Stock into shares of common stock of the Company in November 2017 and December 2017, with each utilizing the Company's common stock price along with certain Level 3 inputs, as discussed below, in the development of Monte Carlo simulation models, discounted cash flow analyses, and /or Black-Scholes valuation models.

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

Critical Accounting Policies and Significant Judgments and Estimates - continued

Stock-Based Compensation

The Company measures stock-based compensation of stock-based awards granted to employees and members of its board of directors using the grant-date estimated fair value of the stock-based award and recognizes such estimated fair value on a straight-line basis over the requisite service period, which is generally the vesting period of the respective stock-based award, with such straight-line recognition adjusted so the cumulative expense recognized is at-least equal-to-or-greater-than the estimated fair value of the respective vested stock-based award.

The Company measures the expense of stock-based awards granted to non-employees on a vesting date basis, fixing the fair value of vested non-employee stock options as of their respective vesting date. The fair value of vested non-employee stock options is not subject-to- further remeasurement at subsequent reporting dates. The estimated fair value of the unvested non-employee stock options is remeasured to then current fair value at each subsequent reporting date, until such time when the stock options vest, at which time the fair value is fixed, as noted above. The estimated fair value of stock-based awards granted to non-employees is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective non-employee stock-based award, with such straight-line recognition adjusted so the cumulative expense recognized is at-least equal-to-or-greater-than the estimated fair value of the respective vested stock-based award.

The ASU 2018-07 amended ASC-718 guidance is effective for public entities for fiscal years beginning after December 15, 2018, including interim periods within such fiscal year, and for all other entities, including the Company (as a result of its "JOBS Act EGC Accounting Standards Election", as such election is discussed above), such amended guidance is effective for fiscal years beginning after December 15, 2019 - (i.e. December 31, 2020), and interim periods within fiscal years beginning after December 15, 2020 - (i.e. commencing with the interim period three months ending March 31, 2021, and thereafter). Early adoption is permitted, but no earlier than a company's adoption of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606).

Critical Accounting Policies and Significant Judgments and Estimates - continued

Income Taxes

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

Under ASC 740, a "more-likely-than-not" criterion is applied when assessing the estimated realization of deferred tax assets through their utilization to reduce future taxable income, or with respect to a deferred tax asset for tax credit carryforward, to reduce future tax expense. A valuation allowance is established, when necessary, to reduce deferred tax assets, net of deferred tax liabilities, when the assessment indicates it is more-likely-than-not, the full or partial amount of the net deferred tax asset will not be realized. As a result of the evaluation of the positive and negative evidence bearing upon the estimated realizability of net deferred tax assets, and based on a history of operating losses, it is more-likely-than-not the deferred tax assets will not be realized, and therefore a valuation allowance reserve equal to the full amount of the deferred tax assets, net of deferred tax liabilities, has been recognized as a charge to income tax expense as of December 31, 2019 and 2018.

The Company recognizes the benefit of an uncertain tax position it has taken or expects to take on its income tax return if such a position is more-likely-than-not to be sustained upon examination by the taxing authorities, with the tax benefit recognized being the largest amount having a greater than 50% likelihood of being realized upon ultimate settlement. As of December 31, 2019 the Company does not have any unrecognized tax benefits resulting from uncertain tax positions.

The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. There were no amounts accrued for penalties or interest as of December 31, 2019 and December 31, 2018 or recognized during the years ended December 31, 2019 and 2018. The Company is not aware of any issues under review to potentially result in significant payments, accruals, or material deviations from its position.

Critical Accounting Policies and Significant Judgments and Estimates - continued

Going Concern

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

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

Recently Issued Accounting Standards

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

Critical Accounting Policies and Significant Judgments and Estimates - continued

Recently Issued Accounting Standards - continued

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

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

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

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"), which establishes a right-of-use (ROU) model requiring a lessee to recognize a ROU asset and a lease liability for all leases with terms greater-than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods with those fiscal years. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company does not expect this guidance to have a significant effect on its consolidated financial position, results of operations, and cash flows.

JOBS Act

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

Off-Balance sheet arrangements

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

Effect of Inflation and Changes in Prices

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

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019. Based on such evaluation, due to the material weakness in internal control over financial reporting described below, our principal executive officer and principal financial officer concluded our disclosure controls and procedures (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) were not effective as of such date to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

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

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

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

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

Our management conducted an evaluation of the effectiveness of the system of internal control over financial reporting based on the framework in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded our system of internal control over financial reporting was not effective as of December 31, 2019.

Our management's conclusion was due to the material weakness described below. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements would not be prevented or detected on a timely basis. Our management identified the following material weakness in our internal control over financial reporting:

- We did not maintain a properly designed control environment that identified key control risk areas with an appropriate level of precision in order to conclude on the operating effectiveness of our disclosure controls and procedures.

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

Remediation of the Material Weakness

Management intends to implement changes to strengthen our internal control over financial reporting. These changes are intended to address the identified material weakness and enhance our overall control environment and are expected to include the activities described below.

- We intend to hire a consultant to assist us in revising our internal control documentation so that it identifies key control risk areas with sufficient precision for us to properly test the operating effectiveness of our disclosure controls and procedures.

While we believe that the above actions will ultimately remediate the material weakness, we intend to continue to refine those controls and monitor their effectiveness for a sufficient period of time prior to reaching any determination as to whether the material weakness has been remediated.

Notwithstanding the identified material weakness, management believes that the consolidated financial statements included in this Form 10-K present fairly, in all material respects, our financial position, results of operations, and cash flows as of and for the periods presented in accordance with U.S. GAAP.

Changes to Internal Controls Over Financial Reporting

There has been no change in internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. However, we expect to make changes to our internal control over financial reporting in the future to remediate the material weakness identified above.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 is incorporated by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

Item 11. Executive Compensation

The information required by this Item 11 is incorporated by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

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

The information required by this Item 12 is incorporated by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

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

The information required by this Item 13 is incorporated by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 is incorporated by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

(1) The following financial statements:

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets
Consolidated Statements of Operations
Consolidated Statements of Changes in Series A Convertible Preferred Stock and Equity (Deficit)
Consolidated Statements of Cash Flows
Notes to Consolidated Financial Statements

(2) The financial statement schedules:

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

(3) The following exhibits:

Exhibit No.	Description
3.1	Certificate of Incorporation(1)
3.2	Certificate of Amendment to Certificate of Incorporation (1)
3.3	Certificate of Amendment to Certificate of Incorporation, dated October 1, 2018 (13)
3.4	Certificate of Amendment to Certificate of Incorporation, dated June 26, 2019 (10)
3.5	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (11)
3.6	Certificate of Elimination - Series A Convertible Preferred Stock and Series A-1 Convertible Preferred Stock (11)
3.7	Bylaws (1)
4.1	Description of Registrant's Securities †
4.2	Specimen PAVmed Inc. Common Stock Certificate (1)
4.3	Specimen PAVmed Inc. Series W Warrant Certificate (1)
4.4	Series W Warrant Agreement, dated April 28, 2016, between Continental Stock Transfer & Trust Company and the Registrant (3)
4.5	Form of Unit Purchase Option (1)
4.6	Specimen PAVmed Inc. Series Z Warrant Certificate (5)
4.7	Amended and Restated Series Z Warrant Agreement, dated as of June 8, 2018, by and between PAVmed Inc. and Continental Stock Transfer & Trust Company, as Warrant Agent (7)
10.1	Patent Option Agreement (1)
10.2.1	Form of Letter Agreement with HCFP Capital Partners III LLC (1)
10.2.2	Form of Letter Agreement with Pavilion Venture Partners LLC (1)
10.3.1	Letter agreement regarding corporate opportunities executed by Dr. Lishan Aklog (1)
10.3.2	Letter agreement regarding corporate opportunities executed by Michael Glennon (1)
10.3.3	Letter agreement regarding corporate opportunities executed by Dr. Brian deGuzman (1)
10.4.1	Securities Purchase Agreement between PAVmed Inc. and the purchasers of the Series A Preferred Stock Units (2)
10.4.2	Registration Rights Agreement between PAVmed Inc. and the purchasers of the Series A Preferred Stock Units (2)
10.5*	Amended and Restated Employment Agreement between PAVmed Inc. and Lishan Aklog, M.D. (9)
10.6*	Amended and Restated Employment Agreement between PAVmed Inc. and Dennis M. McGrath (9)
10.7*	Employment Agreement between PAVmed Inc. and Brian J. deGuzman, M.D. (4)
10.8*	Third Amended and Restated PAVmed Inc. 2014 Long-Term Equity Incentive Plan (10)

Item 15. Exhibits and Financial Statement Schedules - continued

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

(3) The following exhibits (continued):

Exhibit No.	Description
10.9.1	Form of Securities Purchase Agreement between PAVmed Inc. and Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B (8)
10.9.2	Form of Secured Convertible Promissory Note between PAVmed Inc. and Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B (8)
10.9.3	Form of Security and Pledge Agreement between PAVmed Inc. and Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B (8)
10.9.4	Form of Guaranty between PAVmed Inc. and Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B (8)
10.9.5	Form of Voting Agreement between PAVmed Inc. and Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B (8)
10.9.6	Form of Registration Rights Agreement between PAVmed Inc. and Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B (8)
10.10.1	Form of Securities Purchase Agreement. (11)
10.10.2	Form of Series A and Series B Secured Convertible Promissory Note. (11)
10.10.3	Form of Amend and Restated Security and Pledge Agreement. (11)
10.10.4	Form of Amended and Restated Guaranty. (11)
10.10.5	Form of Note Purchase Agreement. (11)
10.10.6	Form of Investor Note. (11)
10.10.7	Form of Master Netting Agreement. (11)
10.10.8	Form of Registration Rights Agreement. (11)
10.10.9	Form of Voting Agreement. (11)
10.10.10	Form of Amended and Restated Leak-Out Agreement (11)
14	Form of Code of Ethics (1)
21	List of Subsidiaries †
23.1	CONSENT - Marcum LLP †
23.2	Consent of Citrin Cooperman & Company, LLP †
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. †
31.2	Certification of Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. †
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. †
32.2	Certification of Principal Financial and Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. †
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

(1) Incorporated by reference to the Registrant's Registration Statement on Form S-1 - SEC File No. 333-203569
(2) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on February 1, 2017.
(3) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on May 3, 2016.
(4) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 19, 2016.
(5) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on April 5, 2018.
(6) Incorporated by reference to the Registrant's Current Report on Form 8-K/A filed on April 20, 2018.
(7) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on June 8, 2018.
(8) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on December 27, 2018.
(9) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on March 20, 2019.
(10) Incorporated by reference to the Registrant's Current Report on Form 8-K filed June 20, 2019.
(11) Incorporated by reference to the Registrant's Current Report on Form 8-K filed November 4, 2019.

* Management contract or compensatory plan or arrangement.
† Filed herewith

Item 16. Form 10-K Summary

None

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 14, 2020 By: */s/ Lishan Aklog, M.D.*

Lishan Aklog, M.D.
Chairman of Board of Directors
Chief Executive Officer

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

Signature	Title	Date
/s/ Lishan Aklog, M.D. Lishan Aklog, M.D.	Chairman of the Board of Directors Chief Executive Officer (*Principal Executive Officer*)	April 14, 2020
/s/ Dennis M. McGrath Dennis M. McGrath	President Chief Financial Officer (*Principal Financial and Accounting Officer*)	April 14, 2020
/s/ Michael J. Glennon Michael J. Glennon	Vice Chairman Director	April 14, 2020
/s/ David S. Battleman M.D. David S. Battleman M.D.	Director	April 14, 2020
/s/ James L. Cox, M.D. James L. Cox, M.D.	Director	April 14, 2020
/s/ Ronald M. Sparks Ronald M. Sparks	Director	April 14, 2020
/s/ David Weild IV David Weild IV	Director	April 14, 2020

PAVMED INC.
and SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
PAVmed Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of PAVmed Inc. and Subsidiaries (the "Company") as of December 31, 2019, the related consolidated statements of operations, changes in equity (deficit) and cash flows for the year ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019, and the results of its operations and its cash flows for the year ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Marcum llp

Marcum llp

We have served as the Company's auditor since 2019**.**

New York, NY
April 14, 2020

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of PAVmed Inc. and Subsidiaries (the "Company") as of December 31, 2018, the related consolidated statements of operations, Series A Convertible preferred stock and stockholders' deficit, and cash flows, for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018, and the results of their consolidated operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company's recurring losses from operations, recurring cash used in operating activities, accumulated deficit and absence of revenue generation raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 2 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ CITRIN COOPERMAN & COMPANY, LLP

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

New York, New York
April 1, 2019

PAVMED INC.
and SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2019	December 31, 2018
Assets	$	$
Current assets		
Cash	6,219,231	8,222,119
Prepaid expenses and other current assets	328,284	238,040
Total current assets	6,547,515	8,460,159
Other assets	692,937	36,271
Total assets	$ 7,240,452	$ 8,496,430
Liabilities and Equity (Deficit)		
Current liabilities		
Accounts payable	$ 2,352,809	$ 1,738,837
Accrued expenses and other current liabilities	1,386,773	1,330,746
Senior Secured Convertible Note issued December 27, 2018 at fair value, face value principal of $1,692,000 and $7,750,000 at December 31, 2019 and 2018, respectively	1,700,000	7,903,000
Senior Secured Convertible Note issued November 4, 2019 at fair value, face value principal of $7,000,000 at December 31, 2019	6,439,000	-
Total current liabilities	$ 11,878,582	10,972,583
Total liabilities	$ 11,878,582	$ 10,972,583
COMMITMENT AND CONTINGENCIES (NOTE 9)		
Stockholders' Equity (Deficit)		
Preferred Stock, par value $0.001, 20,000,000 shares authorized;		
Series B Convertible Preferred Stock, par value $0.001, 1,158,209 and 1,069,941 shares issued and outstanding at December 31, 2019 and 2018, respectively	2,296,444	2,031,845
Common Stock, par value, $0.001; 100,000,000 shares authorized, 40,478,861 and 27,142,979 shares issued and outstanding as of December 31, 2019 and 2018, respectively	40,479	27,143
Additional paid-in capital	47,553,977	32,619,282
Accumulated deficit	(53,714,751)	(36,992,911)
Total PAVmed Inc. stockholders' equity (deficit)	(3,823,851)	(2,314,641)
Noncontrolling interest in majority-owned subsidiaries	(814,279)	(161,512)
Total deficit	(4,638,130)	(2,476,153)
Total Liabilities and Equity (Deficit)	$ 7,240,452	$ 8,496,430

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2019	**2018**
Revenue	**$ -**	$ -
General and administrative expenses	$ 7,664,965	6,310,206
Research and development expenses	6,630,330	4,252,999
Total operating expenses	$ 14,295,295	10,563,205
Loss from operations	$ (14,295,295)	(10,563,205)
Other income (expense)		
Interest expense	(32,667)	(2,392,447)
Debt extinguishments	(1,831,316)	(1,408,296)
Change in fair value - Senior Secured Convertible Note	(558,599)	(903,000)
Offering costs - issue of Senior Secured Convertible Notes	(550,254)	(614,940)
Modification - Series Z Warrant Agreement	-	(1,140,995)
Series A and Series A-1 Exchange Offer - March 15, 2018 - incremental fair value - Series Z Warrants issued-upon-exchange of Series A-1 Warrants	-	(349,796)
Series W Warrants Exchange Offer - April 5, 2018 - incremental fair value - Series Z Warrants issued-upon-exchange of Series W Warrants	-	(766,456)
Unit Purchase Options (UPOs) Exchange Offer - August 22, 2018 - incremental fair value - UPO-Z issued-upon-exchange of UPO-W	-	(2,120)
Change in fair value - Series A Warrants derivative liability	-	(96,480)
Change in fair value - Series A Convertible Preferred Stock conversion option derivative liability	-	64,913
Other income (expense), net	(2,972,836)	(7,609,617)
Loss before provision for income tax	(17,268,131)	(18,172,822)
Provision for income taxes	-	-
Net loss - before noncontrolling interest	$ (17,268,131)	(18,172,822)
Net loss attributable to noncontrolling interest	810,890	204,072
Net loss - attributable to PAVmed Inc.	$ (16,457,241)	(17,968,750)
Less: Series B Convertible Preferred Stock dividends earned	(269,895)	(203,123)
Less: Series A-1 Convertible Preferred Stock dividends earned	-	(25,148)
Less: Series A Convertible Preferred Stock dividends earned	-	(26,487)
Series A and Series A-1 Exchange Offer - March 15, 2018 - deemed dividend - incremental fair value - Series B Convertible Preferred Stock issued-upon-exchange of Series A Convertible Preferred Stock	-	(726,531)
Series A and Series A-1 Exchange Offer - March 15, 2018 - increase to additional paid-in capital - incremental fair value - Series B Convertible Preferred Stock issued-upon-exchange of Series A-1 Convertible Preferred Stock	-	199,241
Net loss attributable to PAVmed Inc. common stockholders	$ (16,727,136)	$ (18,750,798)
Net loss per share - attributable to PAVmed Inc. - basic and diluted	$ (0.54)	$ (0.81)
Net loss per share - attributable to PAVmed Inc. common stockholders - basic and diluted	$ (0.55)	$ (0.84)
Weighted average common shares outstanding - basic and diluted	30,197,458	22,276,347

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (DEFICIT)
for the YEAR ENDED DECEMBER 31, 2019

	Series B Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Non-controlling	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Interest	Total
Balance at December 31, 2018	1,069,941	$ 2,031,845	-	$ -	27,142,979	$ 27,143	$ 32,619,282	$ (36,992,911)	$ (161,512)	$ (2,476,153)
Issue common stock in registered offerings, net of offering cost					5,480,000	5,480	5,373,422			5,378,902
Exchange Offer - UPOs										
Issue of common stock upon partial conversions of Senior Secured Convertible Debt issued December 27, 2018					7,773,110	7,773	8,081,391			8,089,164
Series B Convertible Preferred Stock dividends declared	88,268	264,599						(264,599)		-
Issue common stock under employee stock purchase plan					82,772	83	67,353			67,436
Stock-based compensation							1,396,707			1,396,707
Stock-based compensation of majority-owned subsidiary							15,822		158,123	173,945
Net loss								(16,457,241)	(810,890)	(17,268,131)
Balance at December 31 2019	1,158,209	$ 2,296,444		$ -	40,478,861	$ 40,479	$ 47,553,977	$ (53,714,751)	$ (814,279)	$ (4,638,130)

PAVMED INC.
and SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN
SERIES A CONVERTIBLE PREFERRED STOCK and EQUITY (DEFICIT)
for the YEAR ENDED DECEMBER 31, 2018

	PAVmed Inc. Stockholders											
	PAVmed Inc. Stockholders' Equity (Deficit)											
	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Noncontrolling	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Interest	Total
Balance at December 31, 2017	249,667	$ -	-	$ -	357,259	$ 1,032,650	14,551,234	$ 14,551	$ 14,012,053	$ (17,907,611)	$ -	$ (2,848,357)
Underwritten public offering of common stock, net of offering cost							2,649,818	2,650	4,272,011			4,274,661
Equity Subscription Rights Offering, net of offering cost							9,000,000	9,000	9,202,326			9,211,326
Debt extinguishment							600,000	600	549,840			550,440
Exercise - common stock purchase warrant, net of offering costs							308,602	309	20,604			20,913
Exchange Offer - March 15, 2018	(249,667)	-	975,568	1,707,244	(357,259)	(1,032,650)			1,406,640	(726,531)		1,354,703
Exchange Offer - April 5, 2018		-							766,456			766,456
Series Z Warrant Modification		-							1,140,995			1,140,995
Exchange Offer - UPOs									2,120			2,120
Common stock issued - conversion Series B Convertible Preferred Stock			(33,325)	(58,319)			33,325	33	58,286			-
Series B Convertible Preferred Stock Dividends			127,698	382,920						(382,920)		-
Series A Convertible Preferred Stock Dividends										(7,099)		(7,099)
Issue of common stock of majority-owned subsidiary											1,812	1,812
Stock-based compensation									1,175,466			1,175,466
Stock-based compensation of majority-owned subsidiary									12,485		40,748	53,233
Net loss										(17,968,750)	(204,072)	(18,172,822)
Balance at December 31, 2018	-	$ -	1,069,941	$ 2,031,845	-	$ -	27,142,979	$ 27,143	$ 32,619,282	$ (36,992,911)	$ (161,512)	$ (2,476,153)

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2019	**2018**
Cash flows from operating activities		
Net loss - before noncontrolling interest ("NCI")	$ (17,268,131)	$ (18,172,822)
Adjustments to reconcile net loss - before NCI to net cash used in operating activities		
Depreciation expense	14,226	9,790
Stock-based compensation	1,570,652	1,228,699
Interest expense added to principal of Senior Secured Note	-	591,574
Interest expense – amortization of debt discount – Senior Secured Note	-	1,606,302
Debt extinguishment – Senior Secured Convertible Notes	1,831,317	-
Debt extinguishment – Senior Secured Note	-	1,408,296
Change in fair value – Senior Secured Convertible Notes	558,599	903,000
Modification expense – Series Z Warrant	-	1,140,995
Series A and Series A-1 Exchange Offer – March 15, 2018	-	349,796
Series W Warrants Exchange Offer - April 5, 2018	-	766,456
Unit Purchase Options Exchange Offer - August 22, 2018	-	2,120
Change in fair value - Series A Warrants derivative liability		96,480
Change in fair value - Series A Convertible Preferred Stock conversion option derivative liability	-	(64,913)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(90,244)	(149,573)
Accounts payable	613,283	872,111
Accrued expenses and other current liabilities	56,027	623,782
Deposits - Long-Term	(643,000)	-
Net cash flows used in operating activities	(13,357,271)	(8,787,907)
Cash flows from investing activities		
Purchase of equipment	(27,203)	(26,609)
Net cash flows used in investing activities	(27,203)	(26,609)
Cash flows from financing activities		
Proceeds - issue of Senior Secured Convertible Note	-	7,000,000
Repayment of debt - Senior Secured Note	-	(5,000,000)
Proceeds - issue of units in an equity subscription rights offering	-	9,437,000
Payment - offering costs - equity subscription rights offering	-	(225,674)
Proceeds - issue of common stock in an underwritten public offering	-	4,388,099
Payment - offering costs - underwritten public offering	-	(113,438)
Proceeds - issue of common stock of majority-owned subsidiary	-	1,812
Proceeds - issue of common stock- registered offerings	5,480,000	-
Payment - offering costs – registered offerings	(101,098)	-
Proceeds - issue of Senior Convertible Note	6,300,000	-
Payment - issue of Senior Convertible Note	(85,750)	-
Payment - issue of Senior Convertible Note – non-installment	(279,002)	-
Proceeds - issue of common stock under employee stock purchase plan	67,436	-
Payment - Series A Convertible Preferred Stock Dividends	-	(7,099)
Proceeds - issue of common stock upon exercise of warrants, net	-	20,913
Net cash flows provided by financing activities	11,381,586	15,501,613
Net increase (decrease) in cash	(2,002,888)	6,687,097
Cash, beginning of period	8,222,119	1,535,022
Cash, end of period	$ 6,219,231	$ 8,222,119

See accompanying notes to the consolidated financial statements.

Note 1 — The Company and Description of the Business

PAVmed Inc. ("PAVmed" or the "Company") is a highly-differentiated multi-product technology medical device company organized to advance a broad pipeline of innovative medical technologies from concept to commercialization, employing a business model focused on capital efficiency and speed to market. The Company is focused on advancing its lead products towards regulatory approval and commercialization, protecting its intellectual property, and building its corporate infrastructure and management team. The Company operates in one segment as a medical device company.

On May 8, 2018, Lucid Diagnostics Inc. ("Lucid") a majority-owned subsidiary of the Company, was incorporated in the State of Delaware. On May 12, 2018, Lucid Diagnostics Inc. entered into the "EsoGuard License Agreement" with Case Western Reserve University ("CWRU"), with respect to the "EsoGuard Technology". See Note 7, *Agreements Related to Acquired Intellectual Property Rights*, for a discussion of the "EsoGuard License Agreement".

On October 7, 2019, Solys Diagnostics Inc. ("Solys") a majority-owned subsidiary of the Company, was incorporated in the State of Delaware. Upon formation, Solys Diagnostics Inc. entered into a research and development license agreement with Liquid Sensing, Inc., a subsidiary of Airware, Inc., each an unrelated-third-party, under which was granted to Solys Diagnostics Inc. a perpetual worldwide license to develop and commercialize products based on intellectual property portfolio covering the use of "Nondispersive Infrared" ("NDIR") laser technology with respect to the potential development of technology to noninvasively measure interstitial concentrations of glucose or other substances through the skin. PAVmed Inc. and Airware Inc. have entered into a shareholder's agreement which, among other customary terms, limits certain transfers of their respective ownership interests in Solys Diagnostics Inc. See Note 7, *Agreements Related to Acquired Intellectual Property Rights*, for a further discussion of such license agreement.

To date, the Company has not recognized revenue. The ability to generate revenue depends upon the Company's ability to successfully complete the development, obtain regulatory approval, and to initiate commercialization of its product candidates. The only product to obtain regulatory clearance to date is EsoCheck, which has received 510(k) marketing clearance from the FDA as a generic esophageal cell collection device. In late December 2019 EsoGuard completed CLIA/CAP certification as a Laboratory Developed Test (LDT) making it commercially available at Lucid's contract diagnostic laboratory service provider in California. Our current research and development activities are focused principally on obtaining FDA approval and clearance and initializing commercialization of the other lead products in our product portfolio pipeline, such as EsoGuard IVD, CarpX and PortIO, while advancing DisappEAR and NextFlo through development. The Company will also engage in research and development activities on other product candidates commensurate with the Company's available capital resources. The Company plans to incur research and development expenses for the foreseeable future from the continued development of its current and future product candidates.

The Company has financed its operations principally through the issuances of its common stock, preferred stock, warrants, and debt, including: proceeds from private offerings of its common stock and common stock purchase warrants prior to the April 8, 2016 closing of its IPO; proceeds from the April 28, 2016 closing of the IPO; and, subsequent issue of shares of convertible preferred stock and common stock purchase warrants in private placements, the issue of shares of common stock of the Company and common stock purchase warrants under effective registration statements; and the issue of debt. See Note 12, *Debt,* Note 13, *Preferred Stock,* and Note 14, *Stockholders' Equity and Common Stock Purchase Warrants*, for further information with respect to the various financing transactions

PAVmed and its subsidiaries have proprietary rights to the trademarks used herein, including, among others, PAVmed™, Lucid Diagnostics™, Caldus™, CarpX™, DisappEAR™, EsoCheck™, EsoGuard™, EsoCheck Cell Collection Device™, EsoCure Esophageal Ablation Device™, NextCath™, NextFlo™, PortIO™, and "Innovating at the Speed of Life" ™. Solely as a matter of convenience, trademarks and trade names referred to herein may or may not be accompanied with the requisite marks of "™" or "®", however, the absence of such marks is not intended to indicate, in any way, PAVmed Inc. or its subsidiaries will not assert, to the fullest extent possible under applicable law, their respective rights to such trademarks and trade names.

Note 2 — Liquidity and Going Concern

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

The Company is an early stage and emerging growth company and is subject-to the corresponding risk of such companies. Since inception the Company has not generated any revenues and has incurred losses and negative cash flows from operating activities. The Company does not expect to generate positive cash flows from operating activities in the near future until it completes the development process and regulatory approvals of its products, and thereafter begins to commercialize and achieve substantial marketplace acceptance for its products.

The Company incurred a net loss attributable to PAVmed Inc. common stockholders of approximately $16.7 million and had net cash flows used in operating activities of approximately $13.4 million for the year ended December 31, 2019. As of December 31, 2019, the Company had negative working capital of approximately $5.3 million, with such working capital inclusive of the Senior Secured Convertible Notes classified as a current liability of an aggregate of approximately $8.1 million and approximately $6.2 million of cash.

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

Note 3 — Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its majority-owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation. The Company holds a majority ownership interest and has a controlling financial interest in Lucid Diagnostics Inc. and Solys Diagnostics Inc., with the corresponding noncontrolling interest included as a separate component of consolidated equity (deficit), including the recognition in the consolidated statement of operations of the net loss attributable to the noncontrolling interest based on the respective minority interest ownership of each respective entity. See Note 14, *Stockholders' Equity and Common Stock Purchase Warrants*, for a discussion of the Company's majority-owned subsidiaries and the corresponding noncontrolling interest. Certain items have been reclassified to conform to the current period presentation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make accounting estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates in these consolidated financial statements include those related to the fair value of each of: debt obligations, common stock purchase warrants, and derivative liabilities. Additional significant estimates include the provision or benefit for income taxes and the corresponding valuation allowance on deferred tax assets. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. On an ongoing basis, the Company evaluates its estimates, judgements, and methodologies. The Company bases its estimates on historical experience and on various other assumptions believed to be reasonable. Due to the inherent uncertainty involved in making such judgements, assumptions, and accounting estimates, the actual financial statement results could differ materially from such accounting estimates and assumptions.

JOBS Act EGC Accounting Election

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

Segment Data

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

Note 3 — Summary of Significant Accounting Policies - continued

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

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

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

Cash

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

Note 3 — Summary of Significant Accounting Policies - continued

Offering Costs

Offering costs consist of certain legal, accounting, and other advisory fees incurred related to the Company's efforts to raise debt and equity capital. Offering costs in connection with equity financing are recognized as either an offset against the financing proceeds to extent the underlying security is equity classified or a current period expense to extent the underlying security is liability classified or for which the fair value option is elected. Offering costs, lender fees, and warrants issued in connection with debt financing, to the extent the fair value option is not elected, are recognized as debt discount, which reduces the reported carrying value of the debt, with the debt discount amortized as interest expense, generally over the contractual term of the debt agreement, to result in a constant rate of interest. Offering costs associated with in-process capital financing are accounted for as deferred offering costs.

Research and Development Expenses

Research and development expenses are recognized as incurred and include the salary and stock-based compensation of employees engaged in product research and development activities, and the costs related to the Company's various contract research service providers, suppliers, engineering studies, supplies, and outsourced testing and consulting fees, as well as depreciation expense and rental costs for equipment used in research and development activities, and fees incurred for access to certain facilities of contract research service providers.

Patent Costs and Purchased Patent License Rights

Patent related costs in connection with filing and prosecuting patent applications and patents filed by the Company are expensed as incurred and are included in the line item captioned "general and administrative expenses" in the accompanying consolidated statements of operations. Patent fee reimbursement expense incurred under the patent license agreement agreements are included in the line item captioned "research and development expenses" in the accompanying consolidated statements of operations.

The Company has entered into agreements with third parties to acquire technologies for potential commercial development. Such agreements generally require an initial payment by the Company when the contract is executed. The purchase of patent license rights for use in research and development activities, including product development, are expensed as incurred and are classified as research and development expense. Additionally, the Company may be obligated to make future royalty payments in the event the Company commercializes the technology and achieves a certain sales volume. In accordance with FASB ASC Topic 730-10-55, "Research and Development", expenditures for research and development, including upfront licensing fees and milestone payments associated with products not yet been approved by the FDA, are charged to research and development expense as incurred. Future contract milestone payments will be recognized as expense when achievement of the milestone is determined to be probable and the amount of the corresponding milestone can be objectively estimated.

Note 3 — Summary of Significant Accounting Policies - continued

Stock-Based Compensation

Stock-based awards are made to employees, members of its board of directors, and non-employees, under each of the PAVmed Inc. 2014 Long-Term Incentive Equity Plan and the Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan.

The stock-based awards granted to employees and members of the Company's board of directors are accounted for in accordance with FASB ASC Topic 718, *Stock Compensation* ("ASC 718") and stock-based awards granted to non-employees are accounted for in accordance with FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees* ("ASC 505-50"). See herein below for a discussion of "ASU 2018-07" with respect to ASC 505-50 non-employee stock-based compensation.

The Company measures stock-based compensation of stock-based awards granted to employees and members of its board of directors using the grant-date estimated fair value of the stock-based award and recognizes such estimated fair value on a straight-line basis over the requisite service period, which is generally the vesting period of the respective stock-based award, with such straight-line recognition adjusted so the cumulative expense recognized is at-least equal-to-or-greater-than the estimated fair value of the respective vested stock-based award.

The Company measures the expense of stock-based awards granted to non-employees on a vesting date basis, fixing the fair value of vested non-employee stock options as of their respective vesting date. The fair value of vested non-employee stock options is not subject-to- further remeasurement at subsequent reporting dates. The estimated fair value of the unvested non-employee stock options is remeasured to then current fair value at each subsequent reporting date, until such time when the stock options vest, at which time the fair value is fixed, as noted above. The estimated fair value of stock-based awards granted to non-employees is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective non-employee stock-based award, with such straight-line recognition adjusted so the cumulative expense recognized is at-least equal-to-or-greater-than the estimated fair value of the respective vested stock-based award.

Note 3 — Summary of Significant Accounting Policies - continued

Financial Instruments Fair Value Measurements

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

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

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

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

As of December 31, 2019, and December 31, 2018, the carrying values of cash, and accounts payable, approximate their respective fair value due to the short-term nature of these financial instruments.

Fair Value Option ("FVO") Election

The Company accounts for the Senior Secured Convertible Notes issued November 4, 2019 (Series A and Series B) and the Senior Secured Convertible Note issued December 27, 2018, under the "fair value option" election of ASC 825, *Financial Instruments* ("ASC-825") as discussed below.

The Senior Secured Convertible Notes noted above are each a debt host financial instrument containing embedded features and /or options which would otherwise be required to be bifurcated from the debt-host and recognized as separate derivative liabilities subject to initial and subsequent periodic estimated fair value measurements under ASC 815, *Derivatives and Hedging* ("ASC-815"). Notwithstanding, ASC 825-10-15-4 provides for the "fair value option" ("FVO") election, to the extent not otherwise prohibited by ASC 825-10-15-5, to be afforded to financial instruments, wherein the financial instrument is initially measured at its issue-date estimated fair value and then subsequently remeasured at estimated fair value on a recurring basis at each reporting period date.

The estimated fair value adjustment, as required by ASC 825-10-45-5, is recognized as a component of other comprehensive income ("OCI") with respect to the portion of the fair value adjustment attributed to a change in the instrument-specific credit risk, with the remaining amount of the fair value adjustment recognized as other income (expense) in the accompanying consolidated statement of operations. With respect to each of the above Senior Secured Convertible Note, as provided for by ASC 825-10-50-30(b), the estimated fair value adjustment is presented in a respective single line item within other income (expense) in the accompanying consolidated statement of operations.

Note 3 — Summary of Significant Accounting Policies - continued

Income Taxes

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

Under ASC 740, a "more-likely-than-not" criterion is applied when assessing the estimated realization of deferred tax assets through their utilization to reduce future taxable income, or with respect to a deferred tax asset for tax credit carryforward, to reduce future tax expense. A valuation allowance is established, when necessary, to reduce deferred tax assets, net of deferred tax liabilities, when the assessment indicates it is more-likely-than-not, the full or partial amount of the net deferred tax asset will not be realized. As a result of the evaluation of the positive and negative evidence bearing upon the estimated realizability of net deferred tax assets, and based on a history of operating losses, it is more-likely-than-not the deferred tax assets will not be realized, and therefore a valuation allowance reserve equal to the full amount of the deferred tax assets, net of deferred tax liabilities, has been recognized as a charge to income tax expense as of December 31, 2019 and 2018.

The Company recognizes the benefit of an uncertain tax position it has taken or expects to take on its income tax return if such a position is more-likely-than-not to be sustained upon examination by the taxing authorities, with the tax benefit recognized being the largest amount having a greater than 50% likelihood of being realized upon ultimate settlement. As of December 31, 2019 the Company does not have any unrecognized tax benefits resulting from uncertain tax positions.

The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. There were no amounts accrued for penalties or interest as of December 31, 2019 and December 31, 2018 or recognized during the years ended December 31, 2019 and 2018. The Company is not aware of any issues under review to potentially result in significant payments, accruals, or material deviations from its position.

Net Loss Per Share

The net loss per share is computed by dividing each of the respective net loss by the number of "basic weighted average common shares outstanding" and diluted weighted average shares outstanding" for the reporting period indicated. The basic weighted-average shares common shares outstanding are computed on a weighted average based on the number of days the shares of common stock of the Company are issued and outstanding during the respective reporting period indicated. The diluted weighted average common shares outstanding are the sum of the basic weighted-average common shares outstanding plus the number of common stock equivalents' incremental shares on an if-converted basis, computed using the treasury stock method, computed on a weighted average based on the number of days potentially issued and outstanding during the period indicated, if dilutive. The Company's common stock equivalents include: stock options, unit purchase options, convertible preferred stock, and common stock purchase warrants.

Notwithstanding, as the Company has a net loss for each reporting period presented, each of the basic and diluted net loss per share for each period presented is computed using only the basic weighted average common shares outstanding for each respective reporting period, as the inclusion of common stock equivalents incremental shares would be anti-dilutive.

The Series B Convertible Preferred Stock has the right to receive common stock dividends, and prior to the March 15, 2018 Exchange Date of the Series A and Series A Exchange Offer, holders of the Series A Warrants and the Series A-1 Warrants previously had the right to receive common stock dividends. As such, the Series B Convertible Preferred Stock and the Series A Warrants and Series A-1 Warrants would potentially been considered participating securities under the two-class method of calculating net loss per share.

Accordingly, as presented in the accompanying consolidated statement of operations, basic weighted average common shares outstanding are used to compute the basic and diluted net loss per share attributable to PAVmed Inc. and the basic and diluted net loss per share attributable to PAVmed Inc. common stockholders, for each reporting period presented.

Note 3 — Summary of Significant Accounting Policies - continued

Recent Accounting Standards

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2019-12, *"Income Taxes: Simplifying the Accounting for Income Taxes",* which removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. The ASU is effective for annual or interim periods beginning after December 15, 2020. Early adoption is permitted for periods for which financial statements have not been issued. The Company does not expect the standard to have a significant impact on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,* which modifies the disclosure requirements on fair value measurement. The guidance is effective for annual periods beginning after December 15, 2019 and interim periods within those annual periods, and early adoption is permitted. The Company does not expect the standard to have a significant impact on its consolidated financial statements.

In June 2018, the FASB has issued Accounting Standards Update ("ASU") 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), which, upon its effective date, will supersede the application of ASC 505-50, resulting in non-employee stock-based awards to be within the scope of ASC-718, with the principal changes including the use of the "expected term" (and not the ASC 505-50 required "contractual term") as an input to the option pricing model used to compute estimated fair value and the use of the grant date estimated fair value, as the measurement of a stock-based award granted to a non-employee, thus conforming to the measurement of a stock-based award granted to an employee. Early adoption is permitted, but no earlier than a company's adoption of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606").

The ASU 2018-07 amended ASC-718 guidance is effective for public entities for fiscal years beginning after December 15, 2018, including interim periods within such fiscal year, and for all other entities, including the Company (as a result of its "JOBS Act EGC Accounting Standards Election", as such election is discussed above), such amended guidance is effective for fiscal years beginning after December 15, 2019 (i.e. December 31, 2020), and interim periods within fiscal years beginning after December 15, 2020 (i.e. commencing with the interim period three months ending March 31, 2021, and thereafter). The Company does not expect the standard to have a significant impact on its consolidated financial statements.

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

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASC 842"), which establishes a right-of-use ("ROU") model requiring a lessee to recognize a ROU asset and a lease liability for all leases with terms greater-than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The ASC 842 effective date for the Company is December 31, 2021 for its annual financial statement, and for interim quarterly financial statements commencing March 31, 2022.

Note 4 — Prepaid Expenses and Other Current Assets

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

	December 31,	
	2019	2018
Deposits	$ 34,119	$ 44,250
Advanced payments to service providers and suppliers	294,165	193,790
Total prepaid expenses and other current assets	$ 328,284	$ 238,040

Note 5 — Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2019	2018
Bonus	$ 1,025,497	$ 873,621
Payroll	—	145,937
Vacation	28,848	38,763
Employee stock purchase plan	20,796	—
EsoGuard License Agreement fee	222,553	222,553
Operating Expenses	89,079	49,872
Total accrued expenses and other current liabilities	$ 1,386,773	$ 1,330,746

The accrued bonus as of December 31, 2019 and 2018 represents the guaranteed bonus payment to the Company's Chief Executive Officer ("CEO") under the CEO Employment Agreement and discretionary bonus payments to the CEO and other employees.

The Company's CEO agreed to the payment of a reduced salary of $4,200 per month for the period July 1, 2017 through January 31, 2018, with such earned but unpaid salary to be paid to the CEO only upon the Senior Secured Note first being repaid-in-full. The earned but unpaid salary has been recognized as an accrued salary expense liability of $145,937 as of December 31, 2018. There was no such liability as of December 31, 2019 as the accrued CEO payroll was paid in January 2019 upon the Senior Secured Note being repaid-in-full on December 27, 2018 concurrent with the issue of the Senior Secured Convertible Note. See Note 12 *Debt*, for a discussion of each of the "Senior Secured Convertible Note" and the "Senior Secured Note".

The PAVmed Inc. Employee Stock Purchase Plan ("ESPP") is discussed in Note 10,*Stock-Based Compensation.*

The EsoGuard License Agreement fee is the remaining unpaid balance of such fee incurred in connection with the EsoGuard License Agreement, as discussed in Note 7, *Agreements Related to Acquired Intellectual Property Rights.*

Note 6 — Income Taxes

Income tax (benefit) expense for respective periods noted is as follows:

	Year Ended	
	December 31, 2019	December 31, 2018
Current		
Federal, State, and Local	$ -	$ -
Deferred:		
Federal	(3,342,301)	(2,990,653)
State and local	(4,808,053)	(1,825,988)
	(8,150,354)	(4,816,641)
Less: Valuation allowance reserve	8,150,354	4,816,641
	$ -	$ -

The reconciliation of the federal statutory income tax rate to the effective income tax rate for the respective period noted is as follows:

	Year Ended	
	December 31, 2019	December 31, 2018
U.S. federal statutory rate	21.0%	21.0%
U.S. state and local income taxes, net of federal tax benefit	14.2%	8.3%
Permanent Differences	-3.5%	-2.8%
Other	15.5%	0.0%
Valuation Allowance	-47.2%	-26.5%
Effective tax rate	0.0%	0.0%

The tax effects of temporary differences which give rise to the net deferred tax assets for the respective period noted is as follows:

	Year Ended	
	December 31, 2019	December 31, 2018
Deferred tax assets		
Net operating loss	$ 14,060,172	$ 7,155,358
Non-deductible interest expense	357,021	247,938
Debt issue costs	285,114	426,817
Stock-based compensation expense	1,212,864	586,164
Patent licenses	13,886	15,826
Research and development tax credit carryforward	396,371	91,535
Accrued expenses	371,179	12,123
Section 195 deferred start-up costs	27,434	24,286
Deferred tax assets	$ 16,724,041	$ 8,560,047
Deferred Tax Liabilities		
Depreciation	(16,407)	(2,766)
Deferred Tax Liabilities	(16,407)	(2,766)
Deferred tax assets, net of deferred tax liabilities	16,707,634	8,557,281
Less: valuation allowance	(16,707,634)	(8,557,281)
Deferred tax assets, net after valuation allowance	$ -	$ -

Deferred tax assets and deferred tax liabilities resulting from temporary differences are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of the change in the tax rate is recognized as income or expense in the period the change in tax rate is enacted.

Note 6 — Income Taxes - continued

As required by FASB ASC Topic 740, *Income* Taxes" ("ASC 740), a "more-likely-than-not" criterion is applied when assessing the estimated realization of deferred tax assets through their utilization to reduce future taxable income, or with respect to a deferred tax asset for tax credit carryforward, to reduce future tax expense. A valuation allowance is established, when necessary, to reduce deferred tax assets, net of deferred tax liabilities, when the assessment indicates it is more-likely-than-not, the full or partial amount of the net deferred tax asset will not be realized. Accordingly, the Company evaluated the positive and negative evidence bearing upon the estimated realizability of the net deferred tax assets, and based on the Company's history of operating losses, concluded it is more-likely-than-not the deferred tax assets will not be realized, and therefore recognized a valuation allowance reserve equal to the full amount of the deferred tax assets, net of deferred tax liabilities, as of December 31, 2019 and 2018.

The Company has total estimated federal and state net operating loss ("NOL") carryforward of approximately $40 million and $27.4 million as of December 31, 2019 and 2018, respectively, which is available to reduce future taxable income, of which approximately $13.8 million begin to expire in 2035, and approximately $26.2 million which do not have an expiration date. The Company has not yet conducted a formal analysis and the NOL carryforward may be subject-to limitation under U.S. Internal Revenue Code ("IRC") Section 382, provided there was a greater then 50% ownership change, as computed under such IRC Section 382. The State and Local NOL carryforwards of approximately $40.0 million begin to expire in 2035. The Company has total estimated research and development ("R&D") tax credit carryforward of approximately $0.4 million as of December 31, 2019 which are available to reduce future tax expense, and begin to expire in 2035.

The Company files income tax returns in the United States in federal and applicable state and local jurisdictions. The Company's tax filings for the years 2016 and thereafter each remain subject to examination by taxing authorities. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. The Company has not recognized any penalties or interest related to its income tax provision.

Note 7 — Agreements Related to Acquired Intellectual Property Rights

Patent License Agreement - Case Western Reserve University - EsoGuard Technology

On May 12, 2018, Lucid Diagnostics Inc., a majority-owned subsidiary of the Company, entered into a patent license agreement with Case Western Reserve University ("CWRU"), referred to as the "EsoGuard™ License Agreement". See Note 14, *Stockholders' Equity and Common Stock Purchase Warrants*, for a discussion of the Company's majority-owned subsidiary Lucid Diagnostics Inc. and the corresponding noncontrolling interest.

The EsoGuard License Agreement provides for the exclusive worldwide license of the intellectual property rights for the proprietary technologies of two distinct components - the "EsoCheck Cell Collection Device" referred to as the "EsoCheck, and EsoGuard, a panel of methylated DNA biomarkers, and together are collectively referred to as the "EsoGuard Technology".

Under the EsoGuard License Agreement, Lucid Diagnostics Inc. incurred a payment obligation to CWRU of approximately $273,000, referred to as the "EsoGuard License Agreement Fee", with such license fee requiring an initial payment of $50,000, which the Company has paid, and quarterly payments of $50,000 until such fee is paid-in-full, provided, however, the commencement of such quarterly payments is subject to Lucid Diagnostics Inc. consummation of a bona fide financing with an unrelated third-party in excess of $500,000. As of December 31, 2019, there is $222,553 EsoGuard License Agreement that is unpaid and included in Accrued expenses and other current liabilities.

Lucid Diagnostics Inc. will also be required to pay a minimum annual royalty commencing the year after the first commercial sale of products resulting from the commercialization of the EsoGuard Technology, with the minimum amount based on net sales of such product(s), if any. Additionally, the EsoGuard License Agreement provides for Lucid Diagnostics Inc. to make payments to CWRU upon the achievement of certain regulatory milestones. The EsoGuard License Agreement also provides for potential payments upon the achievement of certain product development and regulatory clearance milestones. In this regard, upon FDA clearance on June 21, 2019 of the EsoCheck device, the Company paid a $75,000 milestone payment. The license agreement also provides for two additional milestone obligations with a payment of $100,000 due within 30 days upon the first commercial sale of a licensed product and a payment of $200,000 due upon a PMA submission to the FDA related to a licensed product.

On the May 12, 2018 effective date of the EsoGuard License Agreement, the EsoGuard License Agreement fee was recognized as a current period research and development expense in the consolidated statement of operations, with the remaining unpaid balance included in accrued expenses and other current liabilities in the consolidated balance sheet. The EsoGuard License Agreement was determined to not meet the "business combination" criteria under FASB ASC Topic 805, *Business Combinations* ("ASC 805"), as such license agreement did not meet the ASC 805 definition of a business, as the transaction resulted in an intangible asset of acquired intellectual property rights only, and the Company did not acquire any employees or tangible assets, or any processes, protocols, or operating systems. Accordingly, the transaction was determined to be to be an asset acquisition under ASC 805. Further, as noted, the cost of the acquired intellectual property rights were recognized as a current period research and development expense, as required under FASB ASC Topic 730, *Research and Development* (ASC 730), as the acquired intellectual property rights were purchased from others for use in a research and development activity, and for which there are no alternative future uses.

The EsoGuard License Agreement also provides for potential payments upon the achievement of certain product development and regulatory clearance milestones. If Lucid Diagnostics Inc. does not meet certain milestones listed in the EsoGuard License Agreement, then CWRU has the right, in its sole discretion, to require the Company to transfer to CWRU a percentage, varying up to 100%, of the shares of common stock of Lucid Diagnostics Inc. held by the Company. Lucid has not yet met all the milestones required by this provision. Lucid Diagnostics Inc. will also be required to pay a minimum annual royalty commencing the year after the first commercial sale of products resulting from the commercialization of the EsoCheck™ Technology, with the minimum amount rising based on net sales of such product(s), if any. Such contingent milestone and /or royalty payments, if any, will be recognized in the period in which such payment obligations are incurred. Reimbursement of CWRU billed patent fees incurred under the EsoCheck™ License Agreement of $200,437 and $20,978 were recognized as research and development expense in each of the years ended December 31, 2019 and 2018, respectively.

The EsoGuard License Agreement terminates upon the expiration of certain related patents, or on May 12, 2038 in countries where no such patents exist, or upon expiration of any exclusive marketing rights granted by the FDA or other U.S. government agency, whichever comes later.

Note 7 — Agreements Related to Acquired Intellectual Property Rights - continued

Patent License Agreement - Case Western Reserve University - EsoGuard™ Technology(continued)

The three physician inventors of the EsoGuard™ Technology, each entered into consulting agreements with Lucid Diagnostics Inc. to continue to support the development of the EsoGuard Technology. In addition to cash compensation based on a contractual rate per hour, additional compensation under each such consulting agreement includes: the grant under the Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan of stock options dated May 12, 2018 to each individual to purchase 100,000 shares of common stock of Lucid Diagnostics Inc. at an exercise price of $0.50 per share of such common stock; and, the grant under the PAVmed Inc. 2014 Long-Term Incentive Plan of stock options dated May 12, 2018 to each individual to purchase 25,000 shares of PAVmed Inc. common stock at an exercise price of $1.59 per share of such common stock.

In June 2018, Lucid Diagnostics Inc. entered into a contract development and manufacturing organization (CDMO) agreement with an unrelated third-party for the supply of the EsoCheck device, principally for use in research and development activities - referred to herein as the "EsoCheck CDMO Supply Agreement". The EsoCheck CDMO Supply Agreement contains a firm price per unit, and a contractual EsoCheck purchase minimum quantity, is cancellable with 10 day notice, among other routine and customary provisions. With respect to the EsoCheck purchase contractual minimum quantity, if Lucid Diagnostics Inc. terminates the EsoCheck CDMO Supply Agreement without "good reason", as defined, prior to placing purchase orders for 5,000 units of EsoCheck, then Lucid Diagnostics Inc. will make a single one-time $50,000 payment to the unrelated third-party CDMO. The minimum quantity contingent payment, if any, will be recognized as a current period expense if and when such payment obligation is incurred. Further, in June 2018 Lucid Diagnostics Inc. entered into a separate consulting agreement with the owner of the unrelated third-party supplier of the EsoCheck device, with the sole compensation under such consulting agreement being the grant under the Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan of stock options dated June 23, 2018 to purchase 75,000 shares of common stock of Lucid Diagnostics Inc. at an exercise price of $1.00 per share of such common stock. See Note 10, *Stock-Based Compensation*, for information regarding the separate "Lucid Diagnostics Inc 2018 Long-Term Incentive Equity Plan".

Patent License Agreement – Liquid Sensing Inc. – Nondispersive Infared ("NDIR") Laser Technology

On November 14, 2019, Solys Diagnostics Inc., a majority-owned subsidiary of the Company, entered into definitive license and shareholder agreements with Airware Inc., and its newly formed subsidiary Liquid Sensing Inc., each an unrelated third party, to develop and commercialize non-invasive diagnostic products using Nondispersive Infrared (NDIR) laser technology. The agreements are referred to herein as the "Liquid Sensing License Agreement" and "Liquid Sensing Shareholder Agreement".

Pursuant to Liquid Sensing Shareholder Agreement executed concurrently with the Liquid Sensing License Agreement, PAVmed Inc. and Airware Inc. granted to each other 15% non-dilutive equity ownership interests in each of their respective majority-owned subsidiaries of Solys Diagnostics Inc. and Liquid Sensing Inc., respectively, of which, 50% of such equity ownership interests vest immediately and the remaining 50% will vest upon achievement of certain milestones. Such investment in Liquid Sensing Inc. was de minimis as of December 31, 2019, and is included in other assets classified as non-current on the accompanying consolidated balance sheet. The shareholder agreements also provide PAVmed with a right of first offer on any future investment in Liquid Sensing, which would permit it to increase its equity stake at its discretion if the value of the company and its portable or wearable noninvasive glucose technology is realized.

Note 7 — Agreements Related to Acquired Intellectual Property Rights - continued

Patent License Agreement - Tufts University - Antimicrobial Resorbable Ear Tubes

In November 2016, the Company executed a Patent License Agreement (the "Tufts Patent License Agreement") with Tufts University and its co-owners, the Massachusetts Eye and Ear Infirmary and Massachusetts General Hospital (the "Licensors"). Pursuant to the Tufts Patent License Agreement, the Licensors granted the Company the exclusive right and license to certain patents in connection with the development and commercialization of antimicrobial resorbable ear tubes based on a proprietary aqueous silk technology conceived and developed by the Licensors.

Upon execution of the Tufts Patent License Agreement, the Company paid the Licensors an upfront non-refundable fee of $50,000, with such fee recognized as of the transaction date as a current period research and development expense in the statement of operations. The Tufts Patent License Agreement was determined not to be meet the "business combination" criteria under FASB ASC Topic 805, *Business Combinations* ("ASC 805"). Accordingly, the transaction was determined to be to be an asset acquisition under ASC 805, with the cost of the acquired intellectual property rights recognized as a current period research and development expense, under ASC Topic 730, *Research and Development* (ASC 730).

The Tufts Patent License Agreement also provides for potential payments from the Company to the Licensors upon the achievement of certain product development and regulatory clearance milestones as well as royalty payments on net sales upon the commercialization of products developed utilizing the licensed patents. The Company will recognize as a current period expense for contingent milestone payments or royalties in the period in which such payment obligations are incurred, if any. Reimbursement of Tufts University billed patent fees incurred under the Tufts Patent License Agreement of $70,996 and $113,688 were recognized as research and development expense in 2019 and 2018, respectively.

Note 8 — Related Party Transactions

Case Western Reserve University ("CWRU")

In May 2018, Lucid Diagnostics Inc. issued to CWRU 943,464 shares of its common stock for a purchase price of $0.001 per share. During the years December 31, 2019 and 2018, the Company incurred an aggregate of approximately $275,000 and $294,000 under the EsoGuard License Agreement, inclusive of: approximately $200,000 and $21,000 for reimbursement of fees related to patents, in each of the years ended December 31, 2019 and 2018, respectively; a $75,000 milestone payment in the year ended December 31, 2019 (upon FDA clearance of the EsoCheck™ device in June 2019); and, approximately $273,000 with respect to the EsoGuard™ License Agreement Fee in the year ended December 31, 2018. See Note 7, *Agreements Related to Acquired Intellectual Property Rights*, for a discussion of the EsoGuard License Agreement;

Consulting Agreements with Inventors EsoGuard Technology

In May 2018, Lucid Diagnostics Inc. issued 289,679 shares of its common stock for a purchase price of $0.001 per share to each of the three individuals. Additionally, each of the three individuals entered into consulting agreements with the Company to support the continued development of the technologies with respect to the EsoGuard™ License Agreement. In addition to cash compensation based on a contractual rate per hour, additional compensation under each such consulting agreement included the grant of stock options to each individual under each of the PAVmed Inc 2014 Long-Term Incentive Equity Plan and the Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan. The Company recognized as research and development expense in the aggregate of: approximately $110,000 and $41,000 related to such consulting agreements; and approximately $57,000 and $47,000 of stock based compensation expense related to the stock options, in each of the years ended December 31, 2019 and 2018, respectively.

See Note 14, *Stockholders' Equity and Common Stock Purchase Warrants - Noncontrolling Interests,* for a discussion of the issue of common stock of Lucid Diagnostics Inc. to each of CWRU and the three physician inventors of the EsoGuard Technology; Note 7, *Agreements Related to Acquired Intellectual Property Rights*, for a discussion of the EsoGuard License Agreement; and, Note 10, *Stock-Based Compensation*, for information regarding each of the "PAVmed Inc. 2014 Long-Term Incentive Equity Plan" and the separate "Lucid Diagnostics Inc 2018 Long-Term Incentive Equity Plan", with respect to the stock options granted as discussed above.

Management Services Agreement

Previously, in the prior year 2018, the Company had a management services agreement, with HCP/Advisors LLC, an affiliate of a former director of the Company, that expired on October 31, 2018 and was not renewed by the Company. The Company incurred an expense of $225,000 during 2018, with such fees included in "general and administrative expenses" in the accompanying consolidated statements of operations.

Note 9 — Commitments and Contingencies

Office Leases

The Company's corporate office lease is on a month-to-month basis, with a 5% per annum increase in the monthly lease payment effective February 1 of each year, and the lease agreement may be cancelled with three months written notice. Total rent expense incurred under the corporate office space lease arrangement was $142,991 and $125,186 for 2019 and 2018, respectively. As of December 31, 2019, the Company's future minimum lease payments for the corporate office lease on a month-to-month basis are estimated to be approximately $138,000 for the period January 1, 2020 to December 31, 2020. Additionally, the Company entered into two separate short-term lease arrangements for office space, including a lease agreement for the period October 16, 2019 to September 30, 2020 and a lease agreement for the period November 1, 2019 to April 30, 2020, with such lease agreement subsequently renewed for a six-month period of May 1, 2020 to October 31, 2020. The minimum lease payments under both lease agreements is an aggregate of approximately $51,000 for the period January 1, 2020 to October 31, 2020.

EsoGuard Clinical Trials - Agreement with Clinical Research Organization

In September 2019, the Company, through its majority-owned subsidiary Lucid Diagnostics Inc., entered into an agreement with a clinical research organization ("CRO") in connection with EsoGuard clinical trials, referred to as the EsoGuard CRO Agreement. The CRO will assist the Company with conducting two concurrent clinical trials referred to as the "EsoGuard screening study" and the "EsoGuard case control study". The term of the EsoGuard CRO Agreement is from the September 2019 effective date to the conclusion of the respective clinical trials, but not to exceed 60 months from the effective date of the EsoGuard™ CRO Agreement. The CRO agreement may be cancelled with sixty days written notice, without an early termination fee. Under the CRO agreement, the Company paid to the CRO a refundable on-account deposit of $643,000, with such deposit classified as a non-current asset in the line item captioned Deposit and other assets on the accompanying consolidated balance sheet as of December 31, 2019. The Company has recognized as research and development expense approximately $700,000 during the year ended December 31, 2019 with respect to the EsoGuard CRO Agreement.

Legal Proceedings

In the ordinary course of our business, particularly as we begin commercialization of our products, the Company may be subject to certain other legal actions and claims, including product liability, consumer, commercial, tax and governmental matters, which may arise from time to time. Except as otherwise noted herein, the Company does not believe it is currently a party to any other pending legal proceedings. Notwithstanding, legal proceedings are subject-to inherent uncertainties, and an unfavorable outcome could include monetary damages, and excessive verdicts can result from litigation, and as such, could result in a material adverse impact on the Company's business, financial position, results of operations, and /or cash flows. Additionally, although the Company has specific insurance for certain potential risks, the Company may in the future incur judgments or enter into settlements of claims which may have a material adverse impact on the Company's business, financial position, results of operations, and /or cash flows.

The Company executed a "Settlement Agreement & Mutual Releases", dated December 12, 2018, resulting in the Company making a settlement payment of $136,606, inclusive of plaintiff's legal fees of $11,006, to a former financial advisor to the Company.

Note 10 — Stock-Based Compensation

PAVmed Inc. 2014 Long-Term Incentive Equity Plan

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

A total of 7,951,081 shares of common stock of PAVmed Inc. are reserved for issuance under the PAVmed Inc. 2014 Equity Plan, with 2,548,406 shares available for grant as of December 31, 2019, exclusive of 500,854 PAVmed Inc. stock options previously granted outside the PAVmed Inc. 2014 Equity Plan.

PAVmed Inc 2014 Equity Plan - Stock Options

	Number Stock Options		Weighted Average Exercise Price	Remaining Contractual Term (Years)
Outstanding at December 31, 2017	1,936,924	$	5.19	
Granted	1,585,324	$	2.01	
Exercised	—	$	—	
Forfeited	(195,108)	$	5.00	
Outstanding at December 31, 2018	3,327,140	$	3.68	8.3
Vested and exercisable at December 31, 2018	1,620,310	$	4.40	7.8
Outstanding at December 31, 2018	3,327,140	$	3.68	
Granted	1,925,000	$	1.00	
Exercised	—	$	—	
Forfeited	(48,611)	$	5.00	
Outstanding at December 31, 2019	5,203,529	$	2.68	8.1
Vested and exercisable at December 31, 2019	3,270,487	$	3.45	7.5

The aggregate intrinsic value of stock options granted under the PAVmed Inc. 2014 Equity as of December 31, 2019 was $393,500 with respect to such stock options outstanding and $126,375 with respect to such stock options vested and exercisable. The intrinsic value as of December 31, 2018 was $0 with respect to such stock options outstanding and vested and exercisable. The intrinsic value is computed as the difference between the quoted price of the PAVmed Inc. common stock on each of December 31, 2019 and 2018 and the exercise price of the underlying PAVmed Inc. stock options, to the extent such quoted price is greater than the exercise price.

PAVmed Inc 2014 Equity Plan - Restricted Stock Awards

On March 15, 2019, a total of 700,000 restricted stock awards were granted to employees under the PAVmed Inc. 2014 Equity Plan, representing a corresponding number of shares of common stock of the Company, which vest ratably on an annual basis commencing March 15, 2020 and ending March 15, 2022. The restricted stock awards are subject to forfeiture if the requisite service period is not completed. As of December 31, 2019, no restricted stock awards had vested. Subsequent to December 31, 2019, on March 15, 2020, a total of 233,334 restricted stock awards had vested.

PAVmed Inc. Employee Stock Purchase Plan

The PAVmed Inc. Employee Stock Purchase Plan ("ESPP"), adopted by the Company's board of directors effective April 1, 2019, with an initial reservation of 250,000 shares of PAVmed Inc. common stock, which was subsequently increased to 750,000 shares in March 2020, provides eligible employees the opportunity to purchase shares of PAVmed Inc. common stock through payroll deductions during six month periods, wherein the "purchase price per share" is the lower of 85% of the quoted closing price per share of PAVmed Inc. common stock at the beginning or end of each six month share purchase period. The PAVmed Inc. ESPP share purchase dates are March 31 and September 30, with an initial six month payroll deduction period of April 1, 2019 to September 30, 2019. On September 30 2019 82,772 shares of PAVmed Inc. common stock were issued for cash proceeds of $67,436 under the ESPP. Subsequent to December 31, 2019, on March 31, 2020 154,266 shares of PAVmed Inc. common stock were issued for cash proceeds of $125,683. The ESPP liability for payroll deductions as of December 31, 2019 are included in accrued expense and other current liabilities, as discussed in Note 5, *Accrued Expense and Other Current Liabilities.*

Note 10 — Stock-Based Compensation - continued

Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan

The Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan (the "Lucid Diagnostics Inc. 2018 Equity Plan") became effective on May 12, 2018 and is separate from the PAVmed Inc. 2014 Equity Plan discussed above. The Lucid Diagnostics Inc. 2018 Equity Plan is designed to enable Lucid Diagnostics Inc. to offer employees, officers, directors, and consultants, as defined, an opportunity to acquire shares of common stock of Lucid Diagnostics Inc. The types of awards that may be granted under the Lucid Diagnostics Inc. 2018 Equity Plan include stock options, stock appreciation rights, restricted stock, and other stock-based awards subject to limitations under applicable law. All awards are subject to approval by the Lucid Diagnostics Inc. board of directors.

A total of 2,000,000 shares of common stock of Lucid Diagnostics Inc. are reserved for issuance under the Lucid Diagnostics Inc. 2018 Equity Plan, with 1,230,000 shares available for grant as of December 31, 2019, exclusive of 300,000 Lucid Diagnostics Inc. stock options previously granted outside the Lucid Diagnostics Inc. 2018 Equity Plan.

Lucid Diagnostics Inc. 2018 Equity Play – Stock Options

	Number Stock Options		Weighted Average Exercise Price	Remaining Contractual Term (Years)
Outstanding at December 31, 2017	—	$		
Granted	375,000	$	0.60	
Exercised	—	$	—	
Forfeited	—	$	—	
Outstanding at December 31, 2018	375,000	$	0.60	9.4
Vested and exercisable at December 31, 2018	87,500	$	0.57	9.4
Unvested at December 31, 2018	287,500	$	0.61	
Outstanding at December 31, 2018	375,000	$	0.60	
Granted	620,000	$	1.02	
Exercised	—	$	—	
Forfeited	—	$		
Outstanding at December 31, 2019	995,000	$	0.86	9.0
Vested and exercisable at December 31, 2019	507,495	$	0.83	8.9
Unvested at December 31, 2019	487,505	$	0.89	

Note 10 — Stock-Based Compensation (continued)

Stock-Based Compensation Expense

Consolidated stock-based compensation expense recognized for both the PAVmed Inc. 2014 Equity Plan and the Lucid Diagnostics Inc. 2018 Equity Plan, with respect to stock options and restricted stock awards, for the periods indicated, was as follows:

	Year Ended December 31,	
	2019	**2018**
General and administrative expenses	$ 1,162,370	$ 948,143
Research and development expenses	408,282	280,556
Total	$ 1,570,652	$ 1,228,699

The consolidated stock-based compensation expense classified in research and development expenses, as presented above, includes $173,945 and $53,233 in the year ended December 31, 2019 and 2018, respectively, recognized by Lucid Diagnostics Inc., with stock-based compensation expense recognized by Lucid Diagnostics Inc. inclusive of stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan to employees of PAVmed Inc. and to non-employees each providing services to Lucid Diagnostics Inc.; and stock options granted under the PAVmed Inc. 2014 Equity Plan to non-employees providing services to Lucid Diagnostics Inc., summarized as follows for the periods noted:

	Year Ended December 31,	
	2019	2018
Lucid Diagnostics Inc 2018 Equity Plan - research and development expenses	$ 158,123	$ 40,748
PAVmed Inc 2014 Equity Plan - research and development expenses	15,822	12,485
Total stock-based compensation expense - recognized by Lucid Diagnostics Inc.	$ 173,945	$ 53,233

As of December 31, 2019, under the PAVmed Inc. 2014 Equity Plan, total unrecognized stock-based compensation expense of approximately $1.2 million is expected to be recognized over the weighted average remaining requisite service period of 1.1 years; and, under the Lucid Diagnostics Inc. 2018 Equity Plan, total unrecognized stock-based compensation expense of approximately $0.1 million is expected to be recognized over the weighted average remaining requisite service period of 1.8 years.

The Company uses the Black-Scholes valuation model to estimate the fair value of stock options granted under both the Lucid Diagnostics Inc. 2018 Equity Plan and the PAVmed Inc. 2014 Equity Plan, which requires the Company to make certain estimates and assumptions, with the weighted-average valuation assumptions for stock-based awards, as follows:

- The expected term of stock options represents the period of time stock options are expected to be outstanding, which for employees is the expected term derived using the simplified method and for non-employees is the remaining contractual term;
- The expected stock price volatility is based on historical stock price volatilities of similar entities within the medical device industry over the period commensurate with the expected term or remaining contractual term of the respective stock option;
- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period commensurate with the expected term of the stock option; and,
- The expected dividend yield is based on annual dividends of $0.00 as there has not been a dividend paid to-date, and there is no plan to pay dividends for the foreseeable future.

The price per share of PAVmed Inc. common stock used in the computation of estimated fair value of stock options granted under the PAVmed Inc. 2014 Equity Plan is its quoted closing price per share. The price per share of Lucid Diagnostics Inc. common stock used in the computation of estimated fair value of stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan was estimated using a discounted cash flow method applied to a multi-year forecast of its future cash flows.

Note 10 — Stock-Based Compensation - continued

Stock-Based Compensation Expense - continued

Stock-based compensation expense recognized for stock options granted to employees and members of the board of directors under the PAVmed Inc. 2014 Equity Plan was based on a weighted average fair value of $0.92 per share and $1.21 per share, during the year ended December 31, 2019 and 2018, respectively, calculated using the following weighted average Black-Scholes valuation model assumptions:

	Year Ended December 31	
	2019	**2018**
Expected term of stock options (in years)	5.7	5.8
Expected stock price volatility	50%	50%
Risk free interest rate	2.2%	2.1%
Expected dividend yield	0%	0%

Stock-based compensation expense recognized for stock options granted to non-employees under the PAVmed Inc. 2014 Equity Plan was based on a weighted average fair value of $1.97 per share and $1.97 per share, during the year ended December 31, 2019 and 2018, respectively, calculated using the following weighted average Black-Scholes valuation model assumptions:

	Year Ended December 31	
	2019	**2018**
Expected term of stock options (in years)	8.5	8.7
Expected stock price volatility	59%	60%
Risk free interest rate	2.3%	2.5%
Expected dividend yield	0%	0%

Stock-based compensation expense recognized for stock options granted to employees under the Lucid Diagnostics Inc. 2018 Equity Plan was based on a weighted average fair value of $0.32 per share during the year ended December 31, 2019, calculated using the following weighted average Black-Scholes valuation model assumptions:

	Year Ended December 31
	2019
Expected term of stock options (in years)	5.8
Expected stock price volatility	63%
Risk free interest rate	2.1%
Expected dividend yield	0%

There were no stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan to employees during the prior year ended December 31, 2018.

Stock-based compensation expense recognized for stock options granted to non-employees under the Lucid Diagnostics Inc. 2018 Equity Plan was based on a weighted average fair value of $0.29 and $0.51 per share during the years ended December 31, 2019 and 2018, respectively, calculated using the following weighted average Black-Scholes valuation model assumptions:

	Year Ended December 31	
	2019	**2018**
Expected term of stock options (in years)	8.8	9.4
Expected stock price volatility	57%	62%
Risk free interest rate	2.1%	2.7%
Expected dividend yield	0%	0%

Note 11 — Financial Instruments Fair Value Measurements

Recurring Fair Value Measurements

The fair value hierarchy table for the periods indicated is as follows:

	Fair Value Measurement on a Recurring Basis at Reporting Date Using[1]			
	Level - 1 Inputs	Level - 2 Inputs	Level - 3 Inputs	Total
December 31, 2019				
Senior Secured Convertible Note - issued December 27, 2018	$ -	$ -	$ 1,700,000	$ 1,700,000
Senior Secured Convertible Note - Series A - issued November 4, 2019	-	-	$ 6,439,000	$ 6,439,000
Totals	$ -	$ -	$ 8,139,000	$ 8,139,000
December 31, 2018				
Senior Secured Convertible Note - issued December 27, 2018	$ -	$ -	$ 7,903,000	$ 7,903,000
Totals	$ -	$ -	$ 7,903,000	$ 7,903,000

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

Fair Value Option Election - Senior Secured Convertible Notes Issued November 4 2019 and December 27, 2018

The Company has issued each of Senior Secured Convertible Notes issued November 4, 2019 with an aggregate original face value principal of $14.0 million and the Senior Secured Convertible Note issued December 27, 2018 with an original face value of $7.75 million. The Senior Secured Convertible Notes issued November 4, 2019 were further sub-divided into a Series A and Series B, each having a face value principal of $7.0 million, with each referred to herein as the "Series A November 2019 Senior Convertible Note" and the "Series B November 2019 Senior Convertible Note". Under the Series A November 2019 Senior Convertible Note, the investors delivered to the Company cash proceeds of $6.3 million on November 4, 2019, after deducting $0.7 million of lender fees. Subsequent to December 31, 2019, with respect to the Series B November 2019 Senior Convertible Note, the investors, at their election under the prepayment provisions of such note, delivered to the Company cash proceeds of $6.3 million on March 30, 2020 after deducting $0.7 million of lender fees.

The Series A November 2019 Senior Convertible Note and the Senior Secured Convertible Note issued December 27, 2018, are each accounted for under the ASC 825-10-15-4 fair value option ("FVO") election. (As well, the Series B November 2019 Senior Convertible Note will also be accounted for under the FVO election.) Under the FVO election the financial instrument is initially measured at its issue-date estimated fair value and subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. As provided for by ASC 825-10-50-30(b), the estimated fair value adjustment is presented as a single line item within other income (expense) in the accompanying consolidated statement of operations.

Note 11 — Financial Instruments Fair Value Measurements - continued

Fair Value Option Election - Senior Secured Convertible Notes Issued November 4 2019 and December 27, 2018 - continued

Senior Secured Convertible Notes - November 2019 - Series A

As discussed above, under the ASC-825 FVO election the Series A November 2019 Senior Convertible Note was initially measured at its estimated fair value on its issue date of November 4, 2019, summarized as follows:

Series A November 2019 Senior Secured Convertible Note - Issue Date November 4, 2019	Fair Value
Face value principal - Series A November 2019 Senior Convertible Note	$ 7,000,000
Less: lender fees	(700,000)
Cash proceeds - Series A November 2019 Senior Convertible Note	$ 6,300,000
Loss-upon-issue - lender fees	700,000
Fair value adjustment	(648,000)
Fair value - Series A November 2019 Senior Convertible Note - issue date November 4, 2019	$ 6,352,000

The Series A November 2019 Senior Convertible Note estimated fair value and face value principal, and the corresponding changes in estimated fair value and face value principal payable, as of each of the respective dates noted, are as follows:

	Fair Value	Face Value Principal Payable
Fair Value /Face Value principal - issue date November 4, 2019	$ 6,352,000	$ 7,000,000
Less: repayment - bi-monthly Installment Amount - common stock	—	—
Less: repayment - Accelerated Installment Amount - common stock	—	—
Less: non-installment payments - cash	(85,750)	—
Less: non-installment payments - common stock	—	—
Fair value adjustment	172,750	—
Fair Value /Face Value principal - December 31, 2019	$ 6,439,000	$ 7,000,000

The Series A November 2019 Senior Convertible Note fair value adjustment on the November 4, 2019 issue date and at December 31, 2019 of $475,250 was recognized as a current period income in the year ended December 31, 2019 (as no portion of such fair value adjustments resulted from instrument-specific credit risk of such note as of such dates).

The estimated fair value of the Senior Convertible Note Series A as of its November 4, 2019 issue date and as of December 31, 2019, was computed using a Monte Carlo simulation of the present value of its cash flows using a synthetic credit rating analysis and a required rate of return, using the following assumptions:

	December 31, 2019	Issue Date November 4, 2019
Face value principal payable	$ 7,000,000	$ 7,000,000
Original Conversion price	$ 1.60	$ 1.60
Value of common stock	$ 0.89	$ 0.89
Expected term (years)	1.78	1.93
Volatility	55%	55%
Risk free rate	1.58%	1.6%

Note 11 — Financial Instruments Fair Value Measurements - continued

Fair Value Option Election - Senior Secured Convertible Notes Issued November 4 2019 and December 27, 2018 - continued

Senior Secured Convertible Note Issued December 27, 2018

As discussed above, under the ASC-825 FVO election, the December 2018 Senior Convertible Note was initially measured at its estimated fair value on its issue date of December 27, 2018, summarized as follows:

	Fair Value
Face Value principal payable - issue date December 27, 2018	$ 7,750,000
Less: lender fees	(750,000)
Cash proceeds	7,000,000
Loss-upon-issue - lender fees	750,000
Fair value adjustment	—
Fair Value - December 2018 Senior Convertible Note - Issue Date December 27, 2018	$ 7,750,000

The December 2018 Senior Convertible Note estimated fair value and face value principal, and the corresponding changes in estimated fair value and face value principal payable, as of each of the respective dates noted, is summarized as follows:

	Face Value	Face Value Principal Payable
Fair Value /Face Value principal payable - issue date December 27, 2018	$ 7,750,000	$ 7,750,000
Less: repayment - bi-monthly Installment Amount - common stock	—	
Less: repayment - Accelerated Installment Amount - common stock	—	
Less: non-installment payments - cash	—	
Less: non-installment payments - common stock	—	
Fair value adjustment	153,000	—
Fair Value /Face Value Principal Payable - December 31, 2018	$ 7,903,000	7,750,000
Less: repayment - bi-monthly Installment Amount - common stock	1,727,500	1,727,500
Less: repayment - Accelerated Installment Amount - common stock	3,016,500	3,016,500
Less: repayment - voluntary conversion price adjustments - common stock	1,314,000	1,314,000
Less: non-installment payments - cash	279,002	—
Less: non-installment payments - common stock	199,847	—
Fair value adjustment	333,849	—
Fair Value /Face Value Principal Payable - December 31, 2019	$ 1,700,000	$ 1,692,000

The December 2018 Senior Convertible Note fair value adjustments of $333,849 and $153,000 in the years ended December 31, 2019 and 2018, respectively, were recognized as a current period income in the respective accompanying consolidated statement of operations (as no portion of such fair value adjustments resulted from instrument-specific credit risk of such note as of such dates).

The estimated fair value as of December 31, 2019, December 31, 2018 and on issue date of December 27, 2018 of the December 2018 Senior Secured Convertible Note was computed using a combination of the present value of the Senior Secured Convertible Note cash flows using a synthetic credit rating analysis' required rate of return and the Black-Scholes option pricing model, using the following assumptions:

Fair Value Assumptions	Year Ended		Issue Date
December 2018 Senior Secured Convertible Note	**December 31, 2019**	**December 31, 2018**	**December 27, 2018**
Face value principal payable	$ 1,692,000	$ 7,750,000	$ 7,750,000
Required rate of return	11.1%	13.1%	13.2%
Conversion price	$ 1.60	$ 1.60	$ 1.60
Value of common stock	$ 1.20	$ 0.96	$ 0.92
Expected term (years)	0.21	2	2
Volatility	49%	50%	46%
Risk free rate	1.5%	2.5%	2.5%
Dividend yield	0%	0%	0%

Note 11 — Financial Instruments Fair Value Measurements - continued

Series A and Series A-1 Exchange Offer - March 15, 2018

On March 15, 2018, the "Series A and Series A-1 Exchange Offer" was completed, wherein, two shares of Series B Convertible Preferred Stock were issued-upon-exchange of one share of Series A Convertible Preferred Stock, and five Series Z Warrants were issued-upon-exchange of one Series A Warrant; and, 1.33 shares of Series B Convertible Preferred Stock were issued-upon-exchange of one share of Series A-1 Convertible Preferred Stock, and five Series Z Warrants were issued-upon-exchange of one Series A-1 Warrant. Collectively, such exchanges are referred to as the "Series A and Series A-1 Exchange Offer" and the "March 15, 2018 Exchange Date". The Series A and Series A-1 Exchange Offer was offered to and accepted by all holders of the Series A Convertible Preferred Stock and Series A Warrants and the Series A-1 Convertible Preferred Stock and Series A-1 Warrants.

On the March 15, 2018 Exchange Date: (i) a total of 975,568 shares of Series B Convertible Preferred Stock were issued-upon-exchange, including 499,334 shares of Series B Convertible Preferred Stock issued-upon-exchange of 249,667 shares of Series A Convertible Preferred Stock and 476,234 shares of Series B Convertible Preferred Stock issued-upon-exchange of 357,259 shares of Series A-1 Convertible Preferred Stock; and, (ii) a total of 2,739,190 Series Z Warrants were issued-upon-exchange, including 1,340,005 Series Z Warrants issued-upon-exchange of 268,001 Series A Warrants and 1,399,185 Series Z Warrants issued-upon-exchange of 279,837 Series A-1 Warrants.

As of the March 15, 2018 Exchange Date of the Series A and Series A-1 Exchange Offer, there were no issued and outstanding shares of Series A Convertible Preferred Stock and Series A Warrants, nor shares of Series A-1 Convertible Preferred Stock and Series A-1 Warrants, as each were fully exchanged-upon-issue of shares of Series B Convertible Preferred Stock and Series Z Warrants, respectively. Additionally, each of the corresponding Series A Warrants derivative liability and the Series A Convertible Preferred Stock conversion option derivative liability were each fully extinguished-upon-exchange as of the March 15, 2018 Exchange Date of the Series A and Series A-1 Exchange Offer.

See Note 13, *Preferred Stock,* for further information with respect to Series B Convertible Preferred Stock, Series A-1 Convertible Preferred Stock, and Series A Convertible Preferred Stock, and Note 14, *Stockholders' Equity and Common Stock Purchase Warrants*, for further information with respect to Series Z Warrants, Series A-1 Warrants, and Series A Warrants.

Note 11 — Financial Instruments Fair Value Measurements - continued

Series A and Series A-1 Exchange Offer - March 15, 2018 -
Series B Convertible Preferred Stock Issued-Upon-Exchange of Series A Convertible Preferred Stock
Series Z Warrants Issued-Upon-Exchange Of Series A Warrants

As noted above, the Series A and Series A-1 Exchange Offer resulted in the extinguishment of: 249,667 shares of Series A Convertible Preferred Stock along with the corresponding (bifurcated) conversion option derivative liability, and, 268,001 Series A Warrants, each resulting from the issue-upon-exchange of: 499,334 shares of Series B Convertible Preferred Stock and 1,340,005 Series Z Warrants, respectively, each as discussed herein below.

Series A and Series A-1 Exchange Offer - March 15, 2018
Series B Convertible Preferred Stock Issued-Upon-Exchange of Series A Convertible Preferred Stock

The March 15, 2018 Exchange Date estimated fair value of the consideration given of $873,835 of the 499,334 shares of the equity-classified Series B Convertible Preferred Stock issued-upon-exchange, as compared to the (temporary equity) carrying value of 249,667 shares of Series A Convertible Preferred Stock and the estimated fair value of the corresponding conversion option derivative liability of $147,304, resulted in incremental estimated fair value of $726,531 recognized as a deemed dividend charged to accumulated deficit on the March 15, 2018 Exchange Date, with such deemed dividend included as a component of "net loss attributable to PAVmed Inc. common stockholders", summarized as follows:

Series B Convertible Preferred Stock Issued-Upon-Exchange Series A Convertible Preferred Stock and Conversion Option Derivative Liability Extinguished-Upon-Exchange Deemed Dividend Charged to Accumulated Deficit		**Series A Series A-1 Exchange Offer March 15, 2018 Exchange Date**
Fair value - 499,334 shares of Series B Convertible Preferred Stock issued-upon-exchange	$	873,835
Less: Fair value - Series A Convertible Preferred Stock conversion option derivative liability extinguished-upon-exchange		147,304
Less: Carrying value - 249,667 shares of Series A Convertible Preferred Stock extinguished-upon-exchange		-
Deemed dividend charged to accumulated deficit	$	726,531

The March 15, 2018 Exchange Date estimated fair value of $873,835 of the 499,334 shares of Series B Convertible Preferred Stock issued-upon-exchange of 249,667 Series A Convertible Preferred Stock was computed using a combination of the present value of its cash flows using a synthetic credit rating analysis' required rate of return and the Black-Scholes option pricing model, using the following assumptions:

Fair Value Assumptions Series B Convertible Preferred Stock		**Series A Series A-1 Exchange Offer 'March 15, 2018**
Aggregate fair value	$	873,835
Series B Convertible Preferred Stock shares		499,334
Required rate of return		27.0%
Common stock conversion factor numerator	$	3.00
Common stock conversion factor denominator	$	3.00
Value of Common Stock	$	1.70
Expected term (years)		6.1
Volatility		59%
Risk free rate		2.7%
Dividend yield		0%

The Series A Convertible Preferred Stock was classified in temporary equity in the consolidated balance sheet and had a carrying value of $0 resulting from the issuance date initial estimated fair values of the Series A Warrant derivative liability and the Series A Convertible Preferred Stock conversion option derivative liability being in excess of the Series A Preferred Stock Units private placement issuance gross proceeds, with such excess recognized as a current period loss in the consolidated statement of operations. See Note 13, *Preferred Stock,* for a further discussion of the Series A Preferred Stock Units private placement and the Series A Convertible Preferred Stock.

Note 11 — Financial Instruments Fair Value Measurements - continued

Series B Convertible Preferred Stock and Series Z Warrants - Series A and Series A-1 Exchange Offer - March 15, 2018 - continued

Series A and Series A-1 Exchange Offer - March 15, 2018 -
Series Z Warrants Issued-Upon-Exchange of Series A Warrants

The Series Z Warrants issued-upon-exchange of Series A Warrants in the Series A and Series A-1 Exchange Offer, as discussed above, resulted in the recognition of a modification expense under the analogous guidance with respect to stock option modification under FASB ASC 718, wherein an exchange of warrants is deemed to be a modification of the initial warrant agreement by the replacement with a revised warrant agreement, requiring the incremental estimated fair value, measured as the difference between the estimated fair value immediately after the modification as compared to the estimated fair value immediately before the modification, to the extent an increase, recognized as a modification expense. In this regard, the March 15, 2018 Exchange Date adjustment of the estimated fair value of the Series A Warrants derivative liability resulted in the recognition of a net expense of $96,480 comprised of: (i) income of $246,561 upon the Series A Warrant derivative liability being adjusted to its March 15, 2018 Exchange Date estimated fair value of $514,562, as noted above, and (ii) an expense of $343,041 resulting from the incremental estimated fair value of the consideration given of $857,603 of the 1,340,005 Series Z Warrants issued-upon-exchange as compared to the estimated fair value of $514,562 of the 268,001 Series A Warrants derivative liability extinguished-upon-exchange, summarized as follows:

Series Z Warrants Issued Upon Exchange of Series A Warrants - March 15, 2018	Series A Warrants Derivative Liability	Series Z Warrants Additional Paid to Capital Equity	Fair Values Change Series A Warrant Derivative Liability Other Income (Expenses)
Series A Warrants derivative liability - December 31, 2017	$ 761,123	$ -	$ -
Series A Warrants derivative liability change in fair value - March 15, 2018	(246,561)	-	246,561
Sub-Total: Series A Warrants derivative liability - March 15, 2018 Exchange Date	514,562	-	246,561
Series Z Warrants issued-upon-exchange of Series A Warrants - estimated fair value	(514,562)	857,603	(343,041)
Series Z Warrants issued-upon-exchange of Series A Warrants - March 15, 2018	$ -	$ 857,603	$ (96,480)

The March 15, 2018 Exchange Date estimated fair value of $857,603 of the 1,340,005 Series Z Warrants issued-upon-exchange of 268,001 Series A Warrants was computed using a Black-Scholes valuation model, using the following assumptions:

Fair Value Assumptions Series Z Warrants issued upon exchange of Series A Warrants	Series A Series A-1 Exchange Offer March 15, 2018
Aggregate fair value	$ 857,603
Series Z Warrants issued upon exchange of Series A Warrants	1,340,005
Exercise price per share - Series Z Warrant	$ 3.00
Value of Common Stock	$ 1.70
Expected term (years)	6.1
Volatility	59%
Risk free rate	2.7%
Dividend yield	0%

Note 11 — Financial Instruments Fair Value Measurements - continued

Series B Convertible Preferred Stock and Series Z Warrants - Series A and Series A-1 Exchange Offer - March 15, 2018 - continued

Series A and Series A-1 Exchange Offer - March 15, 2018 -
Series B Convertible Preferred Stock Issued-Upon-Exchange of Series A-1 Convertible Preferred Stock
Series Z Warrants Issued-Upon-Exchange of Series A-1 Warrants

As noted above, the Series A and Series A-1 Exchange Offer resulted in the extinguishment of: 357,259 shares of Series A-1 Convertible Preferred Stock and, 279,837 Series A-1 Warrants, resulting from the issue-upon-exchange of 476,234 shares of Series B Convertible Preferred Stock and 1,399,185 Series Z Warrants, respectively, each as discussed herein below.

Series A and Series A-1 Exchange Offer - March 15, 2018
Series B Convertible Preferred Stock Issued Upon Exchange of Series A-1 Convertible Preferred Stock

The March 15, 2018 Exchange Date estimated fair value of the consideration given of $833,410 of the equity-classified 476,234 shares of Series B Convertible Preferred Stock issued-upon-exchange, was less than the carrying value of $1,032,650 of the equity-classified 357,259 shares Series A-1 Convertible Preferred Stock, resulting in an increase to additional paid in capital of $199,241 on the March 15, 2018 Exchange Date, with such amount included as a component of "net loss attributable to PAVmed Inc. common stockholders", summarized as follows:

Series B Convertible Preferred Stock Issued-Upon-Exchange Series A-1 Convertible Preferred Stock Extinguished-Upon-Exchange Increase - Additional Paid-In Capital	**Series A Series A-1 Exchange Offer March 15, 2018 Exchange Date**
Fair value - 476,234 shares of Series B Convertible Preferred Stock issued-upon-exchange	$ 833,410
Less: Carry value - 357,259 shares - Series A-1 Convertible Preferred Stock extinguished-upon-exchange	1,032,650
Increase - additional paid-in capital	$ 199,240

The March 15, 2018 Exchange Date estimated fair value of $833,410 of the 476.234 shares of Series B Convertible Preferred Stock issued-upon-exchange of 357,259 shares of Series A-1 Convertible Preferred Stock was computed using a combination of the present value of its cash flows using a synthetic credit rating analysis required rate of return and the Black-Scholes option pricing model, using the following assumptions:

Fair Value Assumptions Series B Convertible Preferred Stock - issued upon exchange of Series A-1 Convertible Preferred Stock	**Series A Series A-1 Exchange Offer March 15, 2018**
Aggregate fair value	$ 833,410
Series B Convertible Preferred Stock shares	476,234
Required rate of return	27.0%
Common stock conversion factor numerator	$ 3.00
Common stock conversion factor denominator	$ 3.00
Value of Common Stock	$ 1.70
Expected term (years)	6.1
Volatility	59%
Risk free rate	2.7%
Dividend yield	0%

Note 11 — Financial Instruments Fair Value Measurements - continued

Series B Convertible Preferred Stock and Series Z Warrants - Series A and Series A-1 Exchange Offer - March 15, 2018 - continued

Series A and Series A-1 Exchange Offer - March 15, 2018 (continued)
Series Z Warrants Issued-Upon-Exchange of Series A-1 Warrants

The "Series Z Warrants issued-upon-exchange of Series A-1 Warrants" in the Series A and Series A-1 Exchange Offer, as discussed above, resulted in the recognition of a modification expense under the analogous guidance with respect to stock option modification under FASB ASC 718, wherein an exchange of warrants is deemed to be a modification of the initial warrant agreement by the replacement with a revised warrant agreement, requiring the incremental estimated fair value, measured as the difference between the estimated fair value immediately after the modification as compared to the estimated fair value immediately before the modification, to the extent an increase, recognized as a modification expense. In this regard, the March 15, 2018 Exchange Date estimated fair value of $895,478 of the equity-classified 1,399,185 Series Z Warrants issued-upon-exchange as compared to the estimated fair value of $545,682 of the equity-classified 279,837 Series A-1 Warrants extinguished-upon-exchange, resulted in an incremental estimated fair value of $349,796 recognized as a modification expense included in other income (expense) in the consolidated statement of operations, with a corresponding increase to additional paid in capital, summarized as follows:

Series Z Warrants - issued-upon-exchange of Series A-1 Warrants - March 15, 2018		**Series A Aeries A-1 Exchange Offer March 15, 2018 Exchange Date**
Fair value - 1,399,185 Series Z Warrants issued-upon-exchange	$	895,478
Less: fair value - 279,837 Series A-1 Warrants extinguished-upon-exchange		545,682
Modification expense /increase to additional paid in capital		349,796
Carry value - 279,837 Series A-1 Warrants extinguished-upon-exchange - equity classified		1,879,532
Carry value - Series Z Warrants issued-upon-exchange of Series A-1 Warrants - equity classified	$	2,229,328

The March 15, 2018 Exchange Date estimated fair value of $895,478 of the 1,399,185 Series Z Warrants issued-upon-exchange of 279,837 Series A-1 Warrants was computed using a Black-Scholes valuation model, using the following assumptions:

Fair Value Assumptions Series Z Convertible Preferred Stock - issued upon exchange of Series A-1 Convertible Preferred Stock		**Series A Series A-1 Exchange Offer March 15, 2018**
Aggregate fair value	$	895,478
Series Z Convertible Preferred Stock shares		1,399,185
Common stock conversion factor denominator	$	3.00
Value of Common Stock	$	1.70
Expected term (years)		6.1
Volatility		59%
Risk free rate		2.7%
Dividend yield		0%

Note 11 — Financial Instruments Fair Value Measurements - continued

The March 15, 2018 Exchange Date estimated fair value of $545,682 of the 279,837 Series A-1 Warrants extinguished-upon-exchange for 1,399,185 Series Z Warrants was computed using a Black-Scholes valuation model, using the following assumptions:

Fair Value Assumptions Series A-1 Convertible Preferred Stock - issued upon exchange of Series Z Convertible Preferred Stock		**Series A Series A-1 Exchange Offer March 15,2018**
Aggregate fair value	$	545,682
Series A-1 Warrants exchanged for Series Z Warrants		279,837
Exercise price per share - Series A-1 Warrant	$	6.67
Series W Warrants		1,399,185
Exercise price per share - Series W Warrant		5.00
Value of Common Stock	$	1.70
Expected term (years)		6.1
Volatility		67%
Risk free rate		2.5%
Dividend yield		0%

Non-recurring Fair Value Measurements

In addition to the Senior Secured Convertible Debt, the Series A and Series A-1 Exchange Offer on March 15, 2018, and the Series A Exchange Offer on November 17, 2017, each as discussed above, the other issue-date and /or date-of-occurrence non-recurring estimated fair values include: the Series W Warrants Exchange Offer on April 5, 2018, the Series Z Warrant exercise price adjustment on June 1, 2018, and the UPO Exchange Offer on August 22, 2018; along with the Series A Preferred Stock Units private placement during the three months ended March 31, 2017, the Senior Secured Note and Series S Warrants issued in connection with the Note and Security Purchase Agreement between the Company and Scopia Holdings LLC on July 3, 2017; the Series A-1 Preferred Stock Units private placement on August 4, 2017; the Series A-1 Warrants Agreement Amendment No. 1 on October 18, 2017, and the conversion of shares of Series A Convertible Preferred Stock into shares of common stock of the Company in November 2017 and December 2017.

See the following Notes herein for further information regarding these non-recurring estimated fair values, including Note 12, Debt, Note 13, *Preferred Stock, and,* Note 14, *Stockholders' Equity and Common Stock Purchase Warrants.*

The recurring and non-recurring estimated fair values discussed herein, utilize the Company's common stock price along with certain Level 3 inputs, as discussed below, in the development of Monte Carlo simulation models, discounted cash flow analyses, and /or Black-Scholes valuation models.

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

Note 12 — Debt

Senior Secured Convertible Notes - Issued November 4 2019

On November 3, 2019, the Company entered into a Securities Purchase Agreement ("SPA") with two institutional investors ("Investors", "Lender", and /or "Holders"), and pursuant to the SPA, on November 4, 2019 the Company consummated the sale of a Senior Secured Convertible Notes in a private placement with a $14.0 million aggregate face value principal, referred to herein as the "November 2019 Senior Convertible Notes". At the election of the holder, the November 2019 Senior Convertible Notes may be converted into shares of common stock of the Company, as discussed below.

The November 2019 Senior Convertible Notes were further sub-divided into a Series A and Series B, each having a face value principal of $7.0 million, with each referred to herein as the "Series A November 2019 Senior Convertible Note" and the "Series B November 2019 Senior Convertible Note". The Series A and Series B November 2019 Senior Convertible Notes each provide for the payment of a $700,000 lender fee, with such lender fee deducted from the cash proceeds when funded by the investors, and additionally under a separate agreement, the Company is obligated to pay a financial advisory fee to the placement agent of 6.5% of the cash proceeds of each such note upon their receipt.

With respect to the Series A November 2019 Senior Convertible Note, on November 4, 2019, the investors delivered to the Company cash proceeds of $6.3 million, after deducting $0.7 million of lender fees (which were recognized as a current period expense on such date), and the Company incurred total offering costs of $550,254, with such offering costs recognized as an expense in other income (expense) in the accompanying consolidated statement of operations. The Series A November 2019 Senior Convertible Note has a contractual maturity date of September 30, 2021, a face value principal of $7.0 million, and a stated interest rate of 7.875% per annum.

Subsequent to December 31, 2019, with respect to the Series B November 2019 Senior Convertible Note, the investors, at their election under the prepayment provisions, delivered to the Company cash proceeds of $6.3 million on March 30, 2020, after deducting $0.7 million of lender fees (which were recognized as a current period expense on such date), and the Company paid an advisory fee of $409,500 to the placement agent. The Series B November 2019 Senior Convertible Note has a contractual maturity date of September 30, 2021, a face value principal of $7.0 million, and a stated interest rate of 7.875% per annum.

As noted, the Series A and Series B Senior Convertible Notes have a stated interest rate of 7.875% per annum, to the extent the investor has funded the cash proceeds of each such respective note. During the period November 4, 2019 to March 29, 2020, the Company incurred interest expense of 3.0% per annum on the $7.0 million face value principal of the Series B November 2019 Senior Convertible Note, during such period when such note was not funded by the investors.

The SPA contains certain representations and warranties, covenants, and indemnities customary for similar transactions. The Notes are senior secured obligations of the company secured by a lien on all assets.

Note 12 — Debt - continued

Senior Secured Convertible Notes - Issued November 4 2019 - continued

Bi-Monthly Payments and Conversion

With respect to the Series A and Series B November 2019 Senior Convertible Notes, a bi-monthly principal repayment and corresponding interest payment will be due commencing March 30, 2020, and then on each of the successive 15th day of the month and the last trading day of the month, and on the maturity date (each, an "Installment Date"). On each bi-monthly Installment Date, the Company will be required to settle a principal repayment totaling $378,380 for the Series A and Series B November 2019 Senior Convertible Notes together with interest thereon, referred to herein as the "Installment Amount", which shall be satisfied in shares of common stock of the Company, subject to customary equity conditions (including minimum price and volume thresholds), at 100% of the Installment Amount (an "Installment Conversion"), or otherwise (or at the election of the Company, in whole or in part) in cash at 115% of the Installment Amount (an "Installment Redemption").

At the election of the Holder, commencing March 30, 2020, the Series A and Series B November 2019 Senior Convertible Notes may be converted into shares of common stock of the Company at an initial contractual conversion price of $1.60 per share, with such conversion price subject to standard adjustments in the event of any stock split, stock dividend, stock combination, recapitalization or other similar transaction.

In addition to the bi-monthly Installment Amount, the Holder may elect to accelerate the conversion of future bi-monthly Installment Amounts, and interest thereon, referred to herein as an Acceleration Installment Amount, utilizing the then current conversion price of the most recent bi-monthly Installment Conversion, with such Accelerated Installment Amount subject to certain restrictions, as defined.

Measurement and Recognition

The Series A November 2019 Senior Convertible Note fair value adjustment totaled $475,250 and was recognized as current period income in the year ended December 31, 2019 (as no portion of such fair value adjustments resulted from instrument-specific credit risk of such note as of such dates), and was inclusive of the fair value adjustment on the November 4, 2019 issue date and the fair value adjustment as of December 31, 2019.

The (cash) payment of 3.0% interest on the $7.0 million face value principal of the (unfunded) Series B November 2019 Senior Convertible Note, as such interest is discussed above, resulted in the recognition of $32,667 during the period November 4, 2019 through December 31, 2019, with such interest expense included in other income (expense) in the accompanying consolidated statement of operations.

See Note 11, *Financial Instruments Fair Value Measurements*, for Series A November 2019 Senior Convertible Debt November 4, 2019 issue date and December 31, 2019 estimated fair value and face value principal and corresponding changes in fair value and face value principal payable.

Note 12 — Debt - continued

Senior Secured Convertible Notes - Issued November 2019 - continued

Redemption Rights

The Holder has the option to require the Company to redeem all or a portion of the November 2019 Senior Convertible Notes face value principal then unpaid /outstanding, as follows:

* Event of Default - Upon the occurrence of an Event of Default, as defined, the Holder has the option to require the Company to redeem all or a portion of the November 2019 Senior Convertible Notes face value principal then unpaid /outstanding for cash at a price equal to the greater of (a) 115% of the then unpaid /outstanding November 2019 Senior Convertible Notes face value principal, plus earned-but-unpaid Non-Installment Payments, and late charge fees, or (b) the market value of the common stock of the Company underlying the November 2019 Senior Convertible Notes.

* Change of Control - Upon the occurrence of a Change of Control, the Holder has the option to require the Company to redeem all or a portion of the November 2019 Senior Convertible Notes for cash at a price equal to the greater of: (a) 115% of the then unpaid /outstanding November 2019 Senior Convertible Notes face value principal plus earned-but-unpaid Non-Installment Payments, and late charge fees; (b) 115% of the market value of the common stock of the Company underlying the November 2019 Senior Convertible Notes; or, (c) 115% of the aggregate cash consideration payable in respect of the common stock of the Company underlying the November 2019 Senior Convertible Notes.

* Bankruptcy - Upon occurrence of a Bankruptcy Event of Default, as defined, the Company must immediately pay cash to the Holder equal to 115% of the sum of (a) November 2019 Senior Convertible Notes unpaid /outstanding face value principal, (b) earned-but-unpaid Non-Installment Payments, and (c) late charge fees. Notwithstanding, the Holder may waive the right to receive such payment and retain the conversion and payment rights.

Covenants and Other Provisions

Under the November 2019 Senior Secured Convertible Notes, the Company is subject to certain customary affirmative and negative covenants regarding the incurrence of indebtedness, the existence of liens, the repayment of indebtedness, the payment of cash in respect of dividends, distributions or redemptions, and the transfer of assets, and to have an unrestricted cash balance of at least $2.0 million at each quarterly balance sheet date, among other matters, including, under the Securities Purchase Agreement, the following provisions and covenants:

- Through March 30, 2020, to the extent any portion of the November 2019 Senior Convertible Notes (Series A and Series B) face value principal remains outstanding, the Company may not without the consent of the lender, consummate the sale of any equity or equity-linked security at a price per share less than the initial conversion price of the November 2019 Senior Convertible Notes. After March 30, 2020, if $700,000 principal of the November 2019 Senor Convertible Notes remain outstanding, the Company may consummate the sale of any equity or equity-linked security provided the price per share is equal to or greater than the initial conversion price of the November 2019 Senior Convertible Notes.

- The Company agreed to hold a stockholder meeting by no later than June 28, 2020 to approve stockholder resolutions with respect to each of: approving an increase in the authorized shares of common stock of the Company to 150 million shares from the current 100 million shares; and approving the issuance of shares of common stock of the Company in connection with the November 2019 Senior Convertible Notes for the purposes of compliance with the stockholder approval rules of The Nasdaq Stock Market (“Nasdaq”).

- The November 2019 Senior Convertible Notes private placement investors may participate up to 50% in future equity and equity-linked securities offered by the Company during the three year period ended November 4, 2022. The Company will not effect or enter an agreement to effect any variable rate transaction.

Note 12 — Debt - continued

Senior Secured Convertible Notes - Issued November 2019 - continued

Guaranty Agreement

The payment of all amounts due and payable under the November 2019 Senior Convertible Notes (Series A and Series B) are guaranteed by the Company and its majority-owned subsidiary Lucid Diagnostics Inc., and the obligations under the November 2019 Senior Convertible Notes are secured by all of the assets of these entities pursuant to the terms of a Guaranty Agreement executed in connection with the November 2019 Senior Secured Convertible Notes private placement discussed above. The Lender may transfer or assign all or any part of the November 2019 Senior Convertible Notes to any person with the prior written consent of the Company, provided no consent shall be required from the Company for any transfer to an affiliate of the Lender, or upon the occurrence and during the continuance of an Event of Default, as defined.

Senior Secured Convertible Note - Issued December 27, 2018

In a private placement transaction with an institutional investor ("Investor", "Lender", and /or "Holder") on December 27, 2018, the Company entered into a Securities Purchase Agreement under which it issued the December 2018 Senior Secured Convertible Note, having an issue date of December 27, 2018, a contractual maturity date of December 31, 2020, a face value principal of $7.75 million, and a stated interest rate of 7.875% per annum - referred to herein as the "December 2018 Senior Convertible Note". At the election of the Holder, the December 2018 Senior Convertible Note may be converted into shares of common stock of the Company, as discussed below.

The December 2018 Senior Convertible Note proceeds were $7.0 million after deducting $0.750 million of lender fees (which were recognized as a current period expense on the issue date), and the Company incurred total offering costs of $614,940, inclusive of the payment of $455,000 placement agent fee and legal fees, with such offering costs recognized as an expense in other income (expense) in the accompanying consolidated statement of operations. Additionally, concurrent with the December 2018 Senior Convertible Note, on December 27, 2018 a $5.0 million payment was made with respect to the repayment of the Company's previously issued Senior Secured Note (between the Company and Scopia Holdings LLC), as further discussed below.

Bi-Monthly Payments & Conversion

The December 2018 Senior Convertible Note requires bi-monthly payments on the 15th calendar day and the last trading day of the month, commencing January 15, 2019 and ending December 31, 2020, including a contractually stated face value principal repayment, referred to as a bi-monthly Installment Amount, and a payment based on the outstanding face value principal and the 7.875% annual interest rate, referred to herein as a bi-monthly non-installment payment. The bi-monthly payments of January 15, 2019 through June 15, 2019 were non-installment payments only, and the bi-monthly payments from June 28, 2019 through December 31, 2020 include both the Installment Amount and the non-installment payment.

As originally structured, the December 2018 Senior Convertible Note Installment Amount included 35 bi-monthly payments of $193,750 from June 28, 2019 through November 30, 2020, and two final payments of $484,375 on each of December 15, 2020 and December 31, 2020, with such bi-monthly dates referred to as Installment Dates. Notwithstanding, future contractual Installment Amounts are reduced by additional face value principal repayments, with the reductions applied in reverse order of maturity of the bi-monthly Installment Amounts, starting with the final December 31, 2020 bi-monthly Installment Amount. In this regard, as of December 31, 2019, the future bi-monthly Installment Amounts have been reduced by an aggregate of $4,330,500 resulting from conversions in excess of the contractual bi-monthly Installment Amount, including a series of "conversion price voluntary adjustments" and the "Accelerated Installment Amount", each as discussed below.

At the election of the Holder, at any time after the December 27, 2018 issue date, the December 2018 Senior Convertible Note may be converted into shares of common stock of the Company at an initial contractual conversion price of $1.60 per share. As amended on April 11, 2019, commencing with the June 28, 2019 bi-monthly payment, the bi-monthly Installment Amount and non-installment payment will be paid by the issue of shares of common stock of the Company, subject to the satisfaction of customary equity conditions, including minimum price and volume thresholds, referred to as an Installment Conversion.

In addition to the bi-monthly Installment Amount, the Holder may elect to accelerate the conversion of future bi-monthly Installment Amounts, and interest thereon, referred to herein as an Acceleration Installment Amount, utilizing the then current conversion price of the most recent bi-monthly Installment Conversion, with such Accelerated Installment Amount subject to certain restrictions, as defined.

The December 2018 Senior Convertible Note provides for a voluntary adjustment of the conversion price at the discretion of the Company, with the consent of the Holder, wherein during the term of the December 2018 Senior Convertible Note, the Company may at any time reduce the then current conversion price to any amount and for any period of time deemed appropriate by the board of directors of the Company. The Company's board of directors have adopted guidelines surrounding such a December 2018 Senior Convertible Note voluntary adjustment of the conversion price, if any, to be implemented by management when favorable market conditions exist for the Company to orderly and effectively reduce its outstanding debt to the investor. See below for a discussion of the conversion price voluntary adjustments.

Note 12 — Debt - continued

Senior Secured Convertible Note - Issued December 27, 2018 - continued

Measurement and Recognition

The December 2018 Senior Convertible Note fair value adjustments resulted in the recognition of current period expense of $333,849 and $153,000 in the years ended December 31, 2019 and 2018, respectively (as no portion of such fair value adjustments resulted from instrument-specific credit risk of such note as of such dates).

As presented above in Note 11,*Financial Instruments Fair Value Measurements*, the December 2018 Senior Convertible Note had a fair value of $1,700,000 and a face value principal payable of $1,692,000; and in the year ended December 31, 2019, aggregate principal repayments of $6,058,000 and corresponding non-installment payments of $199,847 were settled by the issue of a total of 7,773,110 shares of common stock of the Company with a fair value of $8,089,163, resulting in a debt extinguishment loss in the year ended December 31, 2019 of $1,831,316, summarized as follows:

	Year Ended December 31, 2019
Bi-monthly Installment Amount principal repayments - common stock	$ 1,727,500
Accelerated Installment Amount principal repayments - common stock	3,016,500
Voluntary conversion price adjustments principal repayments - common stock	1,314,000
Sub-Total: principal repayments - common stock	6,058,000
Non-installment payments - common stock	199,847
Total Installment repayments and Non-Installment payments - common stock	$ 6,257,847
Fair Value - Common Stock Issued	$ 8,089,163
Debt Extinguishment Loss	$ 1,831,316

The fair value of the shares of common stock of the Company issued was measured as the respective issue date quoted closing price per share of the common stock of the Company.

December 2018 Senior Convertible Note - Subsequent to December 31, 2019

Subsequent to December 31, 2019, with respect to the December 2018 Senior Convertible Note, a total of $1,642,000 of Acceleration Installment Amount face value principal repayments and corresponding non-installment payments of $3,963, were settled by the issue of 2,042,901 shares of common stock of the Company with a fair value of $2,833,579 (with such fair value measured as the respective issue date quoted closing price per share of the common stock of the Company). As provided for in the December 2018 Senior Secured Convertible Note, the Holder elected to defer the bi-monthly Installment Amount repayments for each of the months January, February, and March 2020.

Note 12 — Debt - continued

Senior Secured Convertible Note - Issued December 27, 2018 - continued

Redemption Rights

The Holder has the option to require the Company to redeem all or a portion of the December 2018 Senior Convertible Note face value principal then unpaid /outstanding, as follows:

* Event of Default - Upon the occurrence of an Event of Default, as defined, the Holder has the option to require the Company to redeem all or a portion of the December 2018 Senior Convertible Note face value principal then unpaid /outstanding for cash at a price equal to the greater of (a) 115% of the then unpaid /outstanding December 2018 Senior Convertible Note face value principal, plus earned-but-unpaid Non-Installment Payments, and late charge fees, or (b) the market value of the common stock of the Company underlying the December 2018 Senior Convertible Note.

* Change of Control - Upon the occurrence of a Change of Control, the Holder has the option to require the Company to redeem all or a portion of the December 2018 Senior Convertible Note for cash at a price equal to the greater of: (a) 115% of the then unpaid /outstanding December 2018 Senior Convertible Note face value principal plus earned-but-unpaid Non-Installment Payments, and late charge fees; (b) 115% of the market value of the common stock of the Company underlying the December 2018 Senior Convertible Note; or, (c) 115% of the aggregate cash consideration payable in respect of the common stock of the Company underlying the December 2018 Senior Convertible Note.

* Bankruptcy - Upon occurrence of a Bankruptcy Event of Default, as defined, the Company must immediately pay cash to the Holder equal to 115% of the sum of (a) December 2018 Senior Convertible Note unpaid /outstanding face value principal, (b) earned-but-unpaid Non-Installment Payments, and (c) late charge fees. Notwithstanding, the Holder may waive the right to receive such payment and retain the conversion and payment rights.

Covenants and Other Provisions

Under the December 2018 Senior Secured Convertible Note, the Company is subject to certain customary affirmative and negative covenants regarding the incurrence of indebtedness, the existence of liens, the repayment of indebtedness, the payment of cash in respect of dividends, distributions or redemptions, and the transfer of assets, and to have an unrestricted cash balance of at least $1.75 million at each quarterly balance sheet date, among other matters, including, under the Securities Purchase Agreement, as follows:

- The December 2018 Senior Convertible Note private placement investor may participate up to 50% in future equity and equity-linked securities offered by the Company during the three year period ended December 27, 2021. The Company will not effect or enter an agreement to effect any variable rate transaction.

Guaranty Agreement

The payment of all amounts due and payable under the December 2018 Senior Convertible Note are guaranteed by PAVmed Inc. and its majority-owned subsidiary Lucid Diagnostics Inc., and the obligations under the December 2018 Senior Convertible Note are secured by all of the assets of these entities pursuant to the terms of a Guaranty Agreement executed in connection with the December 2018 Senior Secured Convertible Note private placement discussed above. The Lender may transfer or assign all or any part of the December 2018 Senior Convertible Note to any person with the prior written consent of the Company, provided no consent shall be required from the Company for any transfer to an affiliate of the Lender, or upon the occurrence and during the continuance of an Event of Default, as defined.

Note 12 — Debt - continued

Senior Secured Note and Series S Warrants -

In July 2017, the Company and Scopia Holdings LLC ("Scopia" or the "Lender") previously entered into a Note and Security Purchase Agreement, whereupon Scopia delivering to the Company $4.8 million in net cash proceeds, the Company issued to Scopia and its designees, a Senior Secured Note with an initial principal of $5.0 million ("Senior Secured Note"), and 2,660,000 Series S Warrants to purchase a corresponding number of shares of common stock of the Company.

On December 27, 2018, concurrent with the issue of the Senior Convertible Note as discussed above, the Company repaid-in-full the previously issued Senior Secured Note, inclusive of the total outstanding principal payable and the accrued but unpaid interest expense payable as of December 27, 2018, with such repayment comprised of a $5.0 million cash payment and the issue to Scopia of 600,000 shares of common stock of the Company. The Senior Secured Note repayment was executed under a Notice of Prepayment agreement dated December 27, 2018. The Senior Secured Note had a contractual maturity date of June 30, 2019, with such maturity date not subject-to any early repayment provisions. The Company recognized as other income (expense), a debt extinguishment loss of $1.4 million, as discussed below.

The Senior Secured Note annual interest rate was 15.0%, with interest payable semi-annually in arrears on June 30 and December 30 of each calendar year, commencing December 30, 2017 ("15% interest expense"). At its sole discretion, the Company was able to defer payment of up to 50% of each of the semi-annual 15% interest expense payable, with such deferred amount added to the outstanding interest-bearing principal balance of the Senior Secured Note. In this regard, the Senior Secured Note principal balance was $5,780,116, as of December 27, 2018 with each such principal amount comprised of the initial principal of $5.0 million and the total unpaid semi-annual interest as of December 27, 2018.

The Senior Secured Note and the Series S Warrants are freestanding financial instruments, as the Series S Warrants were immediately legally detachable from the Senior Secured Note and were immediately exercisable. The Series-S Warrants are equity classified in the consolidated balance sheet. See Note 14, *Stockholders' Equity and Common Stock Purchase Warrants*, for a further discussion of the Series S Warrants.

The $4.8 million of cash proceeds, which were net of the Lender's issue costs, were allocated to the Senior Secured Note and the Series S Warrants based on their respective relative fair value, as discussed below, resulting in an allocation of $1,408,125 to the Senior Secured Note and $3,434,452 to the Series S Warrants, with the resulting difference of $3,591,875 recognized as Senior Secured Note debt discount, amortized as interest expense over the term of the Senior Secured Note.

The Senior Secured Note total interest expense of $2,392,447, for the year ended December 31, 2018, was comprised of $786,145 resulting from the 15% interest expense and $1,606,302 resulting from the amortization of the debt discount. The Senior Secured Note had remaining unamortized debt discount $1,637,972 on the December 27, 2018 date of extinguishment.

On the December 27, 2018 repayment date, the Company recognized a debt extinguishment loss of $1.4 million resulting from the difference between a $5.5 million debt reacquisition price and a $4.1 million debt carrying value, net, of the Senior Secured Note as follows:

Senior Secured Note - Debt Extinguishment	December 27, 2018
Cash payment	$ 5,000,000
Fair value - 600,000 shares of common stock issued	550,440
Debt reacquisition price Senior Secured Note	$ 5,550,440
Senior Secured Note - original principal	$ 5,000,000
Senior Secured Note - additional principal - unpaid interest expense	780,116
Senior Secured Note - total principal	$ 5,780,116
Less: Senior Secured Note - remaining unamortized debt discount	(1,637,972)
Senior Secured Note - debt carrying value, net	$ 4,142,144
Debt extinguishment loss	$ (1,408,296)

Note 13 — Preferred Stock

The Company is authorized to issue 20,000,000 shares of its preferred stock, par value of $0.001 per share, with such designation, rights, and preferences as may be determined from time-to-time by the Company's board of directors.

Series B Convertible Preferred Stock

As of December 31, 2019 and 2018, 1,158,209 and 1,069,941 shares of Series B Convertible Preferred Stock (classified in permanent equity) were issued and outstanding, including: 975,568 shares issued-upon-exchange in the March 15, 2018 Exchange Offer, as such exchange offer is discussed below, 33,325 shares of Series B Convertible Preferred Stock converted into a corresponding number of shares of common stock of the Company in July 2018, at the holders election, and a total of 215,966 shares issued in settlement of the aggregate Series B Convertible Preferred Stock dividend payouts, as discussed below.

The Series B Convertible Preferred Stock has a par value of $0.001 per share, no voting rights, a stated value of $3.00 per share, and is immediately convertible upon its issuance. At the holders' election, a share of Series B Convertible Preferred Stock is convertible into a number of shares of common stock of the Company at a common stock conversion exchange factor equal to a numerator and denominator of $3.00, with each such numerator and denominator not subject to further adjustment, except for the effect of stock dividends, stock splits or similar events affecting the Company's common stock. The Series B Convertible Preferred Stock shall not be redeemed for cash and under no circumstances shall the Company be required to net cash settle the Series B Convertible Preferred Stock. The Series B Convertible Preferred Stock is equity-classified and the initial 975,568 shares issued-upon-exchange were measured at estimated fair value on the March 15, 2018 Exchange Date. See Note 11, *Financial Instruments Fair Value Measurements*, for a discussion of the issue date estimated fair value of the Series B Convertible Preferred Stock.

The Series B Convertible Preferred Stock provides for dividends at a rate of 8% per annum based on the $3.00 per share stated value of the Series B Convertible Preferred Stock, with such dividends compounded quarterly, accumulate, and are payable in arrears upon being declared by the Company's board of directors. The Series B Convertible Preferred Stock dividends from April 1, 2018 through October 1, 2021 are payable-in-kind ("PIK") in additional shares of Series B Convertible Preferred Stock. The dividends may be settled after October 1, 2021, at the option of the Company, through any combination of the issuance of additional Series B Convertible Preferred Stock, shares of common stock, and /or cash payment. The Series B Convertible Preferred Stock dividends are included in the calculation of basic and diluted net loss attributable to PAVmed Inc. common stockholders as applicable for each of the periods presented.

As of December 31, 2019 and 2018, the Company's board of directors declared Series B Convertible Preferred Stock dividends, of $264,599 and $382,920, respectively, each settled by the issue of 88,268 and 127,698 additional shares of Series B Convertible Preferred Stock, respectively, each in accordance with the PAVmed Inc. Certificate of Designation of Preferences, Rights, and Limitations of Series B Convertible Preferred Stock ("Series B Convertible Preferred Stock Certificate of Designation").

The Series B Convertible Preferred Stock dividend payable as of July 1, 2018 of earned but unpaid dividends as of June 30, 2018, was inclusive of $243,994 of total dividends related to the previously held and exchanged respective shares of Series A and Series A-1 Convertible Preferred Stock, each earned through the March 15, 2018 Exchange Date, and, upon-exchange, such dividend balance was transferred to the respective holders' Series B Convertible Preferred Stock dividend balances.

Series B Convertible Preferred Stock dividends as of December 31, 2019 and 2018 of $69,493 and $64,196, respectively, were cumulatively earned, unpaid, accumulated, and in arrears, as the Company's board of directors had not declared such dividends payable as of such dates, and, therefore, were not recognized as a dividend payable liability in the Company's accompanying consolidated balance sheet. Subsequent to December 31, 2019, in January 2020, the Company's board-of-directors declared a Series B Convertible Preferred Stock dividend payment of earned but unpaid dividends as of December 31, 2019, payable as of January 1, 2020, of $69,493, with such dividend payment settled by the issue of an additional 23,182 shares of Series B Convertible Preferred Stock; and in January 2019, the Company's board-of-directors declared a Series B Convertible Preferred Stock dividend payment of earned but unpaid dividends as of December 31, 2018, payable as of January 1, 2019, of $64,196, with such dividend payment settled by the issue of an additional 21,413 shares of Series B Convertible Preferred Stock, with each such dividends in accordance with the Series B Convertible Preferred Stock Certificate of Designation.

Note 13 — Preferred Stock - continued

Series A and Series A-1 Convertible Preferred Stock

As a result of the completion of the Series A and Series A-1 Exchange on the March 15, 2018 Exchange Date, there were no issued and outstanding shares of Series A Convertible Preferred Stock and Series A Warrants, nor shares of Series A-1 Convertible Preferred Stock and Series A-1 Warrants, as each were fully exchanged-upon-issue of shares of Series B Convertible Preferred Stock and Series Z Warrants, respectively. Additionally, each of the corresponding Series A Warrants derivative liability and the Series A Convertible Preferred Stock conversion option derivative liability were each fully extinguished-upon-exchange as of the March 15, 2018 Exchange Date of the Series A and Series A-1 Exchange Offer. See Note 11, *Financial Instruments Fair Value Measurements*, for further detail regarding each such derivative liability.

On April 13, 2018, the Company filed with the State of Delaware a Certificate of Elimination for the Series A and Series A-1 Convertible Preferred Stock to cancel all previous and future issuances of Series A and Series A-1 Convertible Preferred stock.

In August 2018, the Company's board of directors declared a Series A Convertible Preferred Stock dividend payment dated July 1, 2018 of earned but unpaid dividends totaling $7,099 with respect to the shares of Series A Convertible Preferred Stock previously converted in November and December 2017, as discussed above. The Series A Convertible Preferred Stock dividends were settled with cash payments. See below for a further discussion of the Series A Convertible Preferred Stock dividends.

The Series A Convertible Preferred Stock provided for dividends at a rate of 8% per annum based on the $6.00 per share stated value of the Series A Convertible Preferred Stock, with such dividends compounded quarterly, accumulate, and are payable in arrears upon being declared by the Company's board of directors.. Upon the closing of the Series A and Series A-1 Exchange Offer on the March 15, 2018 Exchange Date, cumulative aggregate earned, unpaid, and undeclared Series A Convertible Preferred Stock dividends of $139,058 were transferred to the respective holders' Series B Convertible Preferred Stock dividend balances, with such balance transferred inclusive of $26,487 earned for the period January 1, 2018 through the March 15, 2018 Exchange Date. I The Series A Convertible Preferred Stock dividends earned and undeclared for the year ended December 31, 2018 are included in the calculation of basic and diluted net loss attributable to PAVmed Inc. common stockholders for each respective period.

The Series A-1 Convertible Preferred Stock provided for dividends at a rate of 8% per annum on the $4.00 per share stated value of the Series A-1 Convertible Preferred Stock, with such dividends compounded quarterly, accumulate, and are payable in arrears upon being declared by the Company's board of directors. The Series A-1 Convertible Preferred Stock dividends from October 1, 2017 through October 1, 2021 were payable-in-kind ("PIK") in additional shares of Series A-1 Convertible Preferred Stock. Upon the closing of the Series A and Series A-1 Exchange Offer on the March 15, 2018 Exchange Date, cumulative aggregate earned, unpaid, and undeclared Series A-1 Convertible Preferred Stock dividends of $104,936 were transferred to the respective holders' Series B Convertible Preferred Stock dividend balances, with such balance transferred inclusive of $25,148 earned for the period January 1, 2018 through the March 15, 2018 Exchange Date. The Series A-1 Convertible Preferred Stock dividends were earned, unpaid, accumulated, and in arrears, as the Company's board of directors had not declared such dividends payable, and, therefore, such dividends were not recognized as a dividend payable liability in the consolidated balance sheet until declared by the Company's board of directors. The Series A-1 Convertible Preferred Stock dividends earned and undeclared for the year ended December 31, 2018 are included in the calculation of basic and diluted net loss attributable to PAVmed Inc. common stockholders for its respective period.

Note 14 — Stockholders' Equity and Common Stock Purchase Warrants

Common Stock

As of December 31, 2019, the Company is authorized to issue up to 100,000,000 million shares of common stock, par value of $0.001 per share. There were 40,478,861 and 27,142,979 shares of common stock issued and outstanding, as of December 31, 2019 and 2018, respectively, summarized as follows:

Shares of Common Stock Issued and Outstanding	
Issued and outstanding as of December 31, 2018	27,142,979
Registered offerings	5,480,000
Conversion of Senior Secured Convertible Note issued December 27, 2018	7,773,110
Employee stock purchase plan	82,772
Issued and outstanding as of December 31, 2019	40,478,861
Issued and outstanding as of December 31, 2017	14,551,234
Equity Subscription Rights Offering	9,000,000
Underwritten public offering	2,649,818
Repayment of debt - Senior Secured Note	600,000
Series W Warrant exercises	34,345
Series S Warrant exercises	274,257
Series B Convertible Preferred Stock conversion	33,325
Issued and outstanding as of December 31, 2018	27,142,979

Year Ended December 31, 2019

- During April, May, and June 2019, a total of 5,480,000 shares of common stock of the Company were issued in registered offerings, including 4,950,000 shares issued under common stock share subscription agreements entered into with individual investors and 530,000 shares issued under a placement agency agreement, resulting in total proceeds of $5,480,000, before placement agent fees and legal fees of $101,098.

- In 2019, a total of 7,773,110 shares of common stock of the Company were issued upon conversions of the December 2018 Senior Secured Convertible Note. See Note 12, Debt, for further information with respect to the Senior Secured Convertible Note issued December 27, 2018, including the issue of shares of common stock of the Company.

- I n October 2019, 82,772 shares of common stock were purchase by employees in participation of the Employee Stock Purchase Plan. See Note 10, Stock-Based Compensation, for further information with respect to the ESPP

Year Ended December 31, 2018

- On December 27, 2018, 600,000 shares of common stock of the Company were issued in connection with the repayment of the Senior Secured Note debt. See Note 12, Debt, for further information with respect to the Senior Secured Note repayment.

- The Company completed an equity subscription rights offering on the June 7, 2018 expiration date of the equity subscription period, with such transaction having a June 12, 2018 close date - referred to herein as the "June 12, 2018 Equity Subscription Rights Offering" ("ESRO") and was completed under a registration statement on Form S-1 - File No. 333-222581 - declared effective by the SEC on May 23, 2018.

- The June 12, 2018 Equity Subscription Rights Offering involved the Company distributing one non-transferable equity subscription for each of the 17,509,654 issued and outstanding shares of common stock of the Company, as of the record date of May 21, 2018, subject-to the acceptance by the Company of a maximum of 9,000,000 fully-paid equity subscriptions tendered as of the June 7, 2018 expiration date of the equity subscription period. The equity subscription provided for the purchase of a common stock unit at a $1.15 per unit, with each such unit comprised of one share of common stock of the Company and one Series Z Warrant, and immediately separated upon issue into its underlying components. The ESRO resulted in approximately $10.4 million of gross cash proceeds, before approximately $1.0 million of commissions and fees to the dealer-managers, and approximately $0.2 million of offering costs incurred by the Company, upon the issue of 9.0 million common stock units, comprised of one share of common stock of the Company and one Series Z Warrant, as noted above. The ESRO proceeds after the dealer-manager commissions and fees and the offering costs incurred by the Company, were allocated based on relative fair value of approximately $7.1 to the shares of common stock par value and additional paid-in capital and approximately $2.1 million to additional paid-in capital with respect to the Series Z Warrants.

Note 14 — Stockholders' Equity and Common Stock Purchase Warrants- continued

Common Stock - continued

Year Ended December 31, 2018 - continued

- In January 2018, the Company conducted an underwritten public offering resulting in the issue of a total of 2,649,818 shares of common stock of the Company pursuant to its previously filed and effective shelf registration statement on SEC Form S-3 - File No. 333-220549 - declared effective October 6, 2017, along with a corresponding prospectus supplement dated January 19, 2018. On January 19, 2018, the Company entered into an underwriting agreement with Dawson James Securities, Inc., as sole underwriter, under which the Company agreed to issue to the underwriter at $1.80 per share, 2,415,278 shares of common stock on a firm commitment basis and up to an additional 362,292 shares solely to cover underwriter over-allotments, if any, at the option of the underwriter, exercisable within 45 calendar days from January 19, 2018. On January 23, 2018, 2,415,278 shares of common stock of the Company were issued, and on January 25, 2018, an additional 234,540 shares of common stock of the Company were issued under the underwriter's over-allotment, resulting in cash proceeds, net of the underwriter's discount of $4,388,099, before $113,438 of offering costs incurred by the Company.

- On February 8, 2018, the Company issued at total 34,345 shares of common stock from the exercise of a corresponding number of Series W Warrants, at temporary exercise price of $2.00 per share, resulting in $68,690 of cash proceeds, before offering costs of $50,520. See herein below for a discussion of the "Series W Warrants Offer-to-Exercise".

- In March 2018, 274,257 shares of common stock of the Company were issued, resulting from a corresponding number of Series S Warrants exercised for $2,743 of cash proceeds.

- In July 2018, 33,325 shares of common stock of the Company were issued upon the conversion of a corresponding number of shares of Series B Convertible Preferred Stock.

Common Stock Purchase Warrants

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

	December 31, 2019	Weighted Average Exercise Price	December 31, 2018	Weighted Average Exercise Price	Expiration Date
Equity classified warrants					
Series Z Warrants	16,815,039	$ 1.60	16,815,039	$ 1.60	April 2024
UPO - Series Z Warrants	53,000	$ 1.60	53,000	$ 1.60	January 2022
Series W Warrants	381,818	$ 5.00	381,818	$ 5.00	January 2022
UPO - Series W Warrants	-	-	-	-	January 2022
Series S Warrants	1,199,383	$ 0.01	1,199,383	$ 0.01	January 2032
Total	18,449,240	$ 1.57	18,449,240	$ 1.57	

Note 14 — Stockholders' Equity and Common Stock Purchase Warrants- continued

Common Stock Purchase Warrants - continued

Series Z Warrants

There were 16,815,039 Series Z Warrants issued and outstanding as of December 31, 2019 and 2018, including: the initial issue of 2,739,190 Series Z Warrants on the March 15, 2018 Exchange Date of the Series A and Series A-1 Exchange Offer; the issue of 5,075,849 Series Z Warrants on the April 5, 2018 Exchange Date of the Series W Warrants Exchange Offer; and the issue of 9,000,000 Series Z Warrants on the June 12, 2018 close date of the Equity Subscription Rights Offering.

Upon issue, a Series Z Warrant is exercisable to purchase one share of common stock of the Company at an exercise price of $1.60 per share, effective June 1, 2018. The Series Z Warrant exercise price was initially $3.00 per share through May 31, 2018. On May 15, 2018, the Company's board of directors approved a reduction to the Series Z Warrant exercise price to $1.60 per share, effective June 1, 2018, upon completion of the period-of-notice to the holders of Series Z Warrants then issued and outstanding. See herein below for further information with respect to the modification expense recognized in connection with the Series Z Warrant exercise price adjustment. The Series Z Warrant $1.60 exercise price is not subject-to further adjustment, unless by action of the PAVmed Inc board of directors, or the effect of stock dividends, stock splits or similar events affecting the common stock of the Company. Under no circumstances will the Company be required to net cash settle the Series Z Warrants, nor to pay any liquidated damages in lieu of delivery of shares of common stock of the Company resulting from a failure to satisfy any obligations under the Series Z Warrant, and, the Series Z Warrants expire after the close of business on April 30, 2024, if not earlier redeemed by the Company, as discussed below.

Commencing on May 1, 2019, the Company may redeem the outstanding Series Z Warrants, at the Company's option, in whole or in part, at a price of $0.01 per Series Z Warrant at any time while the Series Z Warrants are exercisable, upon a minimum of 30 days' prior written notice of redemption, if, and only if, the volume weighted average closing price of the common stock of the Company equals or exceeds $9.00 (subject to adjustment) for any 20 out of 30 consecutive trading days ending three business days before the Company issues its notice of redemption, and provided the average daily trading volume in the common stock of the Company during such 30-day period is at least 20,000 shares per day; and if, and only if, there is a current registration statement in effect with respect to the shares of Common Stock underlying such Series Z Warrants.

As noted above, on April 5, 2018, a total of 5,075,849 Series Z Warrants were issued-upon-exchange of 10,151,682 Series W Warrants, referred to as the "Series W Warrants Exchange Offer" and the "April 5, 2018 Exchange Date". In this regard, pursuant to an offer-to-exchange letter dated February 20, 2018, as included in a Tender Offer Statement on Schedule TO filed with the SEC on February 20, 2018, the Company offered to issue one Series Z Warrant in exchange for two Series W Warrants. Such Series W Warrants Exchange Offer commenced on February 20, 2018 and had April 2, 2018 expiration date. The Series W Warrants Offer-to-Exchange was completed after expiration of the guaranteed delivery period on April 5, 2018.

The Series Z Warrant exercise price adjustment to $1.60 per share from $3.00 per share, as discussed above, resulted in the recognition of a modification expense on the June 1, 2018 effective date of the Series Z Warrant exercise price adjustment, under the analogous guidance with respect to stock option modification under FASB ASC Topic 718, *Stock-Based Compensation* (ASC 718), wherein an exchange of warrants is deemed to be a modification of the initial warrant agreement by the replacement with a revised warrant agreement, requiring the incremental fair value, measured as the difference between the fair value immediately after the modification as compared to the fair value immediately before the modification, to the extent an increase, recognized as a modification expense. In this regard, the Series Z Warrant June 1, 2018 exercise price adjustment resulted in the recognition of a current period modification expense of $1,140,995 included in other income (expense) in the consolidated statement of operations, with a corresponding increase to additional paid-in capital in the consolidated balance sheet. The modification expense incremental fair value was estimated using a Black-Scholes valuation model, using the following assumptions:

Fair Value Assumptions - June 1, 2018 Series Z Warrant Exercise Price Adjustment	**Immediately after Modification**	**Immediately before Modification**
Calculated aggregate estimated fair value	$ 3,477,692	$ 2,336,697
Series Z Warrants - issued and outstanding - June 1, 2018	7,815,039	7,815,039
Value of common stock per share	$ 1.00	$ 1.00
Exercise price per share - Series Z Warrant	$ 1.60	$ 3.00
Expected term - years	5.9	5.9
Volatility	58%	58%
Risk free interest rate	2.8%	2.8%
Dividend yield	0%	0%

Note 14 — Stockholders' Equity and Common Stock Purchase Warrants- continued

Common Stock Purchase Warrants - continued

Series Z Warrants - continued

Additionally, the Series Z Warrants issued in both the Series A and Series A-1 Exchange Offer on March 15, 2018 and the Series W Warrants Exchange Offer on April 5, 2018, as each exchange offer is discussed above, were issued under the (original) "Series Z Warrant Agreement". The Company's board of directors approved Amendment No. 1 to the original Series Z Warrant Agreement, resulting in the "Amended and Restated Series Z Warrant Agreement", dated June 8, 2018, referred to as the Amended Series Z Warrant Agreement. The principal provisions of the Series Z Warrant Agreement Amendment No. 1, include among other items: to provide for a "late delivery fee" for shares issued outside of the "standard delivery period", including delivery of shares upon Series Z Warrant exercise for open market or other purchase transactions - i.e. "buy-in fee", with each such payment, if any, in addition to and not in lieu of delivery of shares, and, to provide for a standard provision ("plain vanilla") in the event the Company engages in a "Fundamental Transaction", as defined, wherein the Series Z Warrant may participate pari passu with common stockholders in the consideration paid by an acquiror for the Company's shares, with such payment, if any, made by the acquiring entity and not paid by the Company as issuer. The Series Z Warrant Agreement Amendment No. 1, was evaluated under the analogous guidance with respect to stock option modification under FASB ASC 718, as discussed above, but did not result in the recognition of a modification expense as there was no incremental increase in the estimated fair value as described above.

Series W Warrants

There were 381,818 Series W Warrants issued and outstanding as of December 31, 2019 and 2018. The Series W Warrants have an exercise price of $5.00 per share, with such exercise price not subject to further adjustment, except in the event of stock dividends, stock splits or similar events affecting the common stock of the Company, and became exercisable on October 28, 2016 and expire on January 29, 2022, or earlier upon redemption by the Company, as discussed below. Under no circumstances will the Company be required to net cash settle the Series W Warrants, nor to pay any liquidated damages resulting from a failure to satisfy any obligations under the Series W Warrant.

The Series W Warrant Exchange Offer resulted in the recognition of a modification expense on the April 5, 2018 Exchange Date, under the analogous guidance with respect to stock option modification under FASB ASC 718, as described above with respect to the "Series Z Warrant June 1, 2018 exercise price adjustment". In this regard, the Series W Warrants exchanged-upon-issue of the Series Z Warrants resulted in the recognition of a current period modification expense of $766,456 included in other income (expense) in the consolidated statement of operations, with a corresponding increase to additional paid-in capital, resulting from the incremental estimated fair value of the consideration given of $3,304,377 of the 5,075,849 Series Z Warrants issued-upon-exchange as compared of the $2,537,921 estimated fair value of the 10,151,682 Series W Warrants extinguished-upon-exchange. The April 5, 2018 Exchange Date estimated fair values of each of the Series Z Warrants and Series W Warrants noted above, were each computed using the Black-Scholes option pricing model, using the following assumptions:

	Series Z Warrants	Series W Warrants
Calculated aggregate estimated fair value	$ 3,304,377	$ 2,537,921
Series Z Warrants issued-upon-exchange	5,075,849	-
Series W Warrants extinguished-upon-exchange	-	10,151,682
Value of common stock	$ 1.66	$ 1.66
Exercise price per share	$ 3.00	$ 5.00
Expected term (years)	2.7	3.8
Volatility	55%	55%
Risk free rate	2.7%	2.5%
Dividend yield	0%	0%

Note 14 — Stockholders' Equity and Common Stock Purchase Warrants- continued

Common Stock Purchase Warrants - continued

Series W Warrants - continued

On January 11, 2018, the Company filed with the SEC a Tender Offer Statement on Schedule TO offering Series W Warrants holders a temporary exercise price of $2.00 per share, with such offer having an expiry of February 8, 2018, referred to as the "Series W Warrants Offer-to-Exercise". As of the February 8, 2018 expiry date, a total of 34,345 Series W Warrants were exercised at the temporary exercise of $2.00 per share, resulting in $68,690 of cash proceeds, before offering costs of $50,520.

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

Series S Warrants

There were 1,199,383 Series S Warrants issued and outstanding as of December 31, 2019 and 2018, respectively. Previously, under the Note and Security Purchase Agreement with Scopia, the Company issued a total of 2,660,000 Series S Warrants to Scopia and its designees, which were immediately exercisable upon issuance and each may be exercised for one share of common stock of the Company at an exercise price of $0.01 per share, with such exercise price not subject to further adjustment, except for the effect of stock dividends, stock splits or similar events affecting the common stock of the Company. The Series S Warrants may be exercised for cash or on a cashless basis. The Senior Secured Note and the Series S Warrants are freestanding financial instruments, as the Series S Warrants were immediately legally detachable from the Senior Secured Note and were immediately exercisable. Under no circumstances will the Company be required to net cash settle the Series S Warrants, nor to pay any liquidated damages resulting from a failure to satisfy any obligations under the Series S Warrant. The Series-S Warrants are classified as equity in the consolidated balance sheet.

Subsequent to December 31, 2019, in January 2020, the remaining 1,199,383 Series S Warrants were exercised for $11,994 of cash proceeds and the issue of a corresponding number of shares of common stock of the Company. Previously, in March 2018, a total of 274,257 Series S Warrants exercised for $2,743 of cash proceeds, resulting in the issue of a corresponding number of a shares of common stock of the Company.

Note 14 — Stockholders' Equity and Common Stock Purchase Warrants- continued

Unit Purchase Options

Previously, on the April 28, 2016 closing date of the Company's IPO, a total of 53,000 unit purchase options were issued to the IPO selling agents, with each such unit purchase option issued on April 28, 2016 referred to as an "UPO-W". The UPO-W, with an exercise price of $5.50 per unit, could have been exercised to purchase the same unit issued in the Company's IPO, with such unit comprised of one share of common stock of the Company and one Series W Warrant to purchase one share of common stock of the Company at an exercise price of $5.00 per share, along with the other provisions of the Series W Warrant as discussed above. The UPO-W had a January 29, 2021 expiration date. The issue of the UPO-W to the IPO selling agents was recognized as an offering cost of the Company's IPO, with an estimated fair value of $105,100, determined using a Black-Scholes option pricing model with the following assumptions: fair value of the underlying unit of $5.00, expected volatility of 50%, risk free rate of 1.28%, remaining contractual term of 4.6 years, and a dividend yield of 0%.

On August 22, 2018, the "UPO Exchange Offer" was completed, wherein, 53,000 "UPO-Z" were issued-upon-exchange of all the previously issued and outstanding 53,000 UPO-W. The UPO-Z, with an exercise price of $5.50 per unit, may be exercised to purchase a unit comprised of one share of common stock of the Company and one Series Z Warrant to purchase one share of common stock of the Company at an exercise price of $1.60 per share, along with the other provisions of the Series Z Warrant as discussed above. The UPO-Z has a January 29, 2021 expiration date.

The UPO Exchange Offer resulted in the recognition of a modification expense under the analogous guidance with respect to stock option modification under FASB ASC 718, as described above with respect to the "June 1, 2018 Series Z Warrant exercise price adjustment". In this regard, the UPO-Z issued-upon-exchange of the UPO-W resulted in the recognition of a modification expense of $2,120 included in other income (expense) in the consolidated statement of operations, with a corresponding increase to additional paid-in capital in the consolidated balance sheet, resulting from the incremental estimated fair value of the consideration given of $3,180 of the 53,000 UPO-Z issued-upon-exchange as compared to the estimated fair value of $1,060 of the 53,000 UPO-W extinguished-upon-exchange. The August 22, 2018 estimated fair values of each of the UPO-Z and UPO-W were each computed using the Black-Scholes option pricing model, using the following assumptions:

Fair Value Assumptions

August 22, 2018 UPO Exchange Offer Exchange Date	UPO-Z	UPO-W
Calculated aggregate estimated fair value	$ 3,180	$ 1,060
UPO-Z issued-upon-exchange /UPO-W extinguished-upon-exchange	53,000	53,000
Value of common stock	$ 1.38	$ 1.38
Value of Series Z Warrant /Series W Warrants	$ 0.53	$ 0.05
Exercise price per unit - UPO-Z /UPO-W	$ 5.50	$ 5.50
Expected term (years)	2.4	2.4
Volatility	42%	42%
Risk free rate	2.6%	2.6%
Dividend yield	0%	0%

Note 14 — Stockholders' Equity and Common Stock Purchase Warrants- continued

Noncontrolling Interest

The noncontrolling interest ("NCI") included as a component of consolidated total stockholders' equity for the periods indicated is as follows:

	Year Ended	
	December 31, 2019	**December 31, 2018**
NCI - equity (deficit) - beginning of period	(161,512)	-
Investment in majority-owned subsidiary- Lucid Diagnostics Inc.	-	1,812
Investment in majority-owned subsidiary- Solys Diagnostics Inc.	889	-
Share Subscription Receivable - Solys Diagnostics Inc.	(889)	-
Net loss attributable to NCI- Lucid Diagnostics Inc.	(801,224)	(204,072)
Net loss attributable to NCI- Solys Diagnostics Inc.	(9,666)	-
Stock-based compensation expense - Lucid Diagnostics Inc 2018 Equity Plan	158,123	40,748
NCI - equity (deficit) - end of period	(814,279)	(161,512)

The consolidated noncontrolling interest presented above is with respect to the Company's majority-owned subsidiaries Lucid Diagnostics Inc. (inception date of May 8, 2018) and Solys Diagnostics Inc. (inception date of October 7, 2019).

As of December 31, 2019, there were 10.0 million shares of common stock of Lucid Diagnostics Inc. issued and outstanding, of which PAVmed Inc. holds a 81.875% majority-interest ownership and has a controlling financial interest, with the remaining 18.125% minority-interest ownership held by CWRU and each of the three physician inventors of the "EsoGuard Technology". Accordingly, Lucid Diagnostics Inc. is a consolidated majority-owned subsidiary of the Company, for which a provision of a noncontrolling interest (NCI) is included as a separate component of consolidated stockholders' equity in the consolidated balance sheet as of December 31, 2019 and December 31, 2018, along with the recognition of a net loss attributable to the NCI in the consolidated statement of operations in the year ended December 31, 2019 and December 31, 2018.

As of December 31, 2019, there were 9,189,190 shares of common stock of Solys Diagnostics Inc. issued and outstanding, of which PAVmed Inc. holds a 90.3235% majority-interest ownership and has a controlling financial interest, with the remaining 9.6765% minority-interest ownership held by unrelated third parties. Accordingly, Solys Diagnostics Inc. is a consolidated majority-owned subsidiary of the Company, for which a provision of a noncontrolling interest (NCI) is included as a separate component of consolidated stockholders' equity in the consolidated balance sheet as of December 31, 2019, along with the recognition of a net loss attributable to the NCI in the consolidated statement of operations in the year ended December 31, 2019.

See Note 10, *Stock-Based Compensation*, for further information with respect to the PAVmed Inc. 2014 Equity Plan, the Lucid Diagnostics Inc. 2018 Equity Plan, and the corresponding consolidated stock-based compensation expense recognized by the Company.

Note 15 — Loss Per Share

The "Net loss per share - attributable to PAVmed Inc. - basic and diluted" and "Net loss per share - attributable to PAVmed Inc. common stockholders - basic and diluted" - for the respective periods indicated - is as follows:

	Year Ended December 31,	
	2019	2018
Numerator		
Net loss - before noncontrolling interest	$ (17,268,131)	$ (18,172,822)
Net loss attributable to noncontrolling interest	810,890	204,072
Net loss - as reported, attributable to PAVmed Inc.	$ (16,457,241)	$ (17,968,750)
Convertible Preferred Stock dividends[(1)]:		
Series B	$ (269,895)	$ (203,123)
Series A-1	—	(25,148)
Series A	—	(26,487)
Series A and Series A-1 Exchange Offer - March 15, 2018 - deemed dividend - incremental fair value - Series B Convertible Preferred Stock issued-upon-exchange of Series A Convertible Preferred Stock	—	(726,531)
Series A and Series A-1 Exchange Offer - March 15, 2018 - Series B Convertible Preferred Stock issued-upon-exchange of Series A-1 Convertible Preferred Stock	—	199,241
Net loss attributable to PAVmed Inc. common stockholders	$ (16,727,136)	$ (18,750,798)
Denominator		
Weighted-average common shares outstanding basic and diluted(2) (3)	30,197,458	22,276,347
Loss per share		
Basic and diluted		
- Net loss - as reported, attributable to PAVmed Inc.	$ (0.54)	$ (0.81)
- Net loss attributable to PAVmed Inc. common stockholders	$ (0.55)	$ (0.84)

Note 15 — Loss Per Share- continued

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

	December 31,	
	2019	2018
Stock Options and Unvested Restricted Stock Awards	5,903,529	3,327,140
Unit purchase options - "UPO-Z" /"UPO-W" - as to shares of common stock[4]	53,000	53,000
Unit purchase options - "UPO-Z" - as to shares underlying Series Z Warrants[4]	53,000	53,000
Series Z Warrants	16,815,039	16,815,039
Series W Warrants	381,818	381,818
Series S Warrants[5]	-	1,199,383
Series B Convertible Preferred Stock[6]	1,158,209	1,069,941
Total	24,364,595	22,899,321

(1) The convertible preferred stock dividends earned as of the each of the respective periods noted, are included in the calculation of basic and diluted net loss attributable to PAVmed Inc. common stockholders for each respective periods presented, including: with respect to the Series B Convertible Preferred Stock, for the year ended December 31, 2019 and from March 16, 2018 to December 31, 2018, and with respect to each of the Series A-1 and Series A Convertible Preferred Stock, from January 1, 2018 to March 15, 2018;

(2) Basic weighted-average number of shares of common stock outstanding for the years ended December 31, 2019 and 2018 include the shares of the Company issued and outstanding during the year ended December 31, 2019, and during the year ended December 31, 2019, the Series S Warrants for the period February 1, 2019 to December 31, 2019 (as discussed herein below), each on a weighted average basis. The basic weighted average number of shares outstanding excludes common stock equivalent incremental shares, while diluted weighted average number of shares outstanding includes such incremental shares. However, as the Company was in a loss position for all periods presented, basic and diluted weighted average shares outstanding are the same, as the inclusion of the incremental shares would be anti-dilutive.

(3) The Series B Convertible Preferred Stock has the right to receive common stock dividends, and prior to the March 15, 2018 Exchange Date of the Series A and Series A Exchange Offer, holders of the Series A Warrants and the Series A-1 Warrants previously had the right to receive common stock dividends. As such, the Series B Convertible Preferred Stock and the Series A Warrants and Series A-1 Warrants would potentially been considered participating securities under the two-class method of calculating net loss per share. However, the Company has incurred net losses to-date, and as such holders are not contractually obligated to share in the losses, there is no impact on the Company's net loss per share calculation for the periods indicated.

(4) On August 22, 2018, the "UPO Exchange Offer" was completed, wherein, 53,000 "UPO-Z" were issued-upon-exchange of all the previously issued and outstanding 53,000 UPO-W. The UPO-Z may be exercised to purchase a unit comprised of one share of common stock of the Company and one Series Z Warrant; and the UPO-W was exercisable to purchase a unit comprised of one share of common stock of the Company and one Series W Warrant. See Note 14, *Stockholders' Equity and Common Stock Purchase Warrants*, for a discussion of the UPO-Z, UPO-W, and the August 22, 2018 UPO Exchange Offer.

(5) The Series S Warrants were issued in connection with the Note and Security Purchase Agreement with Scopia Holdings LLC. The Series S Warrants were not included in weighted average shares outstanding for the year ended December 31, 2018 due to certain contractual restrictions on the ability of the holder to exercise the Series S Warrant, with such contractual restrictions ending in January 2019.

(6) If converted at the election of the holder, the shares of Series B Convertible Preferred Stock issued and outstanding would result in a corresponding number of additional outstanding shares of common stock of the Company.

Note 16 — Subsequent Events

Other Matters

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

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, PAVmed Inc. ("PAVmed," the "Company" or "we," "us" or "our") had three classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): (i) common stock, $0.001 par value per share; (ii) warrants to purchase our common stock issued in our initial public offering and in private placements prior thereto ("Series W Warrants"); and (iii) Series Z warrants to purchase our common stock ("Series Z Warrants"). Each of the Company's securities registered under Section 12 of the Exchange Act are listed on The Nasdaq Stock Market LLC.

DESCRIPTION OF COMMON STOCK

In the discussion that follows, we have summarized selected provisions of our certificate of incorporation, bylaws and the Delaware General Corporation Law (the "DGCL") relating to our common stock. This summary is not complete. This discussion is subject to the relevant provisions of Delaware law and is qualified in its entirety by reference to our certificate of incorporation and our bylaws. You should read the provisions of our certificate of incorporation and our bylaws as currently in effect for provisions that may be important to you.

Authorized Capital Stock

We are authorized to issue 100,000,000 shares of common stock, par value $0.001, and 20,000,000 shares of preferred stock, par value $0.001. On March 23, 2018, we filed a certificate of designation of preferences, rights and limitations for a series of preferred stock designated as Series B Convertible Preferred Stock (the "Series B Preferred Stock").

As of December 31, 2019, 40,478,861 shares of our common stock were issued and outstanding. In addition, as of December 31, 2019, we had outstanding: (i) employee stock options to purchase 5,203,529 shares of our common stock at a weighted average exercise price of $2.68 per share; (ii) warrants to purchase 17,196,857 shares of our common stock at a weighted average exercise price of $1.68 per share; (iii) unit purchase options to purchase 53,000 units at an exercise price of $5.50 per unit, with each unit consisting of one share of our common stock and one warrant, and each warrant entitling the holder to purchase one share of our common stock at an exercise price of $1.60 per share; (iv) the Series B Preferred Stock convertible into 1,158,209 shares of our common stock; (v) Senior Secured Convertible Notes issued on November 4, 2019 convertible into 8,750,000 shares of our common stock (assuming such notes were converted in full on such date at the initial fixed conversion price of $1.60 per share); and (vi) a Senior Secured Convertible Note issued on December 27, 2018 convertible in to 4,843,750 shares of our common stock (assuming such note was converted in full on such date at the initial fixed conversion price of $1.60 per share). As of December 31, 2019, we also had 2,548,406 shares reserved for issuance, but not subject to outstanding awards, under our long-term incentive equity plan, and 167,228 shares reserved for issuance under our employee stock purchase plan.

As of December 31, 2019, 1,158,209 shares of Series B Preferred Stock were issued and outstanding.

Common Stock

Holders of common stock are entitled to one vote per share on matters on which our stockholders vote. There are no cumulative voting rights. Subject to any preferential dividend rights of any outstanding shares of preferred stock, holders of common stock are entitled to receive dividends, if declared by our board of directors, out of funds that we may legally use to pay dividends. If we liquidate or dissolve, holders of common stock are entitled to share ratably in our assets once our debts and any liquidation preference owed to any then-outstanding preferred stockholders is paid. Our certificate of incorporation does not provide the common stock with any redemption, conversion or preemptive rights, and there are no sinking fund provisions with respect to our common stock. All shares of common stock that are outstanding are fully-paid and non-assessable.

Preferred Stock

Our certificate of incorporation authorizes the issuance of blank check preferred stock. Accordingly, our board of directors is empowered, without stockholder approval, to issue shares of preferred stock with dividend, liquidation, redemption, voting or other rights which could adversely affect the voting power or other rights of the holders of shares of our common stock. In addition, shares of preferred stock could be utilized as a method of discouraging, delaying or preventing a change in control of us.

Series B Convertible Preferred Stock

The Series B Convertible Preferred stock is senior to our common stock with respect to dividends and, as described below, assets distributed in liquidation. The Series B Convertible Preferred Stock has no voting rights. The stated value of the Series B Convertible Preferred Stock is $3.00 per share.

The Series B Convertible Preferred Stock provides for dividends at a rate of 8% per annum of the stated value per share of the Series B Convertible Preferred Stock. Dividends are payable in arrears on January 1, April 1, July 1, and October 1, 2021. Dividends accrue and cumulate whether or not declared by our board of directors. All accumulated and unpaid dividends compound quarterly at the rate of 8% of the stated value per annum. Dividends through October 1, 2021 are payable in additional shares of Series B Convertible Preferred Stock. Dividends after October 1, 2021 are payable at our election in any combination of shares of Series B Convertible Preferred Stock, cash or shares of our common stock.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of our company or Deemed Liquidation Event (as defined in the certificate of designations for the Series B Convertible Preferred Stock), the holders of shares of Series B Convertible Preferred Stock then outstanding shall be entitled to be paid out of our assets available for distribution to our stockholders, before any payment shall be made to the holders of our common stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the stated value of the Series B Convertible Preferred Stock, plus any dividends accrued but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series B Convertible Preferred Stock been converted into our common stock immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event.

At the holders' election, a share of Series B Convertible Preferred Stock is convertible into a number of shares of our common stock determined by dividing the stated value of such share by the conversion price. The conversion price is $3.00, subject to adjustment for stock dividends, stock splits or similar events affecting our common stock.

Dividends

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

Anti-Takeover Provisions

Provisions of the DGCL and our certificate of incorporation and bylaws could make it more difficult to acquire us by means of a tender offer, a proxy contest or otherwise, or to remove incumbent officers and directors. These provisions, summarized below, are expected to discourage certain types of coercive takeover practices and takeover bids that our board of directors may consider inadequate and to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because, among other things, negotiation of these proposals could result in improved terms for our stockholders.

Delaware Anti-Takeover Statute. We are subject to Section 203 of the DGCL, an anti-takeover statute. In general, Section 203 of the DGCL prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time the person became an interested stockholder, unless the business combination or the acquisition of shares that resulted in a stockholder becoming an interested stockholder is approved in a prescribed manner. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns (or within three years prior to the determination of interested stockholder status did own) 15% or more of a corporation's voting stock. The existence of this provision would be expected to have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Classified Board. Our board of directors is divided into three classes. The number of directors in each class is as nearly equal as possible. Directors elected to succeed those directors whose terms expire shall be elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election. The existence of a classified board may extend the time required to make any change in control of the board when compared to a corporation with an unclassified board. It may take two annual meetings for our stockholders to effect a change in control of the board, because in general less than a majority of the members of the board will be elected at a given annual meeting. Because our board is classified and our certificate of incorporation does not otherwise provide, under Delaware law, our directors may only be removed for cause.

Vacancies in the Board of Directors. Our certificate of incorporation and bylaws provide that, subject to limitations, any vacancy occurring in our board of directors for any reason may be filled by a majority of the remaining members of our board of directors then in office, even if such majority is less than a quorum. Each director elected to fill a vacancy resulting from the death, resignation or removal of a director shall hold office until the expiration of the term of the director whose death, resignation or removal created the vacancy.

Advance Notice of Nominations and Shareholder Proposals. 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.

Special Meetings of Stockholders. Under our bylaws, special meetings of stockholders may be called by the directors, or the president or the chairman, and shall be called by the secretary at the request in writing of stockholders owning a majority in amount of the entire capital stock of the corporation issued and outstanding and entitled to vote.

No Cumulative Voting. The DGCL provides that stockholders are denied the right to cumulate votes in the election of directors unless our certificate of incorporation provides otherwise. Our certificate of incorporation does not provide for cumulative voting.

Listing

Our common stock is traded on the NASDAQ Capital Market under the symbols "PAVM."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company located at 1 State Street, 30th Floor, New York, NY 10004.

DESCRIPTION OF SERIES W WARRANTS

The Series W Warrants are issued under a warrant agreement, dated April 28, 2016, between Continental Stock Transfer & Trust Company, as warrant agent, and us. In the discussion that follows, we have summarized selected provisions of the warrant agreement. This summary is not complete. This discussion is subject to the provisions the warrant agreement and is qualified in its entirety by reference to the warrant agreement. You should read the warrant agreement as currently in effect for provisions that may be important to you.

General

We currently have 381,818 Series W Warrants outstanding. Each Series W Warrant entitles the registered holder to purchase one share of our common stock at a price of $5.00 per share, subject to adjustment as discussed below. Each warrant is currently exercisable and expires on January 29, 2022 at 5:00 p.m., New York City time.

Notwithstanding the foregoing, no Series W Warrants will be exercisable for cash unless we have an effective and current registration statement covering the shares of common stock issuable upon exercise of the warrants and a current prospectus relating to such shares of common stock. If a registration statement covering the shares of common stock issuable upon exercise of the Series W Warrants is not effective when the warrants become exercisable, warrant holders may, until such time as there is an effective registration statement and during any period when we shall have failed to maintain an effective registration statement, exercise the Series W Warrants on a cashless basis in the same manner as if we called the warrants for redemption and required all holders to exercise their warrants on a "cashless basis." In such event, each holder would pay the exercise price by surrendering the warrants for that number of shares of common stock equal to the quotient obtained by dividing (x) the product of the number of shares of common stock underlying the warrants, multiplied by the difference between the exercise price of the warrants and the "fair market value" (defined below) by (y) the fair market value. The "fair market value" for this purpose will mean the average reported last sale price of the shares of common stock for the 10 trading days ending on the trading day prior to the date of exercise.

Redemption

We may redeem the outstanding Series W Warrants (other than those outstanding prior to this offering held by certain of our senior managers, our founders and members thereof), at our option, in whole or in part, at a price of $0.01 per warrant:

- at any time while the warrants are exercisable,
- upon a minimum of 30 days' prior written notice of redemption,
- if, and only if, the volume weighted average price of our common stock equals or exceeds $10.00 (subject to adjustment) for any 20 consecutive trading days ending three business days before we send the notice of redemption, provided that the average daily trading volume in the stock is at least 20,000 shares per day, and
- if, and only if, there is a current registration statement in effect with respect to the shares of common stock underlying such warrants.

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

If we call the Series W Warrants for redemption as described above, we will have the option to require all holders that wish to exercise warrants to do so on a "cashless basis." In such event, each holder would pay the exercise price by surrendering the warrants for that number of shares of common stock equal to the quotient obtained by dividing (x) the product of the number of shares of common stock underlying the warrants, multiplied by the difference between the exercise price of the warrants and the "fair market value" (defined below) by (y) the fair market value. In this case, the "fair market value" shall mean the average reported last sale price of the shares of common stock for the 10 trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the holders of warrants.

Exercise

The exercise price and number of shares of common stock issuable on exercise of the Series W Warrants may be adjusted in certain circumstances including in the event of a share dividend, extraordinary dividend or our recapitalization, reorganization, merger or consolidation. However, the Series W Warrants will not be adjusted for issuances of shares of common stock at a price below their respective exercise prices.

The Series W Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, by certified or official bank check payable to us, for the number of warrants being exercised. The warrant holders do not have the rights or privileges of holders of shares of common stock and any voting rights until they exercise their warrants and receive shares of common stock.

Except as described above, no Series W Warrants will be exercisable and we will not be obligated to issue shares of common stock unless at the time a holder seeks to exercise such warrant, a prospectus relating to the shares of common stock issuable upon exercise of the Series W Warrants is current and the shares of common stock have been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the warrants. Under the terms of the warrant agreement, we have agreed to use our commercially reasonable best efforts to meet these conditions and to maintain a current prospectus relating to the shares of common stock issuable upon exercise of the warrants until the expiration of the warrants.

No fractional shares will be issued upon exercise of the Series W Warrants. If, upon exercise of the warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round up to the nearest whole number the number of shares of common stock to be issued to the warrant holder.

Warrant Agreement

The Series W Warrants are issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us. The warrant agreement provides that the terms of the Series W Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval, by written consent or vote, of the holders of a majority of the then outstanding warrants in order to make any change that adversely affects the interests of the registered holders. Notwithstanding the foregoing, we may lower the exercise price or extend the duration of the Series W Warrants without the consent of the holders.

Listing

Our Series W Warrants are traded on the NASDAQ Capital Market under the symbols "PAVMW."

Warrant Agent and Registrar

The warrant agent and registrar for our Series W Warrants is Continental Stock Transfer & Trust Company located at 1 State Street, 30th Floor, New York, NY 10004.

DESCRIPTION OF SERIES Z WARRANTS

The Series Z Warrants are issued under an amended and restated warrant agreement, dated June 8, 2018, between Continental Stock Transfer & Trust Company, as warrant agent, and us. In the discussion that follows, we have summarized selected provisions of the amended and restated warrant agreement. This summary is not complete. This discussion is subject to the provisions the amended and restated warrant agreement and is qualified in its entirety by reference to the amended and restated warrant agreement. You should read the amended and restated warrant agreement as currently in effect for provisions that may be important to you.

General

We currently have 16,815,039 Series Z Warrants outstanding. Each Series Z Warrant entitles the registered holder to purchase one share of our common stock at a price of $1.60 per share, subject to adjustment as discussed below. Each warrant is currently exercisable and expires on April 30, 2024 at 5:00 p.m., New York City time.

Notwithstanding the foregoing, no Series Z Warrants will be exercisable for cash unless we have an effective and current registration statement covering the shares of common stock issuable upon exercise of the warrants and a current prospectus relating to such shares of common stock. If a registration statement covering the shares of common stock issuable upon exercise of the Series Z Warrants is not effective when the warrants become exercisable, warrant holders may, until such time as there is an effective registration statement and during any period when we shall have failed to maintain an effective registration statement, exercise the Series Z Warrants on a cashless basis in the same manner as if we called the warrants for redemption and required all holders to exercise their warrants on a "cashless basis." In such event, each holder would pay the exercise price by surrendering the warrants for that number of shares of common stock equal to the quotient obtained by dividing (x) the product of the number of shares of common stock underlying the warrants, multiplied by the difference between the exercise price of the warrants and the "fair market value" (defined below) by (y) the fair market value. The "fair market value" for this purpose will mean the average daily volume weighted average price for our common stock for the 10 trading days ending on the trading day prior to the date of exercise.

Redemption

We may redeem the outstanding Series Z Warrants (other than those outstanding prior to this offering held by certain of our senior managers, our founders and members thereof), at our option, in whole or in part, at a price of $0.01 per warrant:

- at any time while the warrants are exercisable,
- upon a minimum of 30 days' prior written notice of redemption,
- if, and only if, the volume weighted average closing price of our common stock equals or exceeds $9.00 (subject to adjustment) for any 20 out of 30 consecutive trading days ending three business days before we send the notice of redemption, provided that the average daily trading volume in the stock during such 30-day period is at least 20,000 shares per day, and
- if, and only if, there is a current registration statement in effect with respect to the shares of common stock underlying such warrants.

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

If we call the Series Z Warrants for redemption as described above, we will have the option to require all holders that wish to exercise warrants to do so on a "cashless basis." In such event, each holder would pay the exercise price by surrendering the warrants for that number of shares of common stock equal to the quotient obtained by dividing (x) the product of the number of shares of common stock underlying the warrants, multiplied by the difference between the exercise price of the warrants and the "fair market value" (defined below) by (y) the fair market value. In this case, the "fair market value" shall mean the average daily volume weighted average price the shares of common stock for the 10 trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the holders of warrants.

Exercise

The exercise price and number of shares of common stock issuable on exercise of the Series Z Warrants may be adjusted in certain circumstances including in the event of a share dividend, extraordinary dividend or our recapitalization, reorganization, merger or consolidation. However, the Series Z Warrants will not be adjusted for issuances of shares of common stock at a price below their respective exercise prices.

If a Fundamental Transaction (as defined in the amended and restated warrant agreement for the Series Z Warrants) is completed, then, upon any subsequent exercise of a Series Z Warrant, the holders of the Series Z Warrants shall have the right to receive, for each share of our common stock that would have been issuable upon exercise of a Series Z Warrant immediately prior to the occurrence of such Fundamental Transaction, at the option of each holder (without regard to the beneficial ownership limitation described below), the number of shares of common stock of the successor or acquiring corporation or of us, if we are the surviving corporation, and any additional consideration receivable as a result of such Fundamental Transaction by a holder of the number of shares of our common stock for which the Series Z Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to the beneficial ownership limitation described below).

The Series Z Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated. Within two trading days following the exercise, the holder will pay in full the exercise price, by certified or official bank check payable to us, for the number of warrants being exercised. The warrant holders do not have the rights or privileges of holders of shares of common stock and any voting rights until they exercise their warrants.

Except as described above, no Series Z Warrants will be exercisable and we will not be obligated to issue shares of common stock unless at the time a holder seeks to exercise such warrant, a prospectus relating to the shares of common stock issuable upon exercise of the Series Z Warrants is current and the shares of common stock have been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the warrants. Under the terms of the amended and restated warrant agreement, we have agreed to use our commercially reasonable best efforts to meet these conditions and to maintain a current prospectus relating to the shares of common stock issuable upon exercise of the warrants until the expiration of the warrants.

No fractional shares will be issued upon exercise of the Series Z Warrants. If, upon exercise of the warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round up to the nearest whole number the number of shares of common stock to be issued to the warrant holder.

We will not effect any exercise of a Series Z Warrant, and a holder shall not have the right to exercise any portion of a Series Z Warrant, to the extent that after giving effect to such issuance after exercise as set forth on the applicable subscription form, the holder (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates), would beneficially own in excess of 4.99% or 9.99% (at the election of the holder) of our common stock outstanding.

Warrant Agreement

The Series Z Warrants are issued in registered form under an amended and restated warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us. The amended and restated warrant agreement provides that the terms of the Series Z Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval, by written consent or vote, of the holders of two-thirds of the then outstanding warrants in order to make any change that adversely affects the interests of the registered holders. Notwithstanding the foregoing, we may lower the exercise price or extend the duration of the Series Z Warrants without the consent of the holders.

Listing

Our Series Z Warrants are traded on the NASDAQ Capital Market under the symbols “PAVMZ.”

Warrant Agent and Registrar

The warrant agent and registrar for our Series Z Warrants is Continental Stock Transfer & Trust Company located at 1 State Street, 30th Floor, New York, NY 10004.

Exhibit 21

List of Subsidiaries of the Registrant
(PAVmed Inc. DE - 47-1214177)

Subsidiary Legal Entity Name	State of Incorporation
Lucid Diagnostics Inc. (82-5488042) - *Majority-Owned*	Delaware
Solys Diagnostics Inc. (84-3484870) - *Majority-Owned*	Delaware

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of PAVmed Inc. on Form S-1 [File No. 333-222581], Form S-3 [File No. 333-227718, File no. 333-220549, File No. 333-221406, File No. 333-229372, File No. 333-235335], Form S-8 [File No. 333-231674] of our report which includes an explanatory paragraph to the Company's ability to continue as a going concern, dated April 14, 2020, with respect to our audit of the consolidated financial statements of PAVmed Inc and Subsidiaries as of December 31, 2019 and for the year ended, which report is included in this Annual Report on Form 10-K of PAVmed Inc. for the year ended December 31, 2019.

/s/ Marcum llp

Marcum llp
New York, NY
April 14, 2020

Exhibit 23.2

[PLACEHOLDER: SUBJECT-TO LEGAL COUNSEL REVIEW]

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated April 1, 2019, with respect to the consolidated financial statements in the Annual Report of PAVmed Inc. on Form 10-K for the year ended December 31, 2018. We consent to the incorporation by reference of said report in Registration Statements of PAVmed Inc. on Form S-1 - File No. 333-222581, File No. 333-214288, File No. 333-216963, File No. 333-222234 and Form S-3 - File No. 333-220549, File No. 333-221406, File No. 333-227718, File No. 333-229372, File No. 333-235335, and Form S-8 - File No. 333-231674. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ CITRIN COOPERMAN & COMPANY, LLP

New York, New York
April 14, 2019

Exhibit 31.1

CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER

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

1. I have reviewed this annual report on Form 10-K of PAVmed Inc.;

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

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

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

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

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

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

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

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

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

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

Date: April 14, 2020

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

Lishan Aklog, M.D., Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION BY PRINCIPAL FINANCIAL OFFICER

I, Dennis M. McGrath, certify that:

1. I have reviewed this annual report on Form 10-K of PAVmed Inc.;

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

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

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

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

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

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

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

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

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

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

Date: April 14, 2020

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of PAVmed Inc. (the "Company") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lishan Aklog, M.D., Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

Date: April 14, 2020

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

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of PAVmed Inc. (the "Company") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Dennis M. McGrath, President & Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

Date: April 14, 2020

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