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, 2020

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. [ ]

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, 2020, 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 $82.3 million, based on 39,007,461 shares of common stock held by non-affiliates and a last reported sales price per share of the registrant's common stock of $2.11 on such date.

As of March 12, 2021 there were 82,460,720 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 2021 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, 2020.

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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;
- our ability of our products to achieve market acceptance;
- our success in retaining or recruiting, or changes required in, our officers, key employees or directors;
- our potential ability to obtain additional financing when and if needed;
- our ability to protect our intellectual property;
- our ability to complete strategic acquisitions;
- our ability to manage growth and integrate acquired operations;
- the potential liquidity and trading of our securities;
- regulatory and operational risks;
- cybersecurity risks;
- risks related to SARS-CoV-2 /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 - "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, commercial-stage 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, regulatory clearances, approvals, and commercialization.

- EsoCheck received 510(k) marketing clearance from the United States Food and Drug Administration, or the "FDA" in June 2019 as an esophageal cell collection device. EsoGuard has been established as a Laboratory Developed Test ("LDT"), and became commercially available in December 2019 after Clinical Laboratory Improvement Amendment certification and College of American Pathologists accreditation of the test at Lucid Diagnostics commercial diagnostic contract laboratory, ResearchDx Inc., headquartered in Irvine, California.

- Our CarpX device is a patented, single-use, disposable, minimally invasive device designed as a precision cutting tool to treat carpal tunnel syndrome while reducing recovery times that was cleared by the FDA under section 510(k) in April 2020 with the first commercial procedure successfully performed in December 2020.

- 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 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, or "CWRU", and for patents covering a proprietary nondispersive infrared technology to non-invasively detect glucose in tissue within the in-patient field of use from Liquid Sensing, Inc.

As discussed herein below, our current lines-of-business are as follows:

- ***GI Health*** - *EsoGuard* Esophageal DNA Laboratory Developed Test, *EsoCheck* Esophageal Cell Collection Device, and *EsoCure* Esophageal Ablation Device with Caldus Technology;

- ***Minimally Invasive Interventions*** - *CarpX* Minimally Invasive Surgical Device for Carpal Tunnel Syndrome;

- ***Infusion Therapy*** - *PortIO* Implantable Intraosseous Vascular Access Device and *NextFlo* Highly Accurate Disposable Intravenous Infusion Platform Technology; and,

- ***Emerging Innovations*** - Non-invasive laser-based glucose monitoring, single-use ventilators, resorbable pediatric ear tubes and mechanical circulatory support cannulas.

GI Health

EsoGuard, EsoCheck, and EsoCure

EsoGuard and EsoCheck are based on patented technology licensed from Case Western Reserve University ("CWRU") through our majority-owned subsidiary Lucid Diagnostics Inc. EsoGuard and EsoCheck have been developed to provide an accurate, non-invasive, patient-friendly screening test for the early detection of adenocarcinoma of the esophagus ("EAC") and Barrett's Esophagus ("BE"), including dysplasia and related pre-cursors to EAC in patients with chronic gastroesophageal reflux ("GERD"). EsoCure is based on our patented Caldus Technology. EsoCure is being developed by us 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 as an "Esophageal Ablation Device" with the intent 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. We have successfully completed a pre-clinical feasibility animal study of EsoCure demonstrating excellent, controlled circumferential ablation of the esophageal mucosal lining. We plan to conduct additional development work and animal testing of EsoCure to support a planned FDA 510(k) submission later in 2021.

We are currently marketing the EsoGuard LDT through a network of independent representatives working with our in-house sales management. The U.S. Center for Medicare and Medicaid Services ("CMS"), finalized the Clinical Laboratory Fee Schedule determination for the EsoGuard Esophageal DNA Test (CPT code 0114U) in the amount of $1,938.10, with such reimbursement expected to be applicable from January 1, 2021 to December 31, 2023. In addition, we have entered into a manufacturing agreement with medical device contract manufacturer Coastline International Inc. to serve as a high-volume, lower-cost manufacturer of the EsoCheck device.

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 use of EsoGuard together with EsoCheck as a screening system must be cleared or approved by the FDA as an in vitro diagnostic, or "IVD", device. The IVD trial consists of a screening study (ESOGUARD-BE-1) and a case control study (ESOGUARD-BE-2).In September 2019, we entered into an agreement with a clinical research organization to assist us with two ongoing clinical trials for EsoGuard as an IVD device. The IVD trial consists of a screening study (ESOGUARD-BE-1) and a case control study (ESOGUARD-BE-2). The IVD trial is now actively enrolling patients after months of delay related to the pandemic resulting from the outbreak of a novel strain of a coronavirus designated as the "Severe Acute Respiratory Syndrome Coronavirus 2" - or "SARS-CoV-2". The pandemic resulting from SARS-CoV-2 is commonly referred to by its resulting illness of "coronavirus disease-2019" ("COVID-19") - - and as such, is referred to herein as the COVID-19 pandemic.

In February 2020 we received Breakthrough Device designation for EsoGuard as an IVD device. 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.

We have received ISO 13485:2016 certification for Lucid Diagnostics quality management system and filed a European Union CE Mark regulatory submission for EsoCheck in November 2020, having confirmed that EsoGuard falls under the self-declaration category of the European Union regulatory requirements.

Minimally Invasive Interventions

CarpX

CarpX, a minimally invasive surgical device for use in the treatment of carpal tunnel syndrome, received FDA 510(k) marketing clearance in April 2020. After months of restricted access to physicians' offices and clinics principally due to the "COVID-19 pandemic, the first commercial procedure was successfully performed in December 2020. We have received ISO 13485:2016 certification for our quality management system and filed European Union ("EU") "CE Mark" regulatory submission for CarpX in December 2020.

We believe CarpX is designed to 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 CarpX, the operator first advances a guidewire through the carpal tunnel under the ligament, and then advanced over the wire and positioned in the carpal tunnel under ultrasonic and/or fluoroscopic guidance. When the CarpX 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 CarpX will be significantly less invasive than existing treatments.

We are commercializing CarpX in the United States of America ("USA", "U.S.", or "United States") through a network of independent sales representatives and/or inventory-stocking medical distributors together with our in-house sales management and marketing teams.

We may eventually choose to build (or obtain through a strategic acquisition) our own sales and marketing team to commercialize CarpX, along with 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 CarpX but outsource some or all of its distribution to a partner, particularly outside the United States, with its own robust distribution channels.

Infusion Therapy

PortIO

PortIO is a novel, patented, 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 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.

Based on encouraging animal data, and after months of delay caused by the COVID-19 pandemic, we plan to initiate a long-term (60-day implant duration) first-in-human 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 a clinical safety study in the U.S. following FDA clearance of our Investigational Device Exemption ("IDE"), submission to begin clinical testing in dialysis patients to support a future *de novo* regulatory submission.

NextFlo

NextFlo is a patented, disposable, and highly accurate infusion platform technology including intravenous "("IV)," infusion sets and disposable infusion pumps 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 U.S. 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.

We are seeking a long-term strategic partnership or acquiror. As part of a formal M&A process for NextFlo we have been working with strategic partners to complete certain testing requirements and modifications suitable for the at-home infusion market. The process is currently active with ongoing discussion occurring with multiple parties while we are simultaneously progressing toward an initial FDA 510(k) submission for the NextFlo IV Infusion System planned for later in 2021.

Emerging Innovations

Emerging Innovations include 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 wide spectrum of clinical conditions, which have either been developed internally or have been presented to us by clinician innovators and academic medical institutions for consideration of a partnership to develop and commercialize these products. This collection of products includes, without limitation, initiatives in non-invasive laser-based glucose monitoring, mechanical circulatory support cannulas, single-use ventilators and resorbable pediatric ear tubes. In June 2020, we announced the execution of a letter of intent to consummate a series of agreements to develop and utilize Canon Virginia's commercial grade and scalable aqueous silk fibroin molding process to manufacture PAVmed's DisappEAR molded pediatric ear tubes for commercialization. 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.

GI Health - Gastroenterology – Opportunity, Solution, and Strategy

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.

Furthermore, we believe EsoGuard and EsoCheck (and later EsoCure, pending 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% 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.

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 the estimated 13 million high risk individuals in the U.S. 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 gel cap. 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 based on Good Laboratory Practices ("GLP") testing results included in our FDA 510(k) submission.

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.

Item 1. Business - continued

Background and Overview - continued

GI Health - Gastroenterology – Opportunity, Solution, and Strategy - continued

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 Diagnostics 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 ("EoE")

In March 2020, we entered into a clinical trial research agreement with the University of Pennsylvania ("Penn") for an ongoing clinical trial designed to evaluate whether the Lucid Diagnostics 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 ongoing clinical 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.

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 September 2019, we entered into an agreement with a clinical research organization to assist us with two ongoing clinical trials for EsoGuard as an IVD device, which after months of delay due to the COVID-19 pandemic are now actively enrolling patients and consist of a screening study (ESOGUARD-BE-1) and a case control study (ESOGUARD-BE-2).

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

Near-Term 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.

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.

Item 1. Business - continued

Background and Overview - continued

GI Health - Gastroenterology – Opportunity, Solution, and Strategy - continued

Near-Term Strategy - Laboratory Developed Test - "LDT"

EsoGuard is an approved "Laboratory Developed Test" ("LDT") and became commercially available in December 2019 after completing CLIA/CAP certification of the test at Lucid Diagnostics commercial diagnostic laboratory partner ResearchDx, headquartered in Irvine, CA.

As noted, EsoGuard is an approved "LDT". A LDT is a clinical laboratory test which is designed, manufactured, and used within a single-source 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.

Near-Term Strategy - 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.

The U.S. Center for Medicare and Medicaid Services ("CMS"), finalized the Clinical Laboratory Fee Schedule determination under the gapfill process for the EsoGuard Esophageal DNA Test, CPT code 0114U "Gastroenterology (Barrett's esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus," in the amount of $1,938.10, with such reimbursement expected to be applicable from January 1, 2021 to 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.

Near-Term Strategy - Reimbursement Strategy - 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.

Near-Term Strategy - Reimbursement Strategy - 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 use of EsoGuard together with EsoCheck as a screening system must be cleared or approved by the FDA as an in vitro diagnostic ("IVD"), device. In September 2019, we entered into an agreement with a clinical research organization to assist us with two ongoing clinical trials for EsoGuard as an IVD device, which are actively enrolling patients and consist of a screening study (ESOGUARD-BE-1) and a case control study (ESOGUARD-BE-2).

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 - "IVD"

In-Vitro Diagnostics - "IVD" - 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.

Lucid Diagnostics Inc. and the CWRU License Agreement

Lucid Diagnostics Inc.

Lucid Diagnostics Inc. is a majority-owned consolidated subsidiary of PAVmed Inc., upon its formation in May 2018, issued an initial 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 shares to PAVmed Inc.; 943,464 shares to CWRU; and 289,679 shares to each of the three individual physician inventors of the of the intellectual property and proprietary technologies underlying the License Agreement with Case Western Reserve University ("CWRU License Agreement - as discussed below). In January 2020, an additional 3,333 shares of common stock of Lucid Diagnostics Inc. were issued to an unrelated third-party consultant upon the exercise for cash at $1.50 per share of a corresponding number of stock options issued under the Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan. As of December 31, 2020, there are 10,003,333 shares of common stock of Lucid Diagnostics Inc. issued and outstanding, with 81.85% of such shares held by PAVmed Inc.

CWRU License Agreement

In May 2018, Lucid Diagnostics entered into a License Agreement with Case Western Reserve University ("CWRU License Agreement"). Under the terms of the CWRU License Agreement, we acquired an exclusive worldwide right to the use of the intellectual property rights to the proprietary technology underlying EsoGuard and EsoCheck with respect to the detection of changes in the esophagus. CWRU retains the right to grant licenses to such intellectual property for other non-overlapping uses.

The CWRU License Agreement requires Lucid Diagnostics Inc. to achieve certain milestones with respect to regulatory filings and clearances and commercialization of products and services. In this regard, in , 2019, the Company recognized a $75,000 research and development expense in connection with a regulatory clearance milestone, which was paid in 2019. The CWRU License Agreement was amended to: change the achievement date of commercialization milestone from November 2020 to August 2021; to eliminate the payment with respect to the commercialization milestone; and to add a non-refundable payment to CWRU in consideration for the aforementioned changes to the commercialization milestone ("CWRU License Agreement Amendment"). In connection with such CWRU License Agreement Amendment, the Company recognized $100,000 of general and administrative expense, with such expense included in accrued expenses as of December 31, 2020. If the Company does not meet the remaining commercialization and regulatory clearance milestones listed in the CWRU License Agreement, then CWRU has the right, in its sole discretion, to require PAVmed Inc. to transfer to CWRU 80% of the shares of common stock of Lucid Diagnostics Inc. then held by PAVmed Inc. Such contingent milestone payments will be recognized in the period in which such payment obligations are incurred.

Lucid Diagnostics Inc. is required to pay a minimum annual royalty of a percentage of recognized net sales revenue resulting from the commercialization of the products and /or services developed using the CWRU License Agreement intellectual property, with the minimum amount of royalty payments based on net sales of such products and services, if any.

Under the CWRU License Agreement, Lucid Diagnostics 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 Diagnostics expense, in any country requested by Lucid Diagnostics, 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 Diagnostics will have no rights under any the patents in such countries unless Lucid Diagnostics 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 CWRU License Agreement, Lucid Diagnostics will have the first right to commence an action against the infringer. Lucid Diagnostics 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 Diagnostics to indemnify CWRU and certain related parties for any claims relating to product liability or similar claims involving acts or omissions by Lucid Diagnostics in connection with the EsoGuard technology and the development, use or sale of products based on such technology, or relating to Lucid Diagnostics 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 Diagnostics 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 Diagnostics Inc. 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 are currently marketing the EsoGuard LDT through a network of independent representatives working with our in-house sales management. 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 is being 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. In addition, we have entered into a manufacturing agreement with medical device contract manufacturer Coastline International Inc. to serve as a high-volume, lower-cost manufacturer of the EsoCheck device.

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.

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.

EsoGuard and EsoCheck Competition **-** continued

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, 2020 and 2019, and there are no material expenditures planned for such purposes for the year ended December 31, 2021.

Item 1. Business - continued

Background and Overview - continued

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.

Item 1. Business - continued

Background and Overview - continued

Minimally Invasive Interventions - continued

Regulatory History

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.. 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. .. 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

We received FDA marketing clearance under section 510(k) in April 2020 for our CarpX minimally invasive surgical device for use in the treatment of carpal tunnel syndrome and after months of delay caused by the COVID-19 pandemic, the first commercial procedure was successfully performed in December 2020. We are commercializing CarpX 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 CarpX, and other high margin products and services, is 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.

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 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 longer term vascular access under *de novo* classification of section 513(f)2 of the FDCA. The broader 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. 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. Based on this encouraging animal data, we are preparing to initiate a long-term (60-day implant duration) first-in-human 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 a clinical safety study in the U.S. following FDA clearance of our Investigational Device Exemption (“IDE”), submission to begin clinical testing in dialysis patients to support a future *de novo* regulatory submission.

NextFlo – Highly-Accurate Disposable Infusion Platform Technology

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.

Item 1. Business - continued

Background and Overview - continued

Infusion Therapy – PortIO and NextFlo - continued

NextFlo – Highly-Accurate Disposable Infusion Platform Technology - continued

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 platform technology includes 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 and we are simultaneously preparing an initial FDA 510(k) submission for the NextFlo IV Infusion Set

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 resorbable 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 in June 2020, we announced the execution of a letter of intent to consummate a series of agreements to develop and utilize Canon Virginia's commercial grade and scalable aqueous silk fibroin molding process to manufacture PAVmed's DisappEAR molded pediatric ear tubes for commercialization.

Noninvasive Glucose Monitoring

Solys Diagnostics Inc.

In October 2019, PAVmed incorporated Solys Diagnostics Inc. ("Solys Diagnostics" or "SOLYS") and upon its formation, Solys Diagnostics, under respective Share Subscription Agreements, issued shares of common stock for $0.001 per share as follows: 8,300,000 shares to PAVmed Inc.; a total of 1,500,000 shares to Airware Inc., an unrelated third-party; of which, 810,810 of such shares are unvested and are subject-to certain performance vesting restrictions, based on the achievement of milestones; and, 200,000 shares to an unrelated third-party consultant. The Airware equity interest in Solys Diagnostics has certain anti-dilution rights under limited circumstances and 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. Under a separate shareholders agreement under which, subject to certain conditions, PAVmed Inc. and Airware Inc. each granted the other a minority equity interest in each of its respective subsidiary, with a portion of each such equity interest unvested and subject-to certain performance vesting restrictions. As of December 31, 2020, there are 9,189,190 shares of common stock of Solys Diagnostics Inc. issued and outstanding, with 90.3% of such shares held by PAVmed Inc., and, accordingly, Solys Diagnostics Inc. is a majority-owned consolidated subsidiary of PAVmed Inc.

License Agreement with Liquid Sensing Inc.

Upon its formation, Solys Diagnostics entered into a licensing agreement with Liquid Sensing, Inc. ("Liquid Sensing"), a subsidiary formed by Airware Inc., ("Liquid Sensing License Agreement"). Under the Liquid Sensing License Agreement, Solys Diagnostics was granted an exclusive worldwide license for six issued and one pending U.S. patents covering a proprietary nondispersive infrared laser technology to develop and commercialize such proprietary technology to non-invasively monitor tissue concentrations of glucose and other substances within the inpatient (*e.g.*, hospital) field of use.

In addition to advancing the research and development plan contemplated in the Liquid Sensing License Agreement, Solys Diagnostics, with the full knowledge of Liquid Sensing and Airware Inc., has been developing and advancing its own proprietary technology to non-invasively monitor tissue concentrations of glucose and other substances, which is not subject to the Liquid Sensing License Agreement. Although the research and development plan was completed by the milestone date specified in the Liquid Sensing License Agreement and produced data in human volunteers and a diabetic rat model consistent with such milestone accuracy parameters, PAVmed Inc. and Solys Diagnostics have determined it would be in the best interests of the shareholders of PAVmed Inc. for: Solys Diagnostics to focus exclusively on the Solys Diagnostics proprietary technology; and, to terminate the Liquid Sensing License Agreement, and to seek a mutually agreeable unwinding of the relationship.

Item 1. Business - continued

Background and Overview - continued

Emerging Innovations - continued

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.

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

We received FDA marketing clearance under section 510(k) in April 2020 for our CarpX minimally invasive surgical device for use in the treatment of carpal tunnel syndrome and launched the device commercially in August 2020 with the first commercial procedure successfully performed in December 2020.

We completed European Union (EU) CE Mark regulatory submissions for EsoCheck in November 2020, CarpX in December 2020, and confirmed that EsoGuard falls under the self-declaration category of the EU IVDD requirements.

Recent Events - Financing Transactions

Our financing transactions in the year ended December 31, 2020, resulted in approximately $35.9 million of gross proceeds, before placement agent fees and expenses and offering costs, summarized as follows:

- We previously consummated a private placement, in November 2019, of the issue of a Senior Secured Convertible Note 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 comprised of a Series A and Series B, each with a $7.0 million face value principal, and each having a $0.7 million lender fee deducted from the cash proceeds when funded, as well as the additional payment of offering costs, inclusive of a financial advisory fee paid to the placement agent and legal fees. The Series A was funded in November 2019 and the Series B was funded in March 2020.

  We issued the November 2019 Senior Convertible Note - Series B on March 30, 2020, with a face value principal of $7.0 million, resulting in cash proceeds of $6.3 million after a $0.7 million of lender fee, and we additionally paid offering costs of $0.4 million, consisting of a financial advisory fee paid to the placement agent. As of December 31, 2020, the remaining unpaid outstanding face value principal was approximately $1.0 million, which was repaid-in-full subsequent to December 31, 2020, as discussed herein below.

- We issued a Senior Convertible Note, dated April 30, 2020, in a private placement, with a face value principal of $4.1 million, resulting in cash proceeds of $3.7 million after a $0.4 million lender fee, and we additionally paid total offering costs of $0.2 million, inclusive of a financial advisory fee paid to the placement agent and legal fees. As of December 31, 2020, the unpaid outstanding face value principal was $4.1 million, which was repaid-in-full subsequent to December 31, 2020, as discussed herein below.

- We issued a Senior Secured Convertible Note, dated August 6, 2020, in a private placement, with a face value principal of $7.75 million, resulting in cash proceeds of $7.0 million after a $0.75 million lender fee, and we additionally paid total offering costs of $0.1 million of legal fees. As of December 31, 2020, the unpaid outstanding face value principal was $7.75 million, which was repaid-in-full subsequent to December 31, 2020, as discussed herein below.

- Subsequent to December 31, 2020, on January 5, 2021, the November 2019 Senior Secured Convertible Note remaining unpaid outstanding face value principal as of December 31, 2020, was settled with the issuance of 667,668 shares of the Company's common stock with a fair value of approximately $1.7 million (with such fair value measured as the respective conversion date quoted closing price of our common stock), with such final conversion resulting in the November 2019 Senior Secured Convertible Note being paid-in-full as of January 5, 2021.

- Subsequent to December 31, 2020: on January 30, 2021, we paid in cash a $0.3 million partial principal repayment of the April 2020 Senior Convertible Note; and on March 2, 2021, we paid in cash a total of $14.5 million of principal repayments, resulting in both the April 2020 Senior Convertible Note and the August 2020 Senior Convertible Note being repaid-in-full as of such date.

Recent Events - Financing Transactions - continued

- In December 2020, we issued a total of 10,647,500 shares of our common stock for gross proceeds of $17.0 million, with cash proceeds of $16.0 million after the payment of a placement agent fee of approximately $1.0 million, and we additionally paid offering costs of $0.1 million. The shares of our common stock were issued in two registered direct offerings each in December 2020, pursuant to respective Prospectus Supplement dated December 11, 2020 and December 18, 2020, each with respect to our effective shelf registration statement on Form S-3 (File No. 333-248709).

- Subsequent to December 31, 2020, on January 5, 2021, we issued 6,000,000 shares of our common stock for gross proceeds of $13.4 million, with cash proceeds of $12.4 million, after the payment of $0.9 million of a placement agent fee and expenses, and we additionally paid offering costs of $0.1 million. The shares of our common stock were issued in a registered direct offering, pursuant to a Prospectus Supplement dated January 5, 2021 with respect to our effective shelf registration statement on Form S-3 (File No. 333-248709).

- Subsequent to December 31, 2020, on February 23, 2021 we issued 9,782,609 shares of our common stock for proceeds of $41.6 million, before underwriter expenses of $0.1 million, and we additionally incurred estimated offering costs of $0.4 million. The shares of our common stock were issued in an underwritten registered offering pursuant to a final Prospectus Supplement dated February 23, 2021 with respect to our effective shelf registration statement on Form S-3 (File No. 333-248709 and File No. 253384).

- Subsequent to December 31, 2020, as of March 12, 2021, a total of 773,842 Series Z Warrants were exercised for cash at a $1.60 per share of our common stock, resulting in the issue of a corresponding number of shares of our common stock.

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 for each product under development 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 regulatory 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. Due to this virtual business model, the Company was able to continue to move its products thru engineering and regulatory development despite the general overall industry slowdown caused by the COVID-19 pandemic.

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 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.

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 products with large market opportunities such as CarpX and EsoGuard/EsoCheck, 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 plan to increase our research and development expenses for the foreseeable future as we continue development of our products Our current research and development activities are focused principally on obtaining FDA approval and clearance and initializing commercialization of the other lead products in our product portfolio pipeline, such as EsoGuard IVD, NextFlo, and PortIO, while advancing DisappEAR and glucose monitoring through development. The research and development activities on the other portfolio products is commensurate with available sufficient capital resources.

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 Inc., 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.

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.

On May 12, 2018, we entered into a license agreement with Case Western Reserve University ("CWRU") - the "CWRU License Agreement" - wherein we acquired an exclusive worldwide right to use the intellectual property rights to the EsoGuard and EsoCheck proprietary technology for the detection of changes in the esophagus.

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, 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 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 July 2019, the USPTO issued patent number 10,335,189 related to our other commercially available product, CarpX. Although this patent does not expire until 2039, we have filed other pending patents which can further expand the protection of our intellectual property for this minimally-invasive carpal tunnel surgical device.

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.

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.

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.

Government Regulation - continued

FDA Regulation - continued

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.

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.

Government Regulation - continued

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 non-covered 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) which was scheduled to go into effect on May 26, 2020 has been extended by one year to May 26, 2021. 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.

Employees

Currently, we have twenty five full-time compensated employees, inclusive of our of Chairman of the Board of Directors and Chief Executive Officer ("CEO"), our President and Chief Financial Officer ("CFO"), and our Chief Medical Officer ("CMO") (with each comprising our named executive officers).. 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 corporate 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 including: Dr. Lishan Aklog M.D., Michael J. Glennon, and Dr. 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.

PAVmed Inc. was founded to be a multi-product company with access to public capital markets. We believe this model allows us to conceive, develop and commercialize our pipeline of laboratory developed tests, diagnostic devices and services, and medical device products based on a model of efficient capital investment and time-to-market, as well as provide a pathway to incorporate outside innovations.

Available Information

We make available free of charge through our website - www.pavmed.com - our periodic reports and registration statements filed with the United States Securities and Exchange Commission ("SEC"), including 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 named executive officers, directors, and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after 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 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 or furnish with and /or submit to 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.

Risks Associated with Our Business

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;
- Commercialize our new products and services;
- Achieve market acceptance of our products and services;
- Establish and expand our sales, marketing, and distribution capabilities for our products and services;
- protect our intellectual property rights or defend, in litigation or otherwise, any claims we infringe third-party patents or other intellectual property rights;
- invest in businesses, products and technologies, although we currently have no commitments or agreements relating to do so.
- Otherwise fund our operations;

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.

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.

Risks Associated with Our Business - continued

We have finite resources, which may restrict our success in commercializing our current products and other products we may develop, and we may be unsuccessful in entering into or maintaining third-party arrangements to support our internal efforts.

To grow our business as planned, we must expand our sales, marketing and customer support capabilities, which will involve developing and administering our commercial infrastructure and/or collaborative commercial arrangements and partnerships. We must also maintain satisfactory arrangements for the manufacture and distribution of our tests and other products. Also, we partner with CLIA-certified lab facilities to process our tests and provide patient results.

We have only three products, EsoGuard, EsoCheck and CarpX, that are commercially available for sale, and have not generated substantial revenue from product sales to date. We have limited experience managing a sales force, customer support operation, manufacturing and clinical laboratory operations for multiple products in multiple locations with divergent regulatory requirements. We may encounter difficulties retaining and managing the specialized workforce these activities require. We may seek to partner with others to assist us with any or all of these functions. Additionally, we may be unable to find appropriate third parties with whom to enter into these arrangements.

Our sales efforts are growing in size and complexity including recruiting and hiring selling resources throughout the United States, supporting those efforts with marketing materials sufficient to attract physicians and patients to our products, and then duplicating those efforts outside the United States either with distributor relationships or hired employees. We must coordinate among our internal sales teams, as well as our partners', to ensure that we are effectively marketing our tests and other products while being fully compliant with all relevant healthcare regulations.

If we are unable to deploy and maintain effective sales, marketing and medical affairs capabilities, we will have difficulty achieving market awareness and selling our tests and other products.

To achieve commercial success for our EsoGuard test and our EsoCheck and CarpX products, as well as any products we develop in the future, we must continue to develop and grow our sales, marketing and medical affairs organizations to effectively explain to healthcare providers the reliability, effectiveness and benefits of our current and future tests and other products as compared to alternatives. We may not be able to successfully manage our dispersed or inside sales forces or our sales force may not be effective. Because of the competition for their services, we may be unable to hire, partner with or retain additional qualified sales representatives or marketing or medical affairs personnel, either as our employees or independent contractors or through independent sales or other third-party organizations. Market competition for commercial, marketing and medical affairs talent is significant, and we may not be able to hire or retain such talent on commercially reasonable terms, if at all.

Establishing and maintaining sales, marketing and medical affairs capabilities will be expensive and time-consuming. Our expenses associated with maintaining our sales force may be disproportional compared to the revenues we may be able to generate on sales of our EsoGuard tests, our EsoCheck and CarpX products or any future tests or other products.

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.

Risks Associated with Our Business - continued

Our products may never achieve market acceptance.

To date, we have not generated sales revenues from our products and services. Our ability to generate sales revenues from product and services, and to achieve profitability will depend upon our ability to successfully commercialize our products and services. As we only recently began to market our first product and service for sale, we have no basis to predict whether our current product and service (or potential future products and services) 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 services and market entry compared to competitive products;
- the effectiveness of our products and services, including any potential side effects, as compared to alternative treatments;
- the rate of adoption of our products and services by hospitals, doctors and nurses and acceptance by the health care community;
- the labeling and /or inserts required by regulatory authorities for each of our products and services;
- the competitive features of our products and services, including price, as compared to other similar products and services;
- the availability of insurance or other third-party reimbursement, such as Medicare, for patients using our products and services;
- the extent and success of our marketing efforts and those of our collaborators; and
- unfavorable publicity concerning our products and services or similar products and services.

Recommendations, guidelines and quality metrics issued by various organizations may significantly affect payers' willingness to cover, and healthcare providers' willingness to prescribe, our products.

Securing influential recommendations, inclusion in healthcare guidelines and inclusion in quality measures are keys to our healthcare provider and payer engagement strategies. These guidelines, recommendations and quality metrics may shape payers' coverage decisions and healthcare providers' cancer screening procedures.

As an example, the U.S. Preventative Services Task Force ("USPSTF"), a panel of primary care providers and epidemiologists and other national experts funded by the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality, makes influential recommendations on clinical preventative services. We intend to seek a USPSTF recommendation in the future for our EsoGuard test. The process of USPSTF recommendation development is lengthy, requires high quality supporting evidence for a positive recommendation, and that the outcome of any USPSTF process is uncertain. A USPSTF recommendations may have the effect of reducing screening, may not include our test in a favorable manner, or may add new technologies could have a material adverse effect on our business. Failing to achieve a high USPSTF recommendation for our tests and other products may have certain other potentially significant collateral implications as well. For instance, the ACA mandates that certain non-grandfathered health insurers cover evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of USPSTF without imposing any patient cost-sharing. Similarly, federal regulations require that Medicare Advantage plans cover "A" or "B" graded preventive services without patient cost-sharing.

Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment and value-based purchasing of healthcare services. Some government and private payers are adopting pay-for-performance programs that differentiate payments for healthcare services based on the achievement of documented quality metrics, cost efficiencies or patient outcomes. Payers may look to quality measures such as the National Committee for Quality Assurance ("NCQA"), Healthcare Effectiveness Data and Information Set ("HEDIS") and the CMS Medicare Advantage Star Ratings to assess quality of care. These measures are intended to provide incentives to service providers to deliver the same or better results while consuming fewer resources. If our tests or other products are not included in HEDIS, the Star Ratings or other quality metrics, payers may be less inclined to reimburse our tests or other products at adequate levels, if at all, which could adversely impact our business. Additionally, if our tests or other products are not included in HEDIS, the Star Ratings or other quality metrics, healthcare providers may not earn quality credit for prescribing Cologuard and therefore may be less inclined to do so.

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

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

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

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

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

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

Risks Associated with Our Business - continued

We currently expect to perform our EsoGuard test in one laboratory facility. If demand for our EsoGuard test grows, we may lack adequate facility space and capabilities to meet increased processing requirements. Moreover, if these or any future facilities or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.

We currently perform the EsoGuard test in a single laboratory facility in Irvine, California. The laboratory facility, without purchasing additional lab equipment applicable to our test, is expected to have an annual capacity of approximately 50,000 tests per year. If demand for the EsoGuard test outstrips this capacity, and the laboratory fails to add additional equipment and staff, or complete, or timely complete, an expansion of its available laboratory facilities, it may significantly delay our EsoGuard processing times and limit the volume of EsoGuard tests we can process, which may adversely affect our business, financial condition and results of operation. In addition, our financial condition may be adversely affected if they are unable to complete these expansion projects on budget and otherwise on terms and conditions acceptable to us. Finally, our financial condition will be adversely affected if demand for our products and services does not materialize in line with our current expectations and if, as a result, we end up building excess capacity that does not yield a reasonable return on our investment.

If our present, or any future, laboratory facilities were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, storms, tornadoes, other inclement weather events or natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, our business could be severely disrupted. We may not be able to perform our EsoGuard test or generate test reports as promptly as patients and healthcare providers require or expect, or possibly not at all. If we are unable to perform our EsoGuard test or generate test reports within a timeframe that meets patient and healthcare provider expectations, our business, financial results and reputation could be materially harmed.

We currently maintain insurance against damage to our property and equipment and against business interruption, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

Our future performance will depend in part 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.

Risks Associated with Our Business - continued

Our products and services 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.

Risks Associated with Our Business - continued

Our products and services 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 our current products and services or any we may develop will prove safe enough to receive regulatory approval. Undesirable side effects caused by our products and services or 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, even after receipt of marketing approval of our products and services, 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 our current products and services and any we may additionally 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.

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.

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

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

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

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

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

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

Risks Associated with Our Business - continued

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;
- health epidemics and /or pandemics, such as the epidemics resulting from the Ebola virus, or the enterovirus, or the avian influenza virus, or the pandemic resulting from a novel strain of a coronavirus designated “Severe Acute Respiratory Syndrome Coronavirus 2” - or “SARS-CoV-2”, 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.

Any future products or services 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 cell sample collection device and our CarpX minimally invasive surgical device. 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.

Risks Associated with Our Business - continued

Our business may be adversely affected by health epidemics and or pandemics, including the pandemic resulting from the "Severe Acute Respiratory Syndrome Coronavirus 2" - "SARS-CoV-2" - and the resulting illness of "Coronavirus Disease 2019" - "COVID-19".

Previously, in 2019, an outbreak of a novel strain of a coronavirus occurred, with such coronavirus designated by the United Nations (UN) World Health Organization ("WHO") as the "Severe Acute Respiratory Syndrome Coronavirus 2" - or "SARS-CoV-2" - which spread on a global basis to other countries, including the United States of America ("USA" "U.S." or "United States"). On March 11, 2020, the WHO declared a pandemic resulting SARS-CoV-2, with such pandemic commonly referred to as the "COVID-19 pandemic" after the resulting illness of "coronavirus disease-2019" ("COVID-19"), and is thus referred to herein as the "COVID-19 pandemic". The COVID-19 pandemic is ongoing, and we continue to monitor the ongoing impact of the COVID-19 pandemic on the United States national economy, the global economy, and our business.

The COVID-19 pandemic may have an adverse impact on our operations, supply chains, and distribution systems and /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 being taken, restrictions on travel, quarantine polices, and social distancing. Such adverse impact may include, for example, the inability of our employees and /or those of our contractors or laboratory partner to perform their work or curtail their services provided to us.

We expect the significance of the COVID-19 pandemic, including the extent of its effect on our consolidated financial condition and consolidated operational results and cash flows, to be dictated by the success of United States and global efforts to mitigate the spread of and /or to contain the SARS-CoV-2 and the impact of such efforts.

In addition, the spread of the SARS-CoV-2 has disrupted the United States' healthcare and healthcare regulatory systems which could divert healthcare resources away from, or materially delay United States Food and Drug Administration ("FDA") approval with respect to our products.

Furthermore, our clinical trials have been and may be further affected by the COVID-19 pandemic, as site initiation and patient enrollment may be delayed, for example, due to prioritization of hospital resources toward the virus and /or illness response, as well as travel restrictions imposed by governments, and the inability to access clinical test sites for initiation and monitoring.

The COVID-19 pandemic may have an adverse impact on the economies and financial markets of many countries, including the USA, resulting in an economic downturn that could adversely affect demand for our products and services and /or our product candidates.

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 pandemic (or a similar health epidemic) is highly uncertain and subject to change, and therefore, its impact on our consolidated financial condition, consolidated results of operations, and /or consolidated cash flows, the adverse impact could be material.

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.

We are and may become the subject of various claims, threats of litigation, litigation or investigations which could have a material adverse effect on our business, financial condition, results of operations or price of our common stock.

We are and may become subject to various claims, threats of litigation, litigation or investigations, including commercial disputes and employee claims, and from time to time may be involved in governmental or regulatory investigations or similar matters. Any claims asserted against us or our management, regardless of merit or eventual outcome, could harm our reputation and have an adverse impact on our relationship with our clients, distribution partners and other third parties and could lead to additional related claims. Furthermore, there is no guarantee that we will be successful in defending ourselves in pending or future litigation or similar matters under various laws. Any judgments or settlements in any pending litigation or future claims, litigation or investigation could have a material adverse effect on our business, financial condition, results of operations and price of our common stock.

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.

Risks Related to Government Regulation - continued

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

We intend to seek distribution and marketing partners in foreign countries for our products and services and any we may develop in the future, if any. 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.

Risks Related to Government Regulation - continued

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 Related to Government Regulation - 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 Related to Government Regulation - continued

If required, clinical trials necessary to support a FDA 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 FDA 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.

Risks Related to Government Regulation - continued

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

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

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

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

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

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

Risks Related to Government Regulation - continued

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 Related to Government Regulation - 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 Related to Government Regulation - 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 150,000,000 shares of common stock, par value $.001 per share, and 20,000,000 shares of preferred stock, par value $.001 per share. We may issue a substantial number of additional shares of our common stock or preferred stock, or a combination of common and preferred stock, to raise additional funds or in connection with any strategic acquisition. The issuance of additional shares of our common stock or any number of shares of our preferred stock:

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

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, 2020, our management and their affiliates collectively own approximately 10% of our issued and outstanding shares of common stock. Accordingly, these individuals would have considerable influence regarding the outcome of any transaction that requires stockholder approval. Furthermore, our Board of Directors is and will be divided into three classes, each of which will generally serve for a term of three years with only one class of directors being elected in each year. As a consequence of our “staggered” Board of Directors, only a minority of the Board of Directors will be considered for election in any given year and our initial stockholders, because of their ownership position, will have considerable influence regarding the outcome.

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

There can be no assurance that we will be able to continue to meet Nasdaq Capital Market listing standards. If we are unable to maintain compliance with all applicable listing standards, our common stock may no longer be listed on the Nasdaq Capital Market or another national securities exchange and the liquidity and market price of our common stock may be adversely affected.

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.

Risks Associated with Ownership of Our Common Stock - continued

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:

- factors in the public trading market for our stock that may produce price movements that may or may not comport with macro, industry or company-specific fundamentals, including, without limitation, the sentiment of retail investors (including as may be expressed on financial trading and other social media sites and online forums), the direct access by retail investors to broadly available trading platforms, the amount and status of short interest in our securities, access to margin debt, trading in options and other derivatives on our common stock and any related hedging and other trading factors
- speculation in the press or investment community about our company or industry
- 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 March 12, 2021, in addition to 82,460,720 shares of our common stock issued and outstanding, we had outstanding and reserved for issuance, but not subject to outstanding stock-based equity awards, as follows:

(i) stock options to purchase 7,023,529 shares of our common stock at a weighted average exercise price of $2.53 per share, under the PAVmed Inc. 2014 Long-Term Incentive Equity Plan ("PAVmed Inc. 2014 Equity Plan");and 1,778,406 shares of our common stock reserved for issuance, but not subject to outstanding stock-based equity awards under the PAVmed Inc. 2014 Equity Plan; and 360,673 shares of our common stock reserved for issuance under the PAVmed Inc. Employee Stock Purchase Plan ("PAVmed Inc. ESPP")

(ii) common stock purchase warrants to purchase 16,422,915 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 Convertible Preferred Stock of 1,252,273 shares, convertible, at the holders election, into a corresponding number of shares of our common stock;

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) December 31, 2021, which is the last day of the fiscal year following the fifth anniversary of the first sale of our common stock pursuant to the effective SEC Registration Statement on Form S-1 in connection with our initial public offering ("IPO") of our common stock on April 14, 2016; (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion; (3) the date on which we have, during a previous three year period, issued more than $1.07 billion in non-convertible debt; or (4) the date on which we are deemed to be a "large accelerated filer", which means the market value of our common stock held by non-affiliates (the "public float") exceeds $700.0 million as of June 30 of the prior year; and

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.

Risks Associated with Ownership of Our Common Stock - continued

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.

Risks Associated with Ownership of Our Common Stock - continued

We identified a material weakness in our internal control over financial reporting, which we subsequently remediated. 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 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 documentation with an appropriate level of precision of the identified key internal control risk areas to conclude on the operating effectiveness of our disclosure controls and procedures. We performed remedial steps to improve our internal control over financial reporting. As of February 19, 2021, we determined the material weakness had been remediated. For further discussion of the material weakness identified and our remedial efforts, see Item 9A.

However, we may experience additional material weakness in the future. 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 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.

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.

Risks Associated with Ownership of Our Common Stock - continued

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 ("DGCL"), 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 corporate offices are located at One Grand Central Place, 60 East 42nd Street, Suite 4600, New York, NY 10165. The office rental agreement is currently on a month-to-month basis, and can be cancelled with two months written notice. We also have short-term office space rental agreements in each of Pennsylvania and Massachusetts. At this time, we consider the office space to be commensurate with our current operations. Notwithstanding, we may obtain additional office space in the future, as warranted by our business operations.

Item 3. Legal Proceedings

In November 2020, a stockholder of the Company, on behalf of himself and other similarly situated stockholders, filed a complaint in the Delaware Court of Chancery alleging broker non-votes were not properly counted in accordance with the Company's bylaws at the Company's Annual Meeting of Stockholders on July 24, 2020, and, as a result, asserted certain matters deemed to have been approved were not so approved (including matters relating to the increase in the size of the 2014 Equity Plan and the ESPP). The relief sought under the complaint includes certain corrective actions by the Company, but does not seek any specific monetary damages. The Company does not believe it is clear the prior approval of these matters is invalid or otherwise ineffective. However, on January 5, 2021, the Company's Board of Directors determined, in order to avoid any uncertainty and to avoid the cost and expense of further litigation of the issue, it would be advisable and in the best interests of the Company and its stockholders to re-submit these proposals to the Company's stockholders for ratification and/or approval. In this regard, the Company held a special meeting of stockholders on March 4, 2021, at which such matters were ratified and approved. The parties have reached agreement on a proposed term sheet to settle the complaint, the terms of which do not contemplate payment of monetary damages to the putative class in the proceeding. The settlement of the complaint is pending and is subject to court approval.

On December 23, 2020, Benchmark Investments, Inc. filed a complaint against the Company in the U.S. District Court of the Southern District of New York alleging the registered direct offerings of shares of common stock of the Company completed in December 2020 were in violation of provisions set forth in an engagement letter between the Company and the plaintiff. The plaintiff is seeking monetary damages of up to $1.3 million. The Company disagrees with the allegations set forth in the complaint and intends to vigorously contest the complaint.

Additionally, 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 12, 2021, there were 82,460,720 shares of our common stock outstanding. Our shares of common stock are held by an estimated 9,000 holders of record and we believe our shares of common stock are held by more than beneficial owners.

Dividends

Common Stock

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.

Series B Convertible Preferred Stock

The Series B Convertible Preferred Stock is issued pursuant to 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”), has a par value of $0.001 per share, no voting rights, a stated value of $3.00 per share, and at the holders’ election, shares of Series B Convertible Preferred Stock is immediately convertible upon issuance into a corresponding number of shares of common stock of PAVmed Inc.

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

During the year ended December 31, 2020, the Company’s board-of-directors declared Series B Convertible Preferred Stock dividends, earned as of December 31, 2019, March 31, 2020, June 30, 2020, and September 30, 2020, of an aggregate of approximately $284,000, which were settled by the issue of an additional aggregate 94,866 shares of Series B Convertible Preferred Stock.

During the prior year ended December 31, 2019, the Company’s board-of-directors declared of Series B Convertible Preferred Stock dividends earned as of December 31, 2018, March 31, 2019, June 30, 2019, and September 30, 2019, of an aggregate of approximately $265,000 which were settled by the issue of an additional aggregate 88,268 shares of Series B Convertible Preferred Stock.

Subsequent to December 31, 2020, in January 2021, the Company’s board-of-directors declared a Series B Convertible Preferred Stock dividend earned as of December 31, 2020 and payable as of January 1, 2021, of approximately $73,000 to be settled by the issue of an additional 24,198 shares of Series B Convertible Preferred Stock

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

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, 2020.

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 Inc. and Subsidiaries ("PAVmed" or "the Company") is a highly differentiated, multi-product, commercial-stage 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 currently organized as "GI Health", "Minimally Invasive Interventions", "Infusion Therapy", and "Emerging Innovations". The Company has ongoing operations conducted through PAVmed Inc. and its majority-owned subsidiaries of Lucid Diagnostics, Inc. ("Lucid Diagnostics" or "LUCID"), and Solys Diagnostics, Inc. ("Solys Diagnostics" or "SOLYS").

PAVmed Inc. and /or 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.

Our multiple products and services are in various phases of development, regulatory clearances, approvals, and commercialization.

- The EsoCheck device received 510(k) marketing clearance from the U.S. Food and Drug Administration ("FDA"), in June 2019 as an esophageal cell collection device; and, 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 accreditation of the test at Lucid Diagnostics commercial diagnostic laboratory partner ResearchDx Inc., headquartered in Irvine, California.

- Our CarpX device is a patented, single-use, disposable, minimally-invasive surgical device designed as a precision cutting tool to treat carpal tunnel syndrome while reducing recovery times that was cleared by the FDA under section 510(k) on April 2020 and was launched commercially in August 2020 with the first commercial procedure successfully performed in December 2020.

- 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 United States 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; the intellectual property licensed from Case Western Reserve University ("CWRU") underlying the technology developed for the EsoGuard diagnostic LDT and the EsoCheck cell sample collection device; and for patents covering a proprietary nondispersive infrared technology to non-invasively detect glucose in tissue within the in-patient field of use from Liquid Sensing, Inc. (an unrelated third-party).

Overview - continued

As discussed herein below, our current lines-of-business are as follows:

- ***GI Health*** - *EsoGuard* Esophageal DNA Laboratory Developed Test, *EsoCheck* Esophageal Cell Collection Device, and *EsoCure* Esophageal Ablation Device with Caldus Technology;

- ***Minimally Invasive Interventions*** - *CarpX* Minimally Invasive Surgical Device for Carpal Tunnel Syndrome;

- ***Infusion Therapy*** - *PortIO* Implantable Intraosseous Vascular Access Device and *NextFlo* Highly Accurate Disposable Intravenous Infusion Platform Technology; and,

- ***Emerging Innovations*** - Non-invasive laser-based glucose monitoring, single-use ventilators, resorbable pediatric ear tubes and mechanical circulatory support cannulas.

GI Health

EsoGuard, EsoCheck, and EsoCure

EsoGuard and EsoCheck are based on patented technology licensed from Case Western Reserve University ("CWRU") through our majority-owned subsidiary Lucid Diagnostics Inc. EsoGuard and EsoCheck have been developed to provide an accurate, non-invasive, patient-friendly screening test for the early detection of adenocarcinoma of the esophagus ("EAC") and Barrett's Esophagus ("BE"), including dysplasia and related pre-cursors to EAC in patients with chronic gastroesophageal reflux ("GERD"). EsoCure is based on our patented Caldus Technology developed by us 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 as an "Esophageal Ablation Device" with the intent 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. We have successfully completed a pre-clinical feasibility animal study of EsoCure demonstrating excellent, controlled circumferential ablation of the esophageal mucosal lining. We plan to conduct additional development work and animal testing of EsoCure to support a planned FDA 510(k) submission later in 2021.

We are currently marketing the EsoGuard diagnostic LDT through a network of independent representatives working with our in-house sales management. The U.S. Center for Medicare and Medicaid Services ("CMS"), finalized the Clinical Laboratory Fee Schedule determination for the EsoGuard Esophageal DNA Test (CPT code 0114U) in the amount of $1,938.10, with such reimbursement expected to be applicable from January 1, 2021 to December 31, 2023. In addition, we have entered into a manufacturing agreement with medical device contract manufacturer Coastline International Inc. to serve as a high-volume, lower-cost manufacturer of the EsoCheck device.

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 use of EsoGuard together with EsoCheck as a screening system must be cleared or approved by the FDA as an in vitro diagnostic ("IVD"), device. In September 2019, we entered into an agreement with a clinical research organization to assist us with two ongoing clinical trials for EsoGuard as an IVD device, which are actively enrolling patients and consist of a screening study (ESOGUARD-BE-1) and a case control study (ESOGUARD-BE-2).

Overview - continued

GI Health - continued

In February 2020, we received a FDA "Breakthrough Device Designation" for EsoGuard as an IVD device. 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.

We have received ISO 13485:2016 certification for Lucid Diagnostics quality management system and filed a European Union CE Mark regulatory submission for EsoCheck in November 2020, having confirmed that EsoGuard falls under the self-declaration category of the European Union regulatory requirements.

Minimally Invasive Interventions

CarpX

CarpX, a minimally invasive surgical device for use in the treatment of carpal tunnel syndrome, received FDA 510(k) marketing clearance in April 2020. CarpX is a minimally invasive surgical device for use in the treatment of carpal tunnel syndrome. We launched CarpX commercially in August 2020 with the first commercial procedure successfully performed in December 2020.

We believe CarpX is designed to 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 CarpX, the operator first advances a guidewire through the carpal tunnel under the ligament, and then advanced over the wire and positioned in the carpal tunnel under ultrasonic and/or fluoroscopic guidance. When the CarpX 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 CarpX will be significantly less invasive than existing treatments.

We are commercializing CarpX 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 CarpX, and other high margin products and services, is 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 may eventually choose to build (or obtain through a strategic acquisition) our own sales and marketing team to commercialize CarpX, along with 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 CarpX but outsource some or all of its distribution to a partner, particularly outside the United States, with its own robust distribution channels.

We have received ISO 13485:2016 certification for PAVmed's quality management system and filed a European Union CE Mark regulatory submission for CarpX in December 2020.

Overview - continued

Infusion Therapy

PortIO

PortIO is a novel, patented, 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 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.

Based on encouraging animal data, we are preparing to initiate a long-term (60-day implant duration) first-in-human 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 a clinical safety study in the U.S. following FDA clearance of our Investigational Device Exemption ("IDE") submission to begin clinical testing in dialysis patients to support a future *de novo* regulatory submission.

NextFlo

NextFlo is a patented, disposable, and highly accurate infusion platform technology including intravenous, or "*IV*," infusion sets and disposable infusion pumps 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 U.S. 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.

We are seeking a long-term strategic partnership or acquiror. We have been running a formal M&A process for NextFlo targeting strategic and financial partners. The process is active with ongoing discussion with multiple parties and we are simultaneously progressing toward an initial FDA 510(k) submission for the NextFlo IV Infusion System planned for later in 2021.

Emerging Innovations

Emerging Innovations include 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 wide spectrum of clinical conditions, which have either been developed internally or have been presented to us by clinician innovators and academic medical institutions for consideration of a partnership to develop and commercialize these products. This collection of products includes, without limitation, initiatives in non-invasive laser-based glucose monitoring, mechanical circulatory support cannulas, single-use ventilators and resorbable pediatric ear tubes. In June 2020, we announced the execution of a letter of intent to consummate a series of agreements to develop and utilize Canon Virginia's commercial grade and scalable aqueous silk fibroin molding process to manufacture PAVmed's DisappEAR molded pediatric ear tubes for commercialization. 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.

Overview - continued

Financing

In the year ended December 31, 2020, we issued debt and equity resulting in approximately $35.9 million of gross proceeds, before placement agent fees and expenses and offering costs, summarized as follows:

- In a private placement, we issued a Senior Secured Convertible Notes dated November 4, 2019, 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 comprised of a Series A and Series B, each with a $7.0 million face value principal, and each having a $0.7 million lender fee deducted from the cash proceeds when funded. The Series A was funded in November 2019 and the Series B was funded in March 2020.

  We issued the November 2019 Senior Convertible Note - Series B on March 30, 2020, with a face value principal of $7.0 million, resulting in cash proceeds of $6.3 million after a $0.7 million of lender fee, and we additionally paid offering costs of $0.4 million, consisting of a financial advisory fee paid to the placement agent. As of December 31, 2020, the November 2019 Senior Convertible Notes (Series A and Series B) remaining unpaid outstanding face value principal was approximately $1.0 million, which was repaid-in-full subsequent to December 31, 2020, as discussed herein below in *Liquidity and Capital Resources*.

- We issued a Senior Convertible Note, dated April 30, 2020, in a private placement, with a face value principal of $4.1 million, resulting in cash proceeds of $3.7 million after a $0.4 million lender fee, and we additionally paid total offering costs of $0.2 million, inclusive of a financial advisory fee paid to the placement agent and legal fees. As of December 31, 2020, the unpaid outstanding face value principal was $4.1 million, which was repaid-in-full subsequent to December 31, 2020, as discussed herein below in *Liquidity and Capital Resources*.

- We issued a Senior Secured Convertible Note, dated August 6, 2020, in a private placement, with a face value principal of $7.75 million, resulting in cash proceeds of $7.0 million after a $0.75 million lender fee, and we additionally paid total offering costs of $0.1 million of legal fees. As of December 31, 2020, the unpaid outstanding face value principal was $7.75 million, of which, subsequent to December 31, 2020, which was repaid-in-full subsequent to December 31, 2020, as discussed herein below in *Liquidity and Capital Resources*.

- In December 2020, we issued a total of 10,647,500 shares of our common stock for gross proceeds of $17.0 million, with cash proceeds of $16.0 million after the payment of a placement agent fee and expenses of approximately $1.0 million, and we additionally paid offering costs of $0.1 million. The shares of our common stock were issued in two registered direct offerings pursuant to respective Prospectus Supplement dated December 11, 2020 and December 18, 2020, each with respect to our effective shelf registration statement on Form S-3 (File No. 333-248709).

- Subsequent to December 31, 2020, on January 5, 2021, we issued 6,000,000 shares of our common stock for gross proceeds of $13.4 million, with cash proceeds of $12.4 million, after the payment of $0.9 million of a placement agent fee and expenses, and we additionally paid offering costs of $0.1 million. The shares of our common stock were issued in a registered direct offering pursuant to a Prospectus Supplement dated January 5, 2021 with respect to our effective shelf registration statement on Form S-3 (File No. 333-248709).

- Subsequent to December 31, 2020, on February 23, 2021 we issued 9,782,609 shares of our common stock for proceeds of $41.6 million, before underwriter expenses of $0.1 million, and we additionally incurred estimated offering costs of $0.4 million. The shares of our common stock were issued in an underwritten registered offering pursuant to a final Prospectus Supplement dated February 23, 2021 with respect to our effective shelf registration statement on Form S-3 (File No. 333-248709 and File No. 253384).

- Subsequent to December 31, 2020, as of March 12, 2021, a total of 773,842 Series Z Warrants were exercised for cash at a $1.60 per share of our common stock, resulting in the issue of a corresponding number of shares of our common stock.

Impact of SARS-CoV-2 - COVID-19 Pandemic

Previously, in December 2019, there was an outbreak of a novel strain of a coronavirus occurred, with such coronavirus designated by the United Nations (UN) World Health Organization ("WHO") as the "Severe Acute Respiratory Syndrome Coronavirus 2" - or "SARS-CoV-2". The SARS-CoV-2 spread on a global basis to other countries, including the United States of America ("USA" "U.S." or "United States"). On March 11, 2020, the WHO declared a pandemic resulting from SARS-CoV-2, with such pandemic commonly referred to by its resulting illness of "COVID-19" ("coronavirus disease-2019"), and is referred to herein as the "COVID-19 pandemic". The COVID-19 pandemic is ongoing, and we continue to monitor the ongoing impact of the COVID-19 pandemic on the United States national economy, the global economy, and our business.

The COVID-19 pandemic may have an adverse impact on our operations, supply chains, and distribution systems and /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 being taken, restrictions on travel, quarantine polices, and social distancing. Such adverse impact may include, for example, the inability of our employees and /or those of our contractors or laboratory partner to perform their work or curtail their services provided to us.

We expect the significance of the COVID-19 pandemic, including the extent of its effect on our consolidated financial condition and consolidated operational results and cash flows, to be dictated by the success of United States and global efforts to mitigate the spread of and /or to contain the SARS-CoV-2 and the impact of such efforts.

In addition, the spread of the SARS-CoV-2 has disrupted the United States' healthcare and healthcare regulatory systems which could divert healthcare resources away from, or materially delay United States Food and Drug Administration ("FDA") approval with respect to our products.

Furthermore, our clinical trials have been and may be further affected by the COVID-19 pandemic, as site initiation and patient enrollment may be delayed, for example, due to prioritization of hospital resources toward the virus and /or illness response, as well as travel restrictions imposed by governments, and the inability to access clinical test sites for initiation and monitoring.

The COVID-19 pandemic may have an adverse impact on the economies and financial markets of many countries, including the USA, resulting in an economic downturn that could adversely affect demand for our products and services and /or our product candidates.

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 pandemic (or a similar health epidemic) is highly uncertain and subject to change, and therefore, its impact on our consolidated financial condition, consolidated results of operations, and /or consolidated cash flows, the adverse impact could be material.

Results of Operations

Overview

General and administrative expenses

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

We anticipate our general and administrative expenses will increase in the future, as we anticipate an increase in payroll and related expenses related to the roll-out of our commercial sales and marketing operations. 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, 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, including:

- 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 clinical and engineering personnel;
- costs associated with regulatory filings;
- patent license fees;
- cost of laboratory supplies and acquiring, developing, and manufacturing preclinical prototypes; and
- product design engineering studies.

We plan to incur research and development expenses for the foreseeable future as we continue the development of our existing products as well as new innovations. Our research and development activities are focused principally on obtaining FDA approvals and developing product improvements or extending the utility of the lead products in our pipeline, including CarpX, EsoCheck and EsoGuard, along with advancing our DisappEAR, PortIO, NextFlo, and non-invasive glucose monitoring products through their respective development phase.

Other Income and Expense, net

Other income and expense, net, consists principally of changes in fair value of our convertible notes, losses on extinguishment of debt upon repayment of such convertible notes; and interest expense recognized in connection with one of our convertible notes.

Year ended December 31, 2020 versus December 31, 2019

General and administrative expenses

In the year ended December 31, 2020, general and administrative costs were approximately $12.4 million, compared to $7.7 million for the year ended December 31, 2019. The net increase of $4.7 million was principally related to:

- approximately $2.3 million increase in compensation related costs principally related to sales staffing levels and other costs related to our commercial launch of EsoGuard and CarpX;
- approximately $2.0 million in consulting services related to patents, regulatory compliance, legal processes for contract review, and public company expenses; and
- approximately $0.3 million in general business expenses.

Research and development expenses

In the year ended December 31, 2020, research and development costs were approximately $11.0 million as compared to $6.6 million for the corresponding period in the prior year, with the approximate $4.4 million increase principally related to:

- approximately $4.0 million increase in clinical trial costs and outside professional and engineering services with respect to CarpX, NextFlo, Port IO, EsoGuard and our glucose monitoring product; and
- approximately $0.4 million increase in compensation related costs related to expanded clinical and engineering staff.

Other Income and Expense

Change in fair value of convertible debt

In the year ended December 31, 2020, the (non-cash) expense recognized for the change in the fair value of our convertible notes was approximately $6.0 million, inclusive of the recognition of other expense of approximately $1.9 million of lender fees incurred with respect to the convertible notes, as compared to $1.1 million for the year ended December 31, 2019, resulting in an increase of approximately $4.9 million principally related to:

- an increase in the face principal amount of our convertible notes of approximately $18.1 million, inclusive of $1.9 million in lender fees;
- among other fair value input assumptions, an increase in the Company's common stock price between the periods resulting in a higher estimated fair value of the convertible notes; and
- a total of approximately $1.9 million of lender fees recognized as other expense, inclusive of approximately $0.7 million with respect to our November 2019 Senior Secured Convertible Note - Series B ; approximately $0.4 million with respect to our April 2020 Senior Convertible Note; and approximately $0.8 million with respect to our August 2020 Senior Secured Convertible Note. These fees were $0.7 million in the corresponding prior year period with respect to our November 2019 Senior Convertible Note – Series A.

See Note 8, *Financial Instruments Fair Value Measurement*, and Note 9, *Outstanding Debt*, of our consolidated financial statements for a further discussion of the change in fair value of our convertible notes, and "—Liquidity and Capital Resources", below.

Loss from Extinguishment of Debt

In the year ended December 31, 2020, a debt extinguishment loss of approximately $6.5 million was recognized in connection with the Senior Secured Convertible Notes issued November 4, 2019 and December 27, 2018, with such debt extinguishment loss resulting from the difference between the sum of the face value principal repayments and the corresponding interest thereon as compared to the fair value of the shares of our common stock issued upon conversion of such convertible notes. In the prior year period ended December 31, 2019, a debt extinguishment loss of approximately $1.8 million was recognized in connection with the Senior Secured Convertible Note issued December 27, 2018. See Note 9, *Outstanding Debt*, of our consolidated financial statements for a further discussion of our convertible notes.

Year ended December 31, 2020 versus December 31, 2019 *- continued*

Interest Expense

The Senior Secured Convertible Notes dated Nov 4, 2019 are comprised of a Series A and Series B, each with a $7.0 million face value principal ("November 2019 Senior Convertible Notes), with the Series A previously funded on November 4, 2019 and the Notes Series B funded on March 30, 2020 (as further discussed herein below). During the period from November 2019 to its funding on March 30, 2020, the Series B incurred interest expense at 3.0% per annum based on its $7.0 million face value principal. In this regard, interest expense of approximately $0.1 million was recognized in each of the year ended December 31, 2020 and 2019 (during the period when the Series B was unfunded from November 4, 2019 to March 29, 2020).

Income Taxes

We have total estimated federal and state net operating loss ("NOL") carryforward of approximately $63 million and $40.0 million as of December 31, 2020 and 2019, respectively, which is available to reduce future taxable income, of which approximately $13.8 million have statutory expiration dates commencing in 2035, and approximately $49.2 million which do not have a statutory expiration date. The State and Local NOL carryforwards of approximately $63.0 million have statutory expiration dates commencing in 2035. We have total estimated research and development ("R&D") tax credit carryforward of approximately $0.4 million as of December 31, 2020 which are available to reduce future tax expense and have statutory expiration dates commencing in 2035. 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, 2020 and 2019.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted in response to the pandemic resulting from the outbreak of a novel strain of a coronavirus designated as the "Severe Acute Respiratory Syndrome Coronavirus 2" - or "SARS-CoV-2". The pandemic resulting from SARS-CoV-2 is commonly referred to by its resulting illness of "coronavirus disease-2019" ("COVID-19"), and is referred to herein as the COVID-19 pandemic.

Among other provisions, the CARES Act increases the limitation on the allowed business interest expense deduction from 30 percent to 50 percent of adjusted taxable income for tax years beginning January 1, 2019 and 2020 and allows businesses to immediately expense the full cost of Qualified Improvement Property, retroactive to tax years beginning on or after January 1, 2018. Additionally, the CARES Act permits net operating loss carryovers ("NOLs") and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. While we are currently evaluating the impact of these CARES Act provisions, it is not expected, at this time, to have a material impact on our consolidated income tax provision.

See our consolidated financial statements Note 13, *Income Taxes*, for additional information with respect to our income tax provision, deferred tax assets, and deferred tax liabilities.

Liquidity and Capital Resources

We have financed our operations principally through the public and private issuances of our common stock, preferred stock, common stock purchase warrants, and debt. We are subject to all of the risks and uncertainties typically faced by medical device and diagnostic and medical device companies that devote substantially all of their efforts to the commercialization of their initial product and services and ongoing R&D and clinical trials. We expect to continue to experience recurring losses from operations, and will continue to fund our operations with debt and equity financing transactions. Notwithstanding, however, together with the cash on-hand as of December 31, 2020, and the cash proceeds from the issue of shares of common stock of the Company subsequent to December 31, 2020 in January and February 2021, as discussed herein below, we expect to be able to fund our future operations for one year from the date of the issue of our consolidated financial statements as included in our Annual Report on Form 10-K for the year ended December 31, 2020.

In the year ended December 31, 2020 and 2019 we issued convertible notes and shares of our common stock, as discussed herein below, which resulted in approximately $35.9 million and $12.5 million, respectively, of gross proceeds, before placement agent fees and expenses and additional offering costs incurred by us.

Subsequent to December 31, 2020, in January and February 2021, we issued shares of our common stock for gross proceeds of approximately $55.0 million before placement agent and underwriter fees and expenses and additional offering costs incurred by us, as discussed herein below. Additionally, subsequent to December 31, 2020, we repaid-in-full the remaining outstanding principal balances of each of our convertible notes, inclusive of the "November 2019 Senior Convertible Notes" as of January 5, 2021 upon conversion into shares of our common stock; and both the "April 2020 Senior Convertible Note" and the "August 2020 Senior Convertible Note" as of March 2, 2021, upon cash repayments, each as discussed herein below.

Senior Secured Convertible Notes dated November 4, 2019 - Series A (November 4, 2019) and Series B (March 30, 2020) ("*November 2019 Senior Convertible Notes*")

We previously consummated a private placement with an accredited investor in November 2019 of the issue of a Senior Secured Convertible Note 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 comprised of a Series A and Series B, each with a $7.0 million face value principal, and each having a $0.7 million lender fee deducted from the cash proceeds when funded, as well as the payment of additional offering costs, inclusive of a financial advisory fee paid to the placement agent and legal fees.

We issued the November 2019 Senior Convertible Note - Series A on November 4, 2019, with a face value principal of $7.0 million, resulting in cash proceeds of $6.3 million after a $0.7 million lender fee, and we paid additional offering costs of $0.6 million, inclusive of a financial advisory fee paid to the placement agent and legal fees.

At the election of the holder, under its prepayment terms, the November 2019 Senior Convertible Note - Series B was issued on March 30, 2020, with a face value principal of $7.0 million, resulting in cash proceeds of $6.3 million after a $0.7 million of lender fee, and we additionally paid offering costs of $0.4 million, consisting of a financial advisory fee paid to the placement agent.

The November 2019 Senior Convertible Notes accrued interest at 7.875% per annum, upon the respective Series A and Series B being funded by the investor. During the period from November 2019 to its funding on March 30, 2020, the November 2019 Senior Convertible Notes - Series B incurred interest expense at 3.0% per annum based on its $7.0 million face value principal.

In the year ended December 31, 2020, with respect to the November 2019 Senior Convertible Notes, approximately $13.0 million of principal repayments and approximately $0.5 million of interest thereon non-installment payments were settled through the issuance of 8,854,004 shares of our common stock with a fair value of approximately $18.8 million. As of December 31, 2020, the November 2019 Senior Convertible Notes remaining unpaid outstanding face value principal was approximately $1.0 million, which was repaid-in-full subsequent to December 31, 2020, as discussed herein below.

Subsequent to December 31, 2020, on January 5, 2021, the November 2019 Senior Secured Convertible Note remaining amount due of approximately $1.0 million was settled with the issuance of 667,668 shares of the Company's common stock with a fair value of approximately $1.7 million (with such fair value measured as the respective conversion date quoted closing price of our common stock), with such final conversion resulting in the November 2019 Senior Secured Convertible Notes being paid-in-full as of January 5, 2021.

Liquidity and Capital Resources - continued

Senior Convertible Note dated April 30, 2020 - ("April 2020 Senior Convertible Note")

In April 2020, in a private placement with an accredited investor, we issued a Senior Convertible Note dated April 30, 2020, with a face value principal of $4.1 million, resulting in cash proceeds of approximately $3.7 million, after a lender fee of approximately $0.4 million (the "April 2020 Senior Convertible Note"). The April 2020 Senior Convertible Note has a contractual maturity date of April 30, 2022, and an annual interest rate of 7.875%, payable in cash on a monthly basis. As of December 31, 2020, the April 2020 Senior Convertible Note unpaid outstanding face value principal was $4.1 million, which was repaid-in-full subsequent to December 31, 2020, as discussed herein below.

Senior Secured Convertible Note dated August 6, 2020 ("August 2020 Senior Convertible Note")

In August 2020, in a private placement with an accredited investor, we issued a Senior Secured Convertible Note dated August 6, 2020, with a face value principal of $7.8 million, resulting in cash proceeds of approximately $7.0 million, after a lender fee of approximately $0.8 million (the "August 2020 Senior Secured Convertible Note"). The August 2020 Senior Secured Convertible Note has a contractual maturity date of August 5, 2022, and an annual interest rate of 7.875%, payable in cash on a monthly basis. As of December 31, 2020, the August 2020 Senior Secured Convertible Note unpaid outstanding face value principal was $7.75 million, which was repaid-in-full subsequent to December 31, 2020, as discussed herein below.

Principal Repayments - April 2020 Senior Convertible Note and August 2020 Senior Convertible Note

Subsequent to December 31, 2020: on January 30, 2021, we paid in cash a $0.3 million partial principal repayment of the April 2020 Senior Convertible Note; and on March 2, 2021, we paid in cash a total of $14.5 million of principal repayments, resulting in both the April 2020 Senior Convertible Note and the August 2020 Senior Convertible Note being repaid-in-full as of such date.

Issue of Common Stock

In the year ended December 31, 2020, we issued a total of 10,647,500 shares of our common stock for gross proceeds of $17.0 million, with cash proceeds of $15.9 million after the payment of a placement agent fee and expenses of approximately $1.0 million, and we additionally paid offering costs of $0.1 million. The shares of our common stock were issued in two registered direct offerings pursuant to a respective Prospectus Supplement dated December 11, 2020 and December 18, 2020, each with respect to our effective shelf registration statement on Form S-3 (File No. 333-248709).

Subsequent to December 31, 2020, on January 5, 2021, we issued 6,000,000 shares of our common stock for gross proceeds of $13.4 million, with cash proceeds of $12.4 million, after the payment of $0.9 million of a placement agent fee and expenses, and we additionally paid offering costs of $0.1 million. The shares of our common stock were issued in a registered direct offering, pursuant to a Prospectus Supplement dated January 5, 2021 with respect to our effective shelf registration statement on Form S-3 (File No. 333-248709).

Subsequent to December 31, 2020, on February 23, 2021 we issued 9,782,609 shares of our common stock for proceeds of $41.6 million, before underwriter expenses of $0.1 million, and we additionally incurred estimated offering costs of $0.4 million. The shares of our common stock were issued in an underwritten registered offering pursuant to a final Prospectus Supplement dated February 23, 2021 with respect to our effective shelf registration statement on Form S-3 (File No. 333-248709 and File No. 253384).

Subsequent to December 31, 2020, as of March 12, 2021, a total of 773,842 Series Z Warrants were exercised for cash at a $1.60 per share of our common stock, resulting in the issue of a corresponding number of shares of our common stock.

In the previous year ended December 31, 2019, we issued a total of 5,480,000 shares of our common stock for gross proceeds of $5.5 million, with cash proceeds of $5.4 million after the payment of a total of $0.1 million of a placement agent fee and expenses, and the payment of additional offering costs. The shares of our common stock were issued in three registered direct offerings pursuant to a respective Prospectus Supplement dated April 12, 2019, May 8, 2019, and June 25, 2019, each with respect to our effective shelf registration statement on Form S-3 (File No. 333-220549).

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 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.

Financial Instruments and Fair Value Measurements

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

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

The 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 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

Fair Value Option ("FVO") Election

The Senior Secured Convertible Notes and Senior Convertible Note 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. Notwithstanding, FASB ASC Topic 825, *Financial Instruments*, ("ASC 825") provides for the "fair value option" ("FVO") election. In this regard, ASC 825-10-15-4 provides for the 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, with changes in the estimated fair value recognized as other income (expense) in the consolidated statement of operations. In this regard, as provided for by ASC 825-10-50-30(b), the estimated fair value adjustment is presented in a single line item within other income (expense) in the consolidated statement of operations. Further, as required by ASC 825-10-45-5, to the extent a portion of the fair value adjustment is attributed to a change in the instrument-specific credit risk, such portion would be recognized as a component of other comprehensive income ("OCI"). Notwithstanding, there was no such portion of the fair value adjustment attributed to a change in the instrument-specific credit risk in the years ended December 31, 2020 and 2019.

Critical Accounting Policies and Significant Judgments and Estimates - continued

Stock-Based Compensation

Stock-based awards are made to members of the board of directors of the Company, the Company's employees 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.

In the year ended December 31, 2020, stock-based compensation is recognized in accordance with the provisions of FASB ASC Topic 718, *Compensation - Stock Compensation* ("ASC 718"), as amended by FASB Accounting Standard Update (ASU) 2018-07 ("ASU 2018-07"). The provisions of ASU 2018-07 amended ASC 718 to align the accounting for stock-based awards granted to nonemployees with the requirements for accounting for stock-based payments to employees; and to supersede the previous guidance of FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees* ("ASC 505-50"). The adoption as of January 1, 2020, of the updated provisions of ASC 718, as amended by ASU 2018-07, had no effect on the Company's consolidated financial statements.

In the year ended December 31, 2020, with respect to stock-based awards granted to members of the board of directors, employees, and non-employees, the Company recognizes stock-based compensation in accordance with the provisions of ASC 718, as amended by ASU 2018-07, wherein the grant-date estimated fair value of the stock-based award is recognized 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, as applicable, so the cumulative expense recognized is at-least equal-to-or-greater-than the estimated fair value of the vested portion of the respective stock-based award as of the reporting date.

In the previous year ended December 31, 2019, the Company recognized stock-based compensation of stock-based awards granted to members of its board of directors and employees in accordance with ASC 718, as described above; and with respect to non-employees the Company recognized stock-based compensation in accordance with previous provisions of ASC 505-50, wherein, the expense of stock-based awards granted to non-employees was recognized on a vesting date basis by 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 was not subject-to further remeasurement at subsequent reporting dates. The estimated fair value of the unvested non-employee stock options was 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 was recognized on a straight-line basis over the requisite service period, which was generally the vesting period of the respective non-employee stock-based award, with such straight-line recognition adjusted so the cumulative expense recognized was at-least equal-to-or-greater-than the estimated fair value of the vested portion of the respective stock-based award.

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 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, 2020 and 2019.

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, 2020, 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, 2020 and December 31, 2019 or recognized during the years ended December 31, 2020 and 2019. 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

Recent Accounting Standards Updates

As noted herein above, as of January 1, 2020, the Company adopted the amended guidance of ASC 718 with respect to stock-based awards granted to non-employees, as amended by ASU 2018-07, which aligned the accounting for stock-based payments to nonemployees for goods and services with the requirements for accounting for stock-based awards granted to employees under ASC 718.In this regard, ASU 2018-07 provides for stock-based payments to non-employees to be measured at the grant date fair value of the equity instruments to be provided to the nonemployee when the goods or services have been delivered. Prior to the ASU 2018-07 amendment, nonemployee share-based payments were accounted for under the superseded provisions of ASC 505-50. The adoption of such amended guidance did not have an effect on the Company's consolidated financial statements.

As of January 1, 2020, the Company adopted 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 adoption of ASU 2018-13 did not have an effect on the Company's consolidated financial statements.

As of January 1, 2020, the Company adopted the guidance of ASU 2017-11, issued by the FASB in July 2017, *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 data will adjust their basic earnings per share 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. With respect to all other entities, including the Company under its JOBS Act EGC Accounting Election, as discussed herein below, the guidance of ASU 2017-11 was effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. The adoption of the ASU 2017-11 guidance as of January 1, 2020 did not have an effect on the Company's consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40)*, ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The ASU 2020-06 amendments are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company's adoption of the ASU 2020-06 guidance as of January 1, 2021 is not expected to have an effect on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *"Income Taxes: Simplifying the Accounting for Income Taxes"*, ("ASU 2019-12"). The guidance of ASU 2019-12 removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation, and calculating income taxes in interim periods, and adds revised guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. Adoption of the guidance of ASU 2019-12 is required for annual and interim financial statements beginning after December 15, 2020. The Company's adoption of the ASU 2019-12 guidance as of January 1, 2021 is not expected to have an effect on the Company's consolidated financial statements.

FASB ASC 842, *Leases*, (ASU No. 2016-02, *Leases*, February-2016 - "ASU 2016-02"*)* which established 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, 2022 for its annual financial statement, and for interim quarterly financial statements commencing March 31, 2023.

Critical Accounting Policies and Significant Judgments and Estimates - continued

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.

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, 2020. Based on such evaluation, our principal executive officer and principal financial officer concluded our disclosure controls and procedures (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) were effective as of such date to provide reasonable assurance the 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;
- provide 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.

Due to 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 effective as of December 31, 2020.

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 - Material Weakness

As of December 31, 2019, our management concluded our system of internal control over financial reporting was not effective, due to the identification of a material weakness in our internal control over financial reporting, namely, 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.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility a material misstatement of our annual or interim consolidated financial statements would not be prevented or detected on a timely basis.

Management implemented changes during 2020 to strengthen our internal control over financial reporting. These changes addressed the identified material weakness and enhanced our overall internal control over financial reporting environment. The changes included the hiring of a consulting firm to assist us in revising our internal control documentation so that it identifies key control risk areas with sufficient precision for us to identify and test the operating effectiveness of our disclosure controls and procedures. The consulting firm assisted us with the design, documentation, evaluation of design adequacy, and testing the operational effectiveness of a revised system of internal control over financial reporting.

We believe these actions remediated the material weakness, and we intend to continue to refine those internal controls over financial reporting and monitor their effectiveness on an ongoing basis.

Changes to Internal Controls Over Financial Reporting

Except for the remediation and enhancements as described herein above, 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 year ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

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

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, 2020.

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, 2020.

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, 2020.

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, 2020.

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 (8)
3.4	Certificate of Amendment to Certificate of Incorporation, dated June 26, 2019 (10)
3.5	Certificate of Amendment to Certificate of Incorporation, dated July 24, 2020 (14)
3.6	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (11)
3.7	Certificate of Elimination - Series A Convertible Preferred Stock and Series A-1 Convertible Preferred Stock (6)
3.8	PAVmed Inc. Amended and Restated Bylaws (13)
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, M.D. (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, M.D. (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)

Item 15. Exhibits and Financial Statement Schedules - continued

Exhibit No.	Description
10.8	PAVmed Inc. Fourth Amended and Restated 2014 Long-Term Incentive Equity Plan (10)(12)
10.9	PAVmed Inc. Employee Stock Purchase Plan (10)(12)
14.1	Form of Code of Ethics (1)
21.1	List of Subsidiaries †
23.1	Consent of Marcum 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 February 1, 2017.
(3)	Incorporated by reference to the Registrant's Current Report on Form 8-K filed May 3, 2016.
(4)	Incorporated by reference to the Registrant's Current Report on Form 8-K filed July 19, 2016.
(5)	Incorporated by reference to the Registrant's Current Report on Form 8-K filed April 5, 2018.
(6)	Incorporated by reference to the Registrant's Current Report on Form 8-K/A filed April 20, 2018.
(7)	Incorporated by reference to the Registrant's Current Report on Form 8-K filed June 8, 2018.
(8)	Incorporated by reference to the Registrant's Current Report on Form 8-K filed October 2, 2018.
(9)	Incorporated by reference to the Registrant's Current Report on Form 8-K filed March 20, 2019.
(10)	Incorporated by reference to the Registrant's Definitive Proxy Statement on Schedule 14A filed June 11, 2020
(11)	Incorporated by reference to the Registrant's Current Report on Form 8-K filed June 27, 2019.
(12)	Incorporated by reference to the Registrant's Current Report on Form 8-K filed July 27, 2020.
(13)	Incorporated by reference to the Registrant's Current Report on Form 8-K filed January 15, 2021.

*	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.

March 15, 2021

By: */s/ Dennis M McGrath.*
Dennis M McGrath
President
Chief Financial Officer

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

Signature	Title	Date
/s/ Lishan Aklog, M.D. Lishan Aklog, M.D.	Chairman of the Board of Directors Chief Executive Officer (*Principal Executive Officer*)	March 15, 2021
/s/ Dennis M. McGrath Dennis M. McGrath	President Chief Financial Officer (*Principal Financial and Accounting Officer*)	March 15, 2021
/s/ Michael J. Glennon Michael J. Glennon	Vice Chairman Director	March 15, 2021
/s/ David S. Battleman M.D. David S. Battleman M.D.	Director	March 15, 2021
/s/ James L. Cox, M.D. James L. Cox, M.D.	Director	March 15, 2021
/s/ Ronald M. Sparks Ronald M. Sparks	Director	March 15, 2021
/s/ David Weild IV David Weild IV	Director	March 15, 2021

PAVMED INC.
and SUBSIDIARIES
INDEX TO 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 sheets of PAVmed Inc. and Subsidiaries (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, changes in equity (deficit) and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ Marcum LLP

Marcum LLP

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

New York, NY
March 15, 2021

PAVMED INC.
and SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(amounts in thousands except shares and per share data)

	December 31, 2020	December 31, 2019
Assets:		
Current assets:		
Cash	$ 17,256	$ 6,219
Prepaid expenses, deposits, and other current assets	1,685	328
Total current assets	18,941	6,547
Other assets	837	693
Total assets	$ 19,778	$ 7,240
Liabilities, Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,966	$ 2,353
Accrued expenses and other current liabilities	2,325	1,386
CARES Act Paycheck Protection Program note payable	300	—
Senior Secured Convertible Notes - at fair value	10,060	8,139
Senior Convertible Note - at fair value	4,600	—
Total liabilities	20,251	11,878
Commitments and contingencies (Note 7)	—	—
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value. Authorized, 20,000,000 shares; Series B Convertible Preferred Stock, par value $0.001, issued and outstanding 1,228,075 at December 31, 2020 and 1,158,209 shares at December 31, 2019	2,537	2,296
Common stock, $0.001 par value. Authorized, 150,000,000 shares; issued and outstanding, 63,819,935 shares at December 31, 2020 and 40,478,861 shares at December 31, 2019	64	41
Additional paid-in capital	87,570	47,554
Accumulated deficit	(88,275)	(53,715)
Total PAVmed Inc. Stockholders' Equity (Deficit)	1,896	(3,824)
Noncontrolling interests	(2,369)	(814)
Total Stockholders' Equity (Deficit)	(473)	(4,638)
Total Liabilities and Stockholders' Equity (Deficit)	$ 19,778	$ 7,240

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)

	Year Ended December 31,	
	2020	2019
Revenue	$ —	$ —
Operating expenses:		
General and administrative	12,388	7,665
Research and development	10,963	6,630
Total operating expenses	23,351	14,295
Loss from operations	(23,351)	(14,295)
Other income (expense):		
Interest expense	(53)	(33)
Change in fair value - Senior Secured Convertible Notes and Senior Convertible Note	(5,327)	(559)
Offering costs - Senior Secured Convertible Note and Senior Convertible Note	(660)	(550)
Debt extinguishments loss - Senior Secured Convertible Notes	(6,497)	(1,831)
Other income (expense), net	(12,537)	(2,973)
Loss before provision for income tax	(35,888)	(17,268)
Provision for income taxes	—	—
Net loss before noncontrolling interests	(35,888)	(17,268)
Net loss attributable to the noncontrolling interests	1,612	811
Net loss attributable to PAVmed Inc.	(34,276)	(16,457)
Less: Series B Convertible Preferred Stock dividends earned	(287)	(270)
Net loss attributable to PAVmed Inc. common stockholders	$ (34,563)	$ (16,727)
Per share information:		
Net loss per share attributable to PAVmed Inc. - basic and diluted	$ (0.72)	$ (0.54)
Net loss per share attributable to PAVmed Inc. common stockholders – basic and diluted	$ (0.73)	$ (0.55)
Weighted average common shares outstanding, basic and diluted	47,432,115	30,197,458

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARIES
CONSOLIDATED STATEMENT OF CHANGES IN EQUITY (DEFICIT)
for the YEAR ENDED December 31, 2020
(in thousands except shares and per share data)

	PAVmed Inc. Stockholders' Deficit							
	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Non controlling Interest	Total
	Shares	Amount	Shares	Amount				
Balance at December 31, 2019	1,158,209	$ 2,296	40,478,861	$ 41	$ 47,554	$ (53,715)	$ (814)	$ (4,638)
Issue common stock – registered offerings, net	—	—	10,647,500	11	15,921	—	—	15,932
Issue common stock upon partial conversions of Senior Secured Convertible Note	—	—	10,929,202	11	21,692	—	—	21,703
Issue common stock – exercise Series S warrants	—	—	1,199,383	1	11	—	—	12
Issue common stock – exercise Series Z warrants	—	—	100	—	—	—	—	—
Issue common stock – conversion Series B Convertible Preferred Stock	(25,000)	(43)	25,000	—	43	—	—	—
Series B Convertible Preferred Stock dividends declared	94,866	284	—	—	—	(284)	—	—
Issue common stock - Employee Stock Purchase Plan	—	—	306,555	—	357	—	—	357
Vesting of restricted stock awards	—	—	233,334	—	—	—	—	—
Stock-based compensation - PAVmed Inc. 2014 Equity Plan	—	—	—	—	1,979	—	—	1,979
Stock-based compensation - majority-owned subsidiary	—	—	—	—	13	—	52	65
Issue common stock of majority- owned subsidiary exercise of stock options	—	—	—	—	—	—	5	5
Loss	—	—	—	—	—	(34,276)	(1,612)	(35,888)
Balance at December 31, 2020	1,228,075	$ 2,537	63,819,935	$ 64	$ 87,570	$ (88,275)	$ (2,369)	$ (473)

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARIES
CONSOLIDATED STATEMENT OF CHANGES IN EQUITY (DEFICIT)
for the YEAR ENDED December 31, 2019
(in thousands except shares and per share data)

	PAVmed Inc. Stockholders' Deficit							
	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Non controlling Interest	Total
	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	1,069,941	$ 2,031	27,142,979	$ 28	$ 32,619	$ (36,993)	$ (161)	$ (2,476)
Issue common stock – registered offerings, net	—	—	5,480,000	5	5,374	—	—	5,379
Issue common stock – upon partial conversions of Senior Secured Convertible Note	—	—	7,773,110	8	8,081	—	—	8,089
Series B Convertible Preferred Stock dividends declared	88,268	265	—	—	—	(265)	—	—
Issue common stock – Employee Stock Purchase Plan	—	—	82,772	—	67	—	—	67
Stock-based compensation - PAVmed Inc. 2014 Equity Plan	—	—	—	—	1,397	—	—	1,397
Stock-based compensation - majority-owned subsidiary	—	—	—	—	16	—	158	174
Loss	—	—	—	—	—	(16,457)	(811)	(17,268)
Balance at December 31, 2019	1,158,209	$ 2,296	40,478,861	$ 41	$ 47,554	$ (53,715)	$ (814)	$ (4,638)

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands except shares and per share data)

	Year Ended December 31,	
	2020	2019
Cash flows from operating activities		
Net loss - before noncontrolling interest ("NCI")	$ (35,888)	$ (17,268)
Adjustments to reconcile net loss - before NCI to net cash used in operating activities		
Depreciation expense	23	14
Stock-based compensation	2,044	1,571
Change in fair value - Senior Secured Convertible Notes and Senior Convertible Note	5,327	559
Debt extinguishment loss - Senior Secured Convertible Notes	6,497	1,831
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,336)	(90)
Accounts payable	501	613
Accrued expenses and other current liabilities	918	56
Deposits – Long Term	—	(643)
Net cash flows used in operating activities	(21,914)	(13,357)
Cash flows from investing activities		
Purchase of equipment	(55)	(27)
Net cash flows used in investing activities	(55)	(27)
Cash flows from financing activities		
Proceeds – issue of Senior Secured Convertible Notes	13,300	—
Proceeds – issue of Senior Convertible Note	3,700	6,300
Proceeds – Cares Act Paycheck Protection Program Loan	300	—
Proceeds – issue of common stock – registered offerings	16,032	5,413
Payment – offering costs – registered offerings	(100)	(34)
Payment –Senior Secured Convertible Note	—	(86)
Payment – Senior Secured Convertible Notes – non-installment payments	(600)	(279)
Proceeds – issue common stock – Employee Stock Purchase Plan	357	67
Proceeds – exercise of Series S Warrants	12	—
Proceeds – exercise of stock options issued under equity incentive plan of majority owned subsidiary	5	—
Net cash flows provided by financing activities	33,006	11,381
Net increase (decrease) in cash	11,037	(2,003)
Cash, beginning of period	6,219	8,222
Cash, end of period	$ 17,256	$ 6,219

See accompanying notes to the consolidated financial statements.

Note 1 — The Company

Description of the Business

PAVmed Inc. ("PAVmed" or the "Company") together with its majority owned subsidiaries, Lucid Diagnostics, Inc. ("Lucid Diagnostics" or "LUCID") and Solys Diagnostics, Inc. ("Solys Diagnostics" or "SOLYS") were 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'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.

The ability of the Company to generate revenue depends upon the Company's ability to successfully advance the commercialization of EsoGuard and CarpX while also completing the development and the necessary regulatory approvals of its other products and services. In this regard:

- The EsoCheck device received 510(k) marketing clearance from the FDA as an esophageal cell collection device in June 2019;
- EsoGuard completed the certification required by the Clinical Laboratory Improvement Amendment ("CLIA") and accreditation of the College of American Pathologists ("CAP") making it commercially available as a Laboratory Developed Test ("LDT") at LUCID's contract diagnostic laboratory service provider in California in December 2019; and,
- CarpX, developed as a patented, single-use, disposable, minimally invasive device designed as a precision cutting tool to treat carpal tunnel syndrome while reducing recovery times, received 510(k) marketing clearance from the FDA in April 2020.

Although the Company's current operational activities are principally focused on the commercialization of EsoGuard and CarpX its development activities are focused on pursuing FDA approval and clearance of other lead products in our product portfolio pipeline, including EsoGuard IVD, PortIO, DisappEAR, NextFlo, and EsoCure.

Financial Condition

The Company has financed its operations principally through the public and private issuances of its common stock, preferred stock, common stock purchase warrants, and debt. The Company is subject to all of the risks and uncertainties typically faced by medical device and diagnostic and medical device companies that devote substantially all of their efforts to the commercialization of their initial product and services and ongoing R&D and clinical trials. The Company expects to continue to experience recurring losses from operations, and will continue to fund its operations with debt and equity financing transactions. Notwithstanding, however, together with the cash on-hand as of December 31, 2020, and the cash proceeds from the issue of shares of common stock of the Company subsequent to December 31, 2020 in January and February 2021, the Company expects to be able to fund its future operations for one year from the date of the issue of the Company's consolidated financial statements, as included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. See Note 12, *Stockholders' Equity, Common Stock Purchase Warrants, and Noncontrolling Interest*, for a discussion of the issue of shares of common stock of the Company subsequent to December 31, 2020, in each of January 2021 and February 2021; and Note 9, *Outstanding Debt*, for a discussion of the principal repaid-in-full of each of the convertible notes subsequent to December 31, 2020, in each of January 2021 and March 2021.

Note 2 — Summary of Significant Accounting Policies and Recent Accounting Standards Updates

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 12, *Stockholders' Equity and Common Stock Purchase Warrants*, for a discussion of the Company's majority-owned subsidiaries and the corresponding noncontrolling interest.

All amounts in these accompanying notes to the accompanying consolidated financial statements are presented in thousands, if not otherwise noted as being presented in millions, except for shares and per share amounts.

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 debt obligations and common stock purchase warrants. Additional significant estimates include the provision or benefit for income taxes and the corresponding valuation allowance on deferred tax assets. 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.

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.

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.

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.

Note 2 — Summary of Significant Accounting Policies and Recent Accounting Standards Updates - continued

Significant Accounting Policies - continued

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 Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") Topic 730, "*Research and Development*", ("ASC 730"), expenditures for research and development, including upfront licensing fees and milestone payments associated with products not yet been approved by the United States Food and Drug Administration ("FDA"), are charged to research and development expense as incurred. Future contract milestone and /or royalty 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.

Stock-Based Compensation

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

In the year ended December 31, 2020, stock-based compensation is recognized in accordance with the provisions of FASB ASC Topic 718, *Stock Compensation* ("ASC 718"), as amended by FASB Accounting Standard Update ("ASU") 2018-07 ("ASU 2018-07"). The provisions of ASU 2018-07 amended ASC 718 to align the accounting for stock-based awards granted to nonemployees with the requirements for accounting for stock-based awards to employees; and to supersede the previous guidance of FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees* ("ASC 505-50"). The adoption as of January 1, 2020 of the updated provisions of ASC 718, as amended by ASU 2018-07, had no effect on the Company's consolidated financial statements.

In the year ended December 31, 2020, with respect to stock-based awards granted to the board of directors, employees, and non-employees, the Company recognizes stock-based compensation in accordance with the provisions of ASC 718, as amended by ASU 2018-07, wherein the grant-date estimated fair value of the stock-based award is recognized 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, as applicable, so the cumulative expense recognized is at-least equal-to-or-greater-than the estimated fair value of the vested portion of the respective stock-based award as of the reporting date.

Note 2 — Summary of Significant Accounting Policies and Recent Accounting Standards Updates - continued

Significant Accounting Policies - continued

Stock-Based Compensation - continued

In the previous year ended December 31, 2019, with respect to stock-based awards granted to the board of directors and employees, the Company recognized stock-based compensation in accordance with ASC 718, as described above; and with respect to non-employees, the Company recognized stock-based compensation in accordance with previous provisions of ASC 505-50, wherein, the expense of stock-based awards granted to non-employees was recognized on a vesting date basis by 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 was not subject-to further remeasurement at subsequent reporting dates. The estimated fair value of the unvested non-employee stock options was 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 was recognized on a straight-line basis over the requisite service period, which was generally the vesting period of the respective non-employee stock-based award, with such straight-line recognition adjusted so the cumulative expense recognized was at-least equal-to-or-greater-than the estimated fair value of the vested portion of the respective stock-based award.

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

- The expected term of stock options represents the period of time stock options are expected to be outstanding, which is the expected term derived using the simplified method and, through December 31, 2019 for non-employees was the remaining contractual term (under the previous provisions of ASC 505-50);

- With respect to the PAVmed Inc. 2014 Equity Plan, the expected stock price volatility is based on the historical stock price volatility of PAVmed Inc. common stock and the volatilities of similar entities within the medical device industry over the period commensurate with the expected term with respect to stock options granted to the board of directors and employees in the years ended December 31, 2020 and 2019; and for stock options granted to non-employees in the year ended December 31, 2019, the period of volatility was commensurate with the remaining contractual term of the respective stock option (under the previous provisions ASC 505-50).

  With respect to stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan, the expected stock price volatility was based on the historical stock price volatility of similar entities within the medical device industry over the period commensurate with the expected term with respect to stock options granted to employees in the year ended December 31, 2019; and for stock options granted to non-employees in the year ended December 31, 2019, the period of volatility was commensurate with the remaining contractual term of the respective stock option (under the previous provisions ASC 505-50). There were no stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan in the year ended December 31, 2020;

- 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 either the expected term or the remaining contractual term, as applicable, of the stock option; and,

- The expected dividend yield is based on annual dividends of $0.00 as there have not been dividends 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 2 — Summary of Significant Accounting Policies and Recent Accounting Standards Updates - continued

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.

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 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.

As of December 31, 2020, and December 31, 2019, 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 Senior Secured Convertible Notes and Senior Convertible Note 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. Notwithstanding, FASB ASC Topic 825, *Financial Instruments,* ("ASC 825") provides for the "fair value option" ("FVO") election. In this regard, ASC 825-10-15-4 provides for the 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, with changes in the estimated fair value recognized as other income (expense) in the accompanying consolidated statement of operations. In this regard, as provided for by ASC 825-10-50-30(b), the estimated fair value adjustment is presented in a single line item within other income (expense) in the accompanying consolidated statement of operations. Further, as required by ASC 825-10-45-5, to the extent a portion of the fair value adjustment is attributed to a change in the instrument-specific credit risk, such portion would be recognized as a component of other comprehensive income ("OCI"). Notwithstanding, there was no such portion of the fair value adjustment attributed to a change in the instrument-specific credit risk in the years ended December 31, 2020 and 2019.

Note 2 — Summary of Significant Accounting Policies and Recent Accounting Standards - continued

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 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, 2020 and 2019.

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, 2020, 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, 2020 and December 31, 2019 or recognized during the years ended December 31, 2020 and 2019. 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 the incremental shares would potentially be issued and outstanding during the periods indicated, if dilutive. The Company's common stock equivalents include convertible preferred stock, common stock purchase warrants, unit purchase options, and stock options.

Notwithstanding, as the Company has a net loss for each reporting period presented, only the 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.

The Series B Convertible Preferred Stock dividends earned as of the each of the respective periods are included in the calculation of basic and diluted net loss attributable to PAVmed Inc. common stockholders for each respective period presented. Further, the Series B Convertible Preferred Stock has the right to receive common stock dividends. As such, the Series B Convertible Preferred Stock would potentially be 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 presented.

Note 2 — Summary of Significant Accounting Policies and Recent Accounting Standards Updates - continued

Significant Accounting Policies - continued

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 after the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected to avail itself of this exemption from new or revised accounting standards, and, therefore, will not be subject to the same new or revised accounting standards as public companies who are not an EGC.

Recent Accounting Standards Updates

As noted herein above, as of January 1, 2020, the Company adopted the amended guidance of ASC 718 with respect to stock-based awards granted to non-employees, as amended by ASU 2018-07, which aligned the accounting for stock-based payments to nonemployees for goods and services with the requirements for accounting for stock-based awards to employees under ASC 718. In this regard, ASU 2018-07 provides for stock-based payments to non-employees to be measured at the grant date fair value of the equity instruments to be provided to the nonemployee when the goods or services have been delivered. Prior to the ASU 2018-07 amendment, nonemployee stock-based payments were accounted for under the superseded provisions of ASC 505-50. The adoption of such amended guidance did not have an effect on the Company's consolidated financial statements.

As of January 1, 2020, the Company adopted 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 adoption of ASU 2018-13 did not have an effect on the Company's consolidated financial statements.

As of January 1, 2020, the Company adopted the guidance of ASU 2017-11, issued by the FASB in July 2017, *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 data will adjust their basic earnings per share 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. With respect to all other entities, including the Company under its JOBS Act EGC Accounting Election, as discussed above, the guidance of ASU 2017-11 was effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. The adoption of the ASU 2017-11 guidance as of January 1, 2020 did not have an effect on the Company's consolidated financial statements.

Note 2 — Summary of Significant Accounting Policies and Recent Accounting Standards Updates - continued

Significant Accounting Policies - continued

Recent Accounting Standards Updates - continued

In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40)*, ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The ASU 2020-06 amendments are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company's adoption of the ASU 2020-06 guidance as of January 1, 2021 is not expected to have an effect on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *"Income Taxes: Simplifying the Accounting for Income Taxes"*, ("ASU 2019-12"). The guidance of ASU 2019-12 removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation, and calculating income taxes in interim periods, and adds revised guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. Adoption of the guidance of ASU 2019-12 is required for annual and interim financial statements beginning after December 15, 2020. The Company's adoption of the ASU 2019-12 guidance as of January 1, 2021 is not expected to have an effect on the Company's consolidated financial statements.

FASB ASC Topic 842, *Leases*, ("ASC 842") (ASU No. 2016-02, *Leases*, February-2016 - "ASU 2016-02"*)* which established 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, 2022 for its annual consolidated financial statements, and for interim quarterly financial statements commencing March 31, 2023.

Note 3 — Agreements Related to Acquired Intellectual Property Rights

Patent License Agreement – Case Western Reserve University

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 "CWRU License Agreement".

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

The CWRU License Agreement requires Lucid Diagnostics Inc. to achieve certain milestones with respect to regulatory filings and clearances and commercialization of products and services. In this regard, in , 2019, the Company recognized a $75 research and development expense in connection with a regulatory clearance milestone, which was paid in 2019. The CWRU License Agreement was amended to: change the achievement date of commercialization milestone from November 2020 to August 2021; to eliminate the payment with respect to the commercialization milestone; and to add a non-refundable payment to CWRU in consideration for the aforementioned changes to the commercialization milestone ("CWRU License Agreement Amendment"). In connection with such CWRU License Agreement Amendment, the Company recognized $100 of general and administrative expense, with such expense included in accrued expenses as of December 31, 2020. If the Company does not meet the remaining commercialization and regulatory clearance milestones listed in the CWRU License Agreement, then CWRU has the right, in its sole discretion, to require PAVmed Inc. to transfer to CWRU 80% of the shares of common stock of Lucid Diagnostics Inc. then held by PAVmed Inc. Such contingent milestone payments will be recognized in the period in which such payment obligations are incurred.

Lucid Diagnostics Inc. is required to pay a minimum annual royalty of a percentage of recognized net sales revenue resulting from the commercialization of the products and /or services developed using the CWRU License Agreement intellectual property, with the minimum amount of royalty payments based on net sales of such products and services, if any. Such contingent royalty payments will be recognized in the period in which such payment obligations are incurred.

As provided for under the CWRU License Agreement, reimbursement of CWRU billed patent fees of $250 and $200 were recognized as research and development expense in the years ended December 31, 2020 and 2019, respectively.

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 granted by the FDA or other U.S. government agency, whichever comes later.

Note 3 — Agreements Related to Acquired Intellectual Property Rights - continued

License Agreement with Liquid Sensing Inc.

Upon its formation in October 2019, Solys Diagnostics Inc., a majority-owned subsidiary of PAVmed Inc. entered into a licensing agreement with Liquid Sensing, Inc., a subsidiary formed by Airware Inc., each an unrelated third-party, ("Liquid Sensing License Agreement"). Under the Liquid Sensing License Agreement, Solys Diagnostics Inc. was granted an exclusive worldwide license for six issued and one pending U.S. patents covering a proprietary nondispersive infrared laser technology to develop and commercialize such proprietary technology to non-invasively monitor tissue concentrations of glucose and other substances within the inpatient (*e.g.*, hospital) field of use.

Solys Diagnostics Inc. advanced the research and development plan and completed a milestone consistent with the parameters and by the date under the Liquid Sensing License Agreement. Notwithstanding, PAVmed Inc. determined it would be in the best interests of the shareholders of PAVmed Inc. to terminate the Liquid Sensing License Agreement. In this regard, subsequent to December 31, 2020, PAVmed Inc. on behalf of itself and Solys Diagnostics Inc., delivered to Airware Inc. and Liquid Sensing Inc. a written notice of termination of the Liquid Sensing License Agreement, dated February 12, 2021 ("Liquid Sensing License Agreement Termination Notice"). The Liquid Sensing License Agreement Termination Notice proposes the development of a negotiated mutually agreeable final settlement between PAVmed Inc., Solys Diagnostics Inc., Airware Inc., and Liquid Sensing Inc.

A discussion of each of the Company's majority-owned subsidiaries and the corresponding noncontrolling interest is presented in Note 12, *Stockholders' Equity and Common Stock Purchase Warrants*.

Patent License Agreement - Tufts University - Antimicrobial Resorbable Ear Tubes

The Company previously 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.

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.

Note 4 — Related Party Transactions

In connection with the CWRU License Agreement, CWRU and each of the three physician inventors of the intellectual property licensed under the CWRU License Agreement hold minority equity ownership interests in Lucid Diagnostics Inc., a majority-owned subsidiary of PAVmed Inc. During the years ended December 31, 2020 and 2019 the Company incurred the following expenses with respect to the minority shareholders of Lucid Diagnostics Inc.:

	For the year ended December 31,	
	2020	2019
CWRU License Agreement – reimbursement of patent legal fees	$ 250	$ 200
CWRU License Agreement Amendment fee	100	75
EsoCheck devices provided to CWRU	15	—
Fees - Physician Inventors' consulting agreements	83	110
Stock-based compensation expense - Physician Inventors' stock option grants	23	57
Total	$ 471	$ 442

Lucid Diagnostics Inc. entered into consulting agreements with each of the three physician inventors of the CWRU License Agreement intellectual property, providing for compensation on a contractual rate per hour for consulting services provided. The consulting agreements have a thirty-six month term ending May 12, 2021. Additionally, each of the three physician inventors were granted stock options under the PAVmed Inc. 2014 Long-Term Incentive Equity Plan and the Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan.

See Note 3, *Agreements Related to Acquired Intellectual Property Rights - Patent License Agreement - CWRU*, for a discussion of the "CWRU License Agreement"; 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"; and Note 12, *Stockholders' Equity, Common Stock Purchase Warrants, and Noncontrolling Interest*, for a discussion of each of the Company's majority-owned subsidiaries and the corresponding noncontrolling interests.

Note 5 — Prepaid Expenses, Deposits and Other Current and Non-Current Assets

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

	December 31, 2020	December 31, 2019
Advanced payments to service providers and suppliers	$ 568	$ 294
Deposits	262	34
EsoCheck cell collection supplies	779	—
EsoGuard mailer supplies	55	—
CarpX devices	21	—
Total prepaid expenses, deposits and other current assets	$ 1,685	$ 328

Non-Current Assets

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. Under the CRO agreement, the Company incurred an on-account deposit of $755 and $643 as of December 31, 2020 and 2019, respectively, of which $643 has been paid as of December 31, 2020, with the deposit classified as a non-current asset in the line item captioned "Other assets" on the accompanying consolidated balance sheet as of December 31, 2020 and 2019. See Note 7, *Commitments and Contingencies*, for a discussion of the EsoGuard CRO Agreement.

Note 6 — Accrued Expenses and Other Current Liabilities

Accrued expenses and Other Current Liabilities consist of the following items as of December 31, 2020 and 2019:

	December 31, 2020	December 31, 2019
Compensation and Employee Benefits	$ 1,777	$ 1,074
CWRU License Agreement fee	223	223
CWRU License Agreement Amendment fee	100	—
Operating expenses	171	89
EsoGuard supplies	22	—
CarpX devices	32	—
Total accrued expenses and other current liabilities	$ 2,325	$ 1,386

The "Compensation and Employee Benefits" includes: the guaranteed bonus payment under the Company's Chief Executive Officer ("CEO") Employment Agreement; discretionary bonus payments to other employees; unused employee vacation time; and employee payroll deductions related to the PAVmed Inc. Employee Stock Purchase Plan ("PAVmed Inc. ESPP"). See Note 11, *Stock-Based Compensation*, for additional information on the PAVmed Inc. ESPP.

The CWRU License Agreement license fee was approximately $273, of which $50 was previously paid. The remaining balance of the license fee is to be paid in quarterly installments of $50, until the license fee is paid-in-full, provided, however, the commencement of the quarterly payments is subject to Lucid Diagnostics Inc. consummation of a bona fide financing with an unrelated third-party in excess of $0.5 million. See Note 3, *Agreements Related to Acquired Intellectual Property Rights - Patent License Agreement - CWRU*, for a discussion of the CWRU License Agreement.

The amounts for operating expenses, EsoGuard supplies, and CarpX devices relate to respective amounts incurred by the Company but not yet invoiced by the respective vendors.

Note 7 — Commitment and Contingencies

Rental Agreements - Office Space

The Company's corporate office rental agreement 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 two months written notice. Additionally, the Company additionally has a short-term (one year or less) and a month-to-month office space rental agreements, which may be cancelled with two months written notice. Total rent expense incurred under short-term and /or month-to-month rental agreements for office space was $189 and $143, for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, the Company's minimum lease payments for such office space rental agreements are estimated to be a total of approximately $157 for the period January 1, 2021 to December 31, 2021.

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.

Legal Proceedings

In November 2020, a stockholder of the Company, on behalf of himself and other similarly situated stockholders, filed a complaint in the Delaware Court of Chancery alleging broker non-votes were not properly counted in accordance with the Company's bylaws at the Company's Annual Meeting of Stockholders on July 24, 2020, and, as a result, asserted certain matters deemed to have been approved were not so approved (including matters relating to the increase in the size of the 2014 Equity Plan and the ESPP). The relief sought under the complaint includes certain corrective actions by the Company, but does not seek any specific monetary damages. The Company does not believe it is clear the prior approval of these matters is invalid or otherwise ineffective. However, in order to avoid any uncertainty and to avoid the expense of further litigation, on January 5, 2021, the Company's Board of Directors determined it would be advisable and in the best interests of the Company and its stockholders to re-submit these proposals to the Company's stockholders for ratification and/or approval. In this regard, the Company held a special meeting of stockholders on March 4, 2021, at which such matters were ratified and approved. The parties have reached agreement on a proposed term sheet to settle the complaint, the terms of which do not contemplate payment of monetary damages to the putative class in the proceeding. The settlement of the complaint is pending and is subject to court approval.

On December 23, 2020, Benchmark Investments, Inc. filed a complaint against the Company in the U.S. District Court of the Southern District of New York alleging the registered direct offerings of shares of common stock of the Company completed in December 2020 were in violation of provisions set forth in an engagement letter between the Company and the plaintiff. The plaintiff is seeking monetary damages of up to $1.3 million. The Company disagrees with the allegations set forth in the complaint and intends to vigorously contest the complaint.

In the ordinary course of our business, particularly as it begins commercialization of its 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.

Note 8 — 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, 2020				
Senior Secured Convertible Note - November 2019	$ —	$ —	$ 1,270	$ 1,270
Senior Convertible Note - April 2020	$ —	$ —	$ 4,600	$ 4,600
Senior Secured Convertible Note – August 2020	$ —	$ —	$ 8,790	$ 8,790
Totals	$ —	$ —	$ 14,660	$ 14,660
December 31, 2019				
Senior Secured Convertible Note - December 2018	$ —	$ —	$ 1,700	$ 1,700
Senior Secured Convertible Note - November 2019	$ —	$ —	$ 6,439	$ 6,439
Totals	$ —	$ —	$ 8,139	$ 8,139

(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. There were no transfers between the respective Levels during the years ended December 31, 2020 and 2019.

The August 2020 Senior Secured Convertible Note, the April 2020 Senior Convertible Note, the November 2019 Senior Secured Convertible Note (Series-A and Series-B), and the December 2018 Senior Secured Convertible Note are each accounted for under the ASC 825-10-15-4 fair value option ("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 with the resulting fair value adjustment recognized as other income (expense) in the consolidated statement of operations. In this regard, 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.

The estimated fair value of financial instruments classified within the Level 3 category was determined using both observable inputs and unobservable inputs. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long- dated volatilities) inputs. Additional information with respect to the changes in Level 3 liabilities measured at fair value for the years ended December 31, 2020 and 2019, is presented in Note 9 – "*Outstanding Debt*."

Note 8 — Financial Instruments Fair Value Measurements - continued

The estimated fair value of each of the convertible notes as of December 31, 2020 and 2019, were 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:

Senior Secured Convertible Notes and Senior Convertible Note - Fair Value and Fair Value Assumptions – December 31, 2020:

	November 2019 Senior Secured Convertible Notes	April 2020 Senior Convertible Note	August 2020 Senior Secured Convertible Note
Fair Value	$ 1,270	$ 4,600	$ 8,790
Face value principal payable	$ 956	$ 4,111	$ 7,750
Required rate of return	0.09%	50.2%	27.2%
Conversion Price	$ 1.60	$ 5.00	$ 5.00
Value of common stock	$ 2.12	$ 2.12	$ 2.12
Expected term (years)	0.25	1.33	1.59
Volatility	70%	70%	70%
Risk free rate	0.09%	0.11%	0.12%
Dividend yield	0%	0%	0%

Senior Secured Convertible Notes Fair Value and Fair Value Assumptions – December 31, 2019:

	December 2018 Senior Secured Convertible Note	November 2019 Senior Secured Convertible Note
Fair Value	$ 1,700	$ 6,439
Face value principal payable	$ 1,692	$ 7,000
Required rate of return	11.4%	11.5%
Conversion Price	$ 1.60	$ 1.60
Value of common stock	$ 1.20	$ 1.20
Expected term (years)	0.21	1.78
Volatility	49%	55%
Risk free rate	1.52%	1.58%
Dividend yield	0%	0%

The estimated fair values reported 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 estimated fair values 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. Changes in these assumptions can materially affect the estimated fair values.

Note 9 — Outstanding Debt

Convertible Notes

The fair value and face value principal of outstanding convertible notes as of December 31, 2020 and 2019 are as follows:

	Contractual Maturity Date	Stated Interest Rate	Conversion Price per Share	Face Value Principal Outstanding	Fair Value
November 2019 Senior Secured Convertible Note	September 30, 2021	7.875%	$ 1.60	$ 956	$ 1,270
April 2020 Senior Convertible Note	April 30, 2022	7.875%	$ 5.00	$ 4,111	$ 4,600
August 2020 Senior Secured Convertible Note	August 6, 2022	7.875%	$ 5.00	$ 7,750	$ 8,790
Balance as of December 31, 2020				$ 12,817	$ 14,660
December 2018 Senior Secured Convertible Note	December 31, 2020	7.875%	$ 1.60	$ 1,692	$ 1,700
November 2019 Senior Secured Convertible Note	September 30, 2021	7.875%	$ 1.60	$ 7,000	$ 6,439
Balance as of December 31, 2019				$ 8,692	$ 8,139

Senior Secured Convertible Note issued December 27, 2018 - ("December 2018 Senior Convertible Note")

The Company previously issued a Senior Secured Convertible Note dated December 27, 2018, with a $7.75 million face value principal, a stated interest rate of 7.875% per annum, and, at the election of the holder, was convertible into shares of common stock of the Company at a contractual conversion price of $1.60 per share - the "December 2018 Senior Convertible Note".

In the year ended December 31, 2020, with respect to the December 2018 Senior Convertible Notes, approximately $1,692 of installment principal repayments and the payment of interest thereon of approximately $6, were settled through the issuance of 2,075,198 shares of common stock of the Company, with a fair value of approximately $2,901 (with such fair value measured as the respective conversion date quoted closing price of the common stock of the Company).

In the previous year ended December 31, 2019, with respect to the December 2018 Senior Convertible Notes, approximately $6,058 of installment principal repayments and the payment of interest thereon of approximately $200, were settled through the issuance of 7,773,110 shares of common stock of the Company, with a fair value of approximately $8,089 (with such fair value measured as the respective conversion date quoted closing price of the common stock of the Company). Additionally, approximately $279 of interest non-installment payments were paid in cash during the year ended December 31, 2019.

The December 2018 Senior Convertible Note was paid-in-full was paid in full as of June 4, 2020.

Note 9 — Outstanding Debt - continued

Convertible Notes - continued

Senior Secured Convertible Note issued November 4, 2019 - Series A and Series B - ("November 2019 Senior Convertible Notes")

The Company previously issued a Senior Secured Convertible Note dated November 4, 2019, with a $14.0 million aggregate face value principal, a stated interest rate of 7.875% per annum (to the extent the investor has funded the cash proceeds), and, at the election of the holder, is convertible into shares of common stock of the Company at a contractual conversion price of $1.60 per share - the "November 2019 Senior Convertible Notes". The November 2019 Senior Convertible Notes were comprised of a Series A and Series B, each with a $7.0 million face value principal, and each having a $0.7 million lender fee deducted from the cash proceeds when funded.

The November 2019 Senior Convertible Note - Series A was issued on November 4, 2019, with a face value principal of approximately $7,000 and a lender fee of approximately $700 (with such lender fee recognized as a current period other expense), resulting in approximately $6,300 of cash proceeds received by the Company on the issue date. Additionally, the Company incurred a current period expense of approximately $550, inclusive of a $410 placement agent advisory fee, along with legal fees.

The November 2019 Senior Convertible Note - Series B was issued on March 30, 2020, with a face value principal of approximately $7,000 and a lender fee of approximately $700 (with such lender fee recognized as a current period other expense), resulting in approximately $6,300 of cash proceeds received by the Company on the issue date. Additionally, the Company incurred a current period expense of approximately $410 with respect to a placement agent advisory fee.

The Company incurred interest expense of 3.0% per annum on the $7.0 million face value principal of the (unfunded) Series B during the period from November 4, 2019 to March 29, 2020 when the Series B was not funded. The (cash) payment of such 3.0% interest on the $7.0 million face value principal resulted in the recognition of approximately $53 and $33 of interest expense during the year ended December 31, 2020 and 2019, respectively, with such interest expense included in other income (expense).

With respect to the November 2019 Senior Convertible Notes, in the year ended December 31, 2020, approximately $13,044 of installment principal repayments and the payment of interest thereon of approximately $465, were settled through the issuance of 8,854,004 shares of common stock of the Company, with a fair value of approximately $18,802 (with such fair value measured as the respective conversion date quoted closing price of the common stock of the Company). As of December 31, 2020, the November 2019 Senior Convertible Notes remaining unpaid outstanding face value principal was approximately $956.

Subsequent to December 31, 2020, on January 5, 2021, the repayment of the remaining face value principal of the November 2019 Senior Convertible Note of approximately $956, along with the payment of interest thereon of approximately $7, were settled with the issuance of 667,668 shares common stock of the Company, with a fair value of approximately $1,723 (with such fair value measured as the respective conversion date quoted closing price of the common stock of the Company), with such final conversion resulting in the November 2019 Senior Convertible Note being paid-in-full as of January 5, 2021.

Note 9 — Outstanding Debt - continued

Convertible Notes - continued

Senior Convertible Note issued April 30, 2020 - ("April 2020 Senior Convertible Note")

The Company issued a Senior Convertible Note dated April 30, 2020, with a face value principal of approximately $4,111, a stated interest rate of 7.875% per annum, and, at the election of the holder, is convertible into shares of common stock of the Company at a contractual conversion price of $5.00 per share - the "April 2020 Senior Convertible Note".

The April 2020 Senior Convertible Note resulted in approximately $3,700 of cash proceeds received by the Company on the issue date, after a lender fee of approximately $411 (with such lender fee recognized as a current period other expense). Additionally, the Company incurred a current period expense of approximately $200, inclusive of a $120 placement agent advisory fee, along with legal fees.

The Company was required to pay the holder in cash all remaining outstanding unpaid face value principal at 115% of such principal amount plus unpaid interest thereon, on the April 30, 2022 maturity date.

In the year ended December 31, 2020, approximately $215 of interest non-installment payments were paid in cash.

The unpaid outstanding face value principal of the April 2020 Senior Convertible Note is approximately $4,111 as of December 31, 2020, of which such principal was repaid-in-full subsequent to December 31, 2020, as discussed herein below.

Senior Secured Convertible Note issued August 6, 2020 - ("August 2020 Senior Convertible Note")

The Company issued a Senior Secured Convertible Note dated August 6, 2020, with a face value principal of approximately $7,750, a stated interest rate of 7.875% per annum, and, at the election of the holder, is convertible into shares of common stock of the Company at a contractual conversion price of $5.00 per share - the "August 2020 Senior Convertible Note".

The August 2020 Senior Convertible Note resulted in approximately $7,000 of cash proceeds received by the Company on the issue date, after a lender fee of approximately $750 (with such lender fee recognized as a current period other expense). Additionally, the Company incurred a current period expense of approximately $50 with respect to legal fees.

The Company was required to pay the holder in cash all remaining outstanding unpaid face value principal at 115% of such principal amount plus unpaid interest thereon on the August 5, 2022 maturity date.

In the year ended December 31, 2020, approximately $246 of interest non-installment payments were paid in cash.

The unpaid outstanding face value principal of the April 2020 Senior Convertible Note is approximately $7,750 as of December 31, 2020, of which such principal was repaid-in-full subsequent to December 31, 2020, as discussed herein below.

Principal Repayments - April 2020 Senior Convertible Note and August 2020 Senior Convertible Note

Subsequent to December 31, 2020: on January 30, 2021, the Company paid in cash a $350 partial principal repayment of the April 2020 Senior Convertible Note; and on March 2, 2021, the Company paid in cash a total of $14,466 of principal repayments, resulting in both the April 2020 Senior Convertible Note and the August 2020 Senior Convertible Note being repaid-in-full as of such date.

Note 9 — Outstanding Debt - continued

Convertible Notes - continued

Covenants - Sr Secured Convertible Notes and Senior Convertible Note

As of December 31, 2020, each of the November 2019 Senior Convertible Note, April 2020 Senior Convertible Note, and the August 2020 Senior Convertible Note were each held by the same investor and its affiliates.

Under the November 2019 Senior Convertible Notes and the April 2020 Senior Convertible Note, as such convertible notes are discussed above, the Company was 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. Additionally, the April 2020 Senior Convertible Note contained a financial covenant requiring the Company to maintain available cash in the amount of approximately $1.8 million at the end of each quarter, with such amount increased to $2.0 million under the August 2020 Senior Convertible Note. As of December 31, 2020, the Company was in compliance with this financial covenant.

The August 2020 Senior Convertible Note contained substantively similar customary affirmative and negative covenants as those described above, as well as the past transactions entered into with the investor, including the November 2019 Senior Convertible Notes. The August 2020 Senior Secured Convertible Note contained security interest with a first priority in all of our assets, including all of the Company’s current and future significant subsidiaries, similar to the November 2019 Senior Secured Convertible Notes.

Notwithstanding, as noted above, subsequent to December 31, 2020: the November 2019 Senior Convertible Note was repaid-in-full as of January 5, 2021; and both the April 2020 Senior Convertible Note and the August 2020 Senior Convertible Note were repaid-in-full as of March 2, 2021.

Note 9 — Outstanding Debt - continued

Convertible Notes - continued

A reconciliation of the fair value of the convertible notes for the years ended December 31, 2020 and 2019 is as follows:

	December 2018 Senior Secured Convertible Note	November 2019 Senior Secured Convertible Notes[1][2]	April 2020 Senior Convertible Note	August 2020 Senior Secured Convertible Note	Sum of Balance Sheet Fair Value Components	Other Income (Expense)
Fair Value - December 31, 2019	$ 1,700	$ 6,439	$ —	$ —	$ 8,139	
Face value principal – issue date	—	7,000	4,111	7,750	18,861	
Fair value adjustment – issue date	—	2,600	(411)	(750)	1,439	$ (1,439)
Installment repayments – common stock	(1,692)	(13,044)	—	—	(14,736)	
Non-installment payments – common stock	(6)	(464)	—	—	(470)	
Non-installment payments – cash	—	(138)	(216)	(246)	(600)	
Change in fair value	(2)	(1,123)	1,116	2,036	2,027	(2,027)
Lender Fees:						
- November 2019 Senior Secured Convertible Note - Series B;						(700)
- April 2020 Senior Convertible Note; and						(411)
- August 2020 Senior Secured Convertible Note	—	—	—	—	—	(750)
Fair Value at December 31, 2020	$ —	$ 1,270	$ 4,600	$ 8,790	$ 14,660	
Other Income (Expense) - Change in fair value – year ended December 31, 2020						$ (5,327)
Fair Value - December 31, 2018	$ 7,903	$ —	$ —	$ —	$ 7,903	
Face value principal – issue date	—	7,000	—	—	7,000	
Fair value adjustment – issue date	—	(648)	—	—	(648)	$ 648
Installment repayments – common stock	(6,059)	—	—	—	(6,059)	
Non-installment payments – common stock	(199)	—	—	—	(199)	
Non-installment payments – cash	(279)	(86)	—	—	(365)	
Change in fair value	334	173	—	—	507	(507)
Lender Fees:						
- November 2019 Senior Secured Convertible Note - Series A	—	—	—	—	—	(700)
Fair Value at December 31, 2019	$ 1,700	$ 6,439	$ —	$ —	$ 8,139	
Other Income (Expense) - Change in fair value – year ended December 31, 2019						$ (559)

The Senior Convertible Notes presented above are each accounted for under the ASC 825-10-15-4 fair value option (“FVO”) election, 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, with the resulting fair value adjustment recognized as other income (expense) in the consolidated statement of operations. In this regard, 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. See Note 8, *Financial Instruments Fair Value Measurements*, for a further discussion of fair value assumptions.

Note 9 — Outstanding Debt - continued

Cares Act Paycheck Protection Program Loan

On April 8, 2020 the Company entered into a loan agreement with JP Morgan Chase, N.A., and received approximately $300 of proceeds, pursuant to the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") Paycheck Protection Program ("PPP") - the "PPP Loan".

The Paycheck Protection Program provides that (1) the use of PPP Loan amount shall be limited to certain qualifying expenses, (2) 100 per cent of the principal amount of the loan is guaranteed by the Small Business Administration and (3) an amount up to the full principal amount may qualify for loan forgiveness in accordance with the terms of CARES Act. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during either, at our discretion, the eight-week period or twenty-four week period beginning on the date of disbursement of proceeds from the PPP loan. In the event the PPP loan, or any portion thereof, is forgiven pursuant to the PPP, the amount forgiven is applied to outstanding principal with the Company being obligated to make equal monthly payments on the unforgiven principal and interest balances to fully amortize the loan balance by the maturity date.

The PPP Loan matures on April 8, 2022 and bears interest at a rate of approximately 1.0% per annum. Monthly amortized principle and interest payments are deferred in accordance with The Paycheck Protection Flexibility Act of 2020 which extended the deferral period for loan payments to either (1) the date that U.S. Small Business Administration remits the borrower's loan forgiveness amount to the lender or (2) if the borrower does not apply for loan forgiveness, 10 months after the end of the borrower's loan forgiveness covered period. As such, as of December 31, 2020, and to date, no principal or interest payments have been made.

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.

As of December 31, 2020, the PAVmed Inc. 2014 Equity Plan has 2,003,406 shares available-for-grant of stock-based awards, inclusive of the supplemental share reservation increase of an additional 2,000,000 shares, approved by the PAVmed Inc. board of directors on March 12, 2020, and approved at the PAVmed Inc. 2020 annual meeting of stockholders on July 24, 2020, and re-approved at a special meeting of stockholders of PAVmed Inc. on March 4, 2021. A discussion of the PAVmed Inc. special meeting of stockholders is presented in Note 7, *Commitments and Contingencies - Legal Proceedings*. The shares available-for-grant exclude a total of 500,854 PAVmed Inc. stock options previously granted outside the PAVmed Inc. 2014 Equity Plan.

PAVmed Inc. 2014 Equity Plan - Stock Options

Stock options issued and outstanding under the PAVmed Inc. 2014 Equity Plan are as follows:

	Number Stock Options	Weighted Average Exercise Price	Remaining Contractual Term (Years)	Intrinsic Value[2]
Outstanding stock options at December 31, 2018	3,327,140	$ 3.68	8.3	
Granted[1]	1,925,000	$ 1.00		
Exercised	—	$ —		
Forfeited	(48,611)	$ 5.00		
Outstanding stock options at December 31, 2019	5,203,529	2.58	8.1	$ 394
Vested and exercisable stock options at December 31, 2019	3,270,487	$ 3.45	7.5	$ 126
Outstanding stock options at December 31, 2019	5,203,529	$ 2.58		
Granted[1]	1,595,000	$ 2.13		
Exercised	—	$ —		
Forfeited	—	$ —		
Outstanding stock options at December 31, 2020	6,798,529	$ 2.55	7.3	$ 2,558
Vested and exercisable stock options at December 31, 2020	4,861,433	$ 2.88	6.7	$ 1,707

(1) Stock options granted under the PAVmed Inc. 2014 Equity Plan vest ratably over twelve quarters generally commencing with the grant date quarter and have a ten year contractual term from date-of-grant.

(2) The intrinsic value is computed as the difference between the quoted price of the PAVmed Inc. common stock on each of December 31, 2020 and 2019 and the exercise price of the underlying PAVmed Inc. stock options, to the extent such quoted price is greater than the exercise price.

Subsequent to December 31, 2020, as approved at the March 4, 2021 special meeting of stockholders, a total of 225,000 stock options were granted with a weighted average exercise price of $2.03 per share of common stock of the Company. A discussion of the PAVmed Inc. special meeting of stockholders is presented in Note 7, *Commitments and Contingencies - Legal Proceedings.*

Note 10 — Stock-Based Compensation – continued

PAVmed Inc. 2014 Equity Plan - Restricted Stock Awards

On May 1, 2020, a total of 950,000 restricted stock awards were granted under the PAVmed Inc. 2014 Equity Plan, vesting as follows: 450,000 restricted stock awards vesting ratably on an annual basis over a three year period with an initial annual vesting date of May 1, 2021; and 500,000 restricted stock awards vesting on May 1, 2023. The restricted stock awards are subject to forfeiture if the requisite service period is not completed.

On March 15, 2019, a total of 700,000 restricted stock awards were granted under the PAVmed Inc. 2014 Equity Plan, vesting as follows: 233,334 restricted stock awards vested on March 15, 2020; and 466,666 restricted awards vesting on March 15, 2022. The restricted stock awards are subject to forfeiture if the requisite service period is not completed.

Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan

The Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan ("Lucid Diagnostics Inc. 2018 Equity Plan") is separate and apart 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 1,305,000 shares available for grant as of December 31, 2020, exclusive of 300,000 Lucid Diagnostics Inc. stock options previously granted outside the Lucid Diagnostics Inc. 2018 Equity Plan.

Lucid Diagnostics Inc. 2018 Equity Plan - Stock Options

Stock options issued and outstanding under the Lucid Diagnostics Inc. 2018 Equity Plan for the period noted is as follows:

	Number Stock Options		Weighted Average Exercise Price	Remaining Contractual Term (Years)
Outstanding stock options at December 31, 2018	375,000	$	0.60	9.4
Granted	620,000	$	1.02	
Exercised	—	$	—	
Forfeited	—	$	—	
Outstanding stock options at December 31, 2019	995,000	$	0.86	9.0
Granted	—	$	—	
Exercised	(3,333)	$	1.50	
Forfeited	—	$	—	
Outstanding stock options at December 31, 2020	991,667	$	0.86	8.0
Vested and exercisable stock options at December 31, 2020	772,491	$	0.83	7.9

(1) Stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan, have a ten-year contractual term from date of grant, and vest ratably over twelve successive calendar quarters, with first vesting date in the quarter of the date of grant.

During the year ended December 31, 2020, 3,333 stock options issued under the Lucid Diagnostics Inc. 2018 Equity Plan were exercised for cash proceeds of $5, resulting in the issue of a corresponding number of shares of common stock of Lucid Diagnostics Inc.

Note 10 — Stock-Based Compensation – continued

Lucid Diagnostics Inc. 2018 Equity Plan - Restricted Stock Awards

Subsequent to December 31, 2020, on March 1, 2021, a total of 1,040,000 restricted stock awards were granted under the Lucid Diagnostics Inc. 2018 Equity Plan, with a single vesting date of March 1, 2023. The restricted stock awards are subject to forfeiture if the requisite service period is not completed.

Stock-Based Compensation Expense

The 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 as discussed above, for the periods indicated, was as follows:

	Year Ended December 31,	
	2020	2019
General and administrative expenses	$ 1,582	$ 1,163
Research and development expenses	462	408
Total	$ 2,044	$ 1,571

The consolidated stock-based compensation expense classified in research and development expenses, as presented above, includes $65 and $174 in the years ended December 31, 2020 and 2019, respectively, recognized by Lucid Diagnostics Inc., with stock-based compensation expense recognized by Lucid Diagnostics Inc. inclusive of each of: stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan to employees of PAVmed Inc. and to non-employee consultants, with each providing services to Lucid Diagnostics Inc.; and stock options granted under the PAVmed Inc. 2014 Equity Plan to non-employee consultants providing services to Lucid Diagnostics Inc., summarized as follows for the periods noted:

	Year Ended December 31,	
	2020	2019
Lucid Diagnostics Inc 2018 Equity Plan – research and development expenses	$ 52	$ 158
PAVmed Inc 2014 Equity Plan - research and development expenses	13	16
Total stock-based compensation expense – recognized by Lucid Diagnostics Inc	$ 65	$ 174

As of December 31, 2020, unrecognized stock-based compensation expense and weighted average remaining requisite service period with respect to stock options and restricted stock awards issued under each of the PAVmed Inc. 2014 Equity Plan and the Lucid Diagnostics Inc. 2018 Equity Plan, as discussed above, is as follows:

	Unrecognized Expense	Weighted Average Remaining Service Period
PAVmed Inc. 2014 Equity Plan		
Stock Options	$ 1,866	0.9 years
Restricted Stock Awards	$ 1,796	2.1 years
Lucid Diagnostics Inc. 2018 Equity Plan		
Stock Options	$ 49	0.8 years

Note 10 — Stock-Based Compensation - continued

Stock-Based Compensation Expense - continued

The stock options granted under the PAVmed Inc. 2014 Equity Plan during the years ended December 31, 2020 and 2019, had a weighted average estimated fair value of $1.27 per share and $0.48 per share, respectively, calculated using the following weighted average Black-Scholes valuation model assumptions:

	Year Ended December 31,	
	2020	2019
Expected term of stock options (in years)	5.8	5.7
Expected stock price volatility	73%	50%
Risk free interest rate	0.5%	2.4%
Expected dividend yield	0%	0%

Stock-based compensation expense recognized with respect to stock options granted under the PAVmed Inc. 2014 Equity Plan to non-employees in the prior year ended December 31, 2019, which was recognized under the previous provisions of ASC 505-50, was based on a weighted average estimated fair value of such stock options of $1.97 per share, calculated using Black-Scholes valuation model weighted-average assumptions of an 8.5 year contractual term, a 59% expected stock price volatility, a 2.3% risk free interest rate, and a 0% expected dividend rate.

The restricted stock awards granted to employees under the PAVmed Inc. 2014 Equity Plan are measured at their grant date estimated fair value based on the date-of-grant quoted price per share of PAVmed Inc. common stock. The 700,000 restricted stock awards granted on March 15, 2019 had an aggregate fair value of approximately $742 with such stock-based compensation expense recognized ratably over the requisite service period, which is the three-year vesting period as discussed above. The 950,000 restricted stock awards granted on May 1, 2020 had an aggregate fair value of approximately $1,938 with such stock-based compensation expense recognized ratably over the requisite service period, which is the three-year vesting period as discussed above.

The stock-based compensation expense recognized in general and administrative expense related to restricted stock awards was approximately $576 and $206 in the years ended December 31, 2020 and 2019, respectively. The stock-based compensation expense recognized in research and development expense related to restricted stock awards was $102 in the year ended December 31, 2020 (there was no stock-based compensation expense recognized in research and development expense with respect to restricted stock awards in the previous year ended December 31, 2019).

As noted above, in the year ended December 31, 2020, there were no stock-based awards granted under the Lucid Diagnostics Inc 2018 Equity Plan. In the previous year ended December 31, 2019, stock-based compensation expense recognized with respect to stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan was based on a weighted average estimated fair value of such stock options of $0.32 per share, and was calculated using the following weighted average Black-Scholes valuation model assumptions:

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

Stock-based compensation expense recognized with respect to stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan to non-employees in the prior year ended December 31, 2019, which was recognized under the previous provisions of ASC 505-50, was based on a weighted average estimated fair value of such stock options of $0.29 per share, calculated using Black-Scholes valuation model weighted-average assumptions of a 8.8 year contractual term, a 57% expected stock price volatility, a 2.1% risk free interest rate, and a 0% expected dividend rate.

Note 10 — Stock-Based Compensation - continued

PAVmed Inc. Employee Stock Purchase Plan ("ESPP")

The PAVmed Inc. Employee Stock Purchase Plan ("PAVmed Inc. ESPP"), adopted by the Company's board of directors effective April 1, 2019, 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 of common stock 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. On each of the March 31, 2020 and September 30, 2020 ESPP purchase dates, 154,266 and 152,289 shares of PAVmed Inc. common stock were issued for proceeds of approximately $126 and $231, respectively; and in the previous year, on the initial September 30, 2019 ESPP purchase date, 82,772 shares of PAVmed Inc. common stock were issued for proceeds of approximately $67.

As of December 31, 2020, the PAVmed Inc. ESPP has a total reservation of 750,000 shares of common stock of PAVmed Inc., with 360,673 shares available-for-issue, inclusive of the supplemental share reservation increase of an additional 500,000 shares, approved by the PAVmed Inc. board of directors on March 12, 2020, and approved at the PAVmed Inc. 2020 annual meeting of stockholders on July 24, 2020, and re-approved at a PAVmed Inc. special meeting of stockholders on March 4, 2021. A discussion of the PAVmed Inc. special meeting of stockholders is presented in Note 7, *Commitments and Contingencies - Legal Proceedings*.

Note 11 - Preferred Stock

The Company is authorized to issue 20 million shares of its preferred stock, par value of $0.001 per share, with such designation, rights, and preferences as may be determined by the Company's board of directors.

Series B Convertible Preferred Stock

As of December 31, 2020 and 2019, there were 1,228,075 and 1,158,209 shares of Series B Convertible Preferred Stock (classified in permanent equity) issued and outstanding, respectively. During the year ended December 31, 2020 and 2019, a total of 94,866 and 88,268 shares, respectively, were issued in settlement of Series B Convertible Preferred Stock dividends declared in the respective year ended December 31, 2020 and 2019, as such dividends are discussed below. Additionally, in March 2020, at the election of the holder, 25,000 shares of Series B Convertible Preferred Stock were converted into a corresponding number of shares of common stock of the Company.

The Series B Convertible Preferred Stock is issued pursuant to 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"), 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 share 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 Certificate of Designation 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, with the dividends earned from April 1, 2018 through October 1, 2021 payable-in-kind ("PIK") by the issue of 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 issue of shares of Series B Convertible Preferred Stock, the issue shares of common stock of the Company, and /or cash payment.

The Series B Convertible Preferred Stock dividends earned are included in the calculation of basic and diluted net loss attributable to PAVmed Inc. common stockholders for each of the corresponding periods presented. Notwithstanding, the Series B Convertible Preferred Stock dividends are recognized as a dividend payable only upon the dividend being declared payable by the Company's board of directors.

During the year ended December 31, 2020, the Company's board-of-directors declared an aggregate of approximately $284 of Series B Convertible Preferred Stock dividends, earned as of each of December 31, 2019, March 31, 2020, June 30, 2020, and September 30, 2020, which have been settled by the issue of an additional aggregate 94,866 shares of Series B Convertible Preferred Stock.

During the prior year ended December 31, 2019, the Company's board-of-directors declared an aggregate of approximately $265 of Series B Convertible Preferred Stock dividends, earned as of December 31, 2018, March 31, 2019, June 30, 2019, and September 30, 2019, which were settled by the issue of an additional aggregate 88,268 shares of Series B Convertible Preferred Stock.

Subsequent to December 31, 2020, in January 2021, the Company's board-of-directors declared a Series B Convertible Preferred Stock dividend earned as of December 31, 2020 and payable as of January 1, 2021, of approximately $73 to be settled by the issue of an additional 24,198 shares of Series B Convertible Preferred Stock (with such dividend not recognized as a dividend payable as the Company's board of directors had not declared such dividends payable as of December 31, 2020).

Note 12 — Stockholders' Equity, Common Stock Purchase Warrants, and Noncontrolling Interest

Common Stock

The Company is authorized to issue up to 150 million shares of its common stock, par value of $0.001 per share, inclusive of an increase of 50 million shares approved by the Company's stockholders at their July 24, 2020 annual meeting. There were 63,819,935 and 40,478,861 shares of common stock issued and outstanding as of December 31, 2020 and December 31, 2019, respectively.

Year Ended December 31, 2020

- During 2020, a total of 10,647,500 shares of common stock of the Company were issued for gross proceeds of approximately $17,036, before a total placement agent fee and expenses of approximately $1,004, and total offering costs of approximately $100. The shares of common stock were issued in two registered direct offerings pursuant to a respective Prospectus Supplement dated December 11, 2020 and December 18, 2020, each with respect to the Company's effective shelf registration statement on Form S-3 (File No. 333-248709).

- In 2020, a total of 10,929,202 shares of common stock of the Company were issued upon partial conversions of each of the December 2018 Senior Convertible Note and the November 2019 Senior Convertible Notes, as discussed in Note 9, *Outstanding Debt*.

- In 2020, 306,555 shares of common stock were purchased by employees through participation in the PAVmed Inc. Employee Stock Purchase Plan, as discussed in Note 10, Stock-Based *Compensation*.

Subsequent to December 31, 2020, in January 2021, 667,668 shares of the Company's common stock were issued upon conversion, at the election of the holder, of the November 2019 Senior Convertible Note remaining face value principal of approximately $956 along with approximately $7 of interest thereon, as discussed in Note 9, *Outstanding Debt*.

Subsequent to December 31, 2020, on January 5, 2021, a total of 6,000,000 shares of common stock of the Company were issued for gross proceeds of approximately $13,440, before a placement agent fee and expenses of approximately $951, and offering costs incurred by the Company of approximately $70. The shares of common stock were issued in a registered direct offering pursuant to a Prospectus Supplement dated January 5, 2021 with respect to the Company's effective shelf registration statement on Form S-3 (File No. 333-248709).

Subsequent to December 31, 2020, on February 23, 2021, a total of 9,782,609 shares of common stock of the Company were issued for proceeds of approximately $41,626, before underwriter expenses of approximately $50, and offering costs incurred by the Company of approximately $360. The shares of common stock were issued in an underwritten registered offering pursuant to a final Prospectus Supplement dated February 23, 2021, with respect to the Company's effective shelf registration statement on Form S-3 (File No. 333-248709 and File No. 333-253384).

Subsequent to December 31, 2020, as of March 12, 2021, a total of 773,842 Series Z Warrants were exercised for cash at a $1.60 per share of common stock of the Company, resulting in the issue of a corresponding number of shares of common stock of the Company. The Series Z Warrants are discussed herein below.

Year Ended December 31, 2019

- During 2019, a total of 5,480,000 shares of common stock of the Company were issued for gross proceeds of approximately $5,480, before placement agent fees and expenses of approximately $67, and total offering costs of $34. The shares of common stock were issued in three registered direct offerings pursuant to respective Prospectus Supplement dated April 12, 2019, May 8, 2019, and June 25, 2019, each with respect to the Company's effective shelf registration statement on Form S-3 (File No. 333-220549).

- In 2019, a total of 7,773,110 shares of common stock of the Company were issued upon conversions of the December 2018 Senior Convertible Note, as discussed in Note 9, *Outstanding Debt*.

- In 2019, 82,772 shares of common stock were purchase by employees through participation in the PAVmed Inc. Employee Stock Purchase Plan, as discussed in Note 10, *Stock-Based Compensation.*

Note 12 — Stockholders' Equity, Common Stock Purchase Warrants, and Noncontrolling Interest

Common Stock Purchase Warrants

The common stock purchase warrants (classified in permanent equity) outstanding as of the dates indicated are as follows:

	Common Stock Purchase Warrants Issued and Outstanding at				
	December 31, 2020	Weighted Average Exercise Price /Share	December 31, 2019	Weighted Average Exercise Price/Share	Expiration Date
Series Z Warrants	16,814,939	$ 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
Series S Warrants	—	$ —	1,199,383	$ 0.01	June 2032
Total	17,249,757	$ 1.68	18,449,240	$ 1.57	

In the year ended December 31, 2020, 1,199,383 Series S Warrants and 100 Series Z Warrants were exercised for cash at their respective exercise price per share, resulting in the issue of a corresponding number of shares of common stock of the Company. Additionally, subsequent to December 31, 2020, as of March 12, 2021, a total of 773,842 Series Z Warrants were exercised for cash at their exercise price per share, resulting in the issue of a corresponding number of shares of common stock of the Company.

Series Z Warrants

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, and expire after the close of business on April 30, 2024, if not earlier redeemed by the Company, as discussed below. The Series Z Warrant exercise price is not subject-to 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.

The Company may redeem the 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.

Series W Warrants

A Series W Warrant is exercisable to purchase one share of common stock of the Company at an exercise price of $5.00 per share, and expire after the close of business on January 29, 2022, if not earlier redeemed by the Company, as discussed below. The Series W Warrant exercise price is not subject-to 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 W 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 W Warrant.

The Company may redeem the Series W Warrants (other than those outstanding prior to the Company's initial public offering ("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.

Note 12 — Stockholders' Equity, Common Stock Purchase Warrants, and Noncontrolling Interest - continued

Noncontrolling Interest ("NCI")

The noncontrolling interest ("NCI") included as a component of consolidated total stockholders' equity is with respect to the Company's majority-owned subsidiaries Lucid Diagnostics Inc. and Solys Diagnostics Inc., summarized for the periods indicated as follows:

	Year Ended December 31, 2020	Year Ended December 31, 2019
NCI - equity (deficit) - beginning of period	$ (814)	$ (161)
Minority Interest investment -Solys Diagnostics Inc.	—	889
Minority Interest share subscription receivable - Solys Diagnostics Inc.	—	(889)
Lucid Diagnostics Inc. 2018 Equity Plan stock option exercise	5	—
Net loss attributable to NCI - Lucid Diagnostics Inc.	(1,503)	(801)
Net loss attributable to NCI - Solys Diagnostics Inc.	(109)	(10)
Stock-based compensation expense - Lucid Diagnostics Inc. 2018 Equity Plan	52	158
NCI - equity (deficit) - end of period	$ (2,369)	$ (814)

Lucid Diagnostics Inc.

As of December 31, 2020 and 2019, there were 10,003,333 and 10,000,000 shares of common stock of Lucid Diagnostics Inc. issued and outstanding, respectively. PAVmed Inc. holds 8,187,499 shares of the common stock of Lucid Diagnostics Inc., as of December 31, 2020 and 2019, representing a majority equity ownership interest of 81.85% and 81.875%, respectively, and has a controlling financial interest. The minority equity ownership interest of the Lucid Diagnostics Inc. common stock includes: 943,464 shares held by CWRU, 289,679 shares held by each of the three individual physician inventors of the intellectual property underlying the CWRU License Agreement (as such license agreement is discussed in Note 3, *Agreements Related to Acquired Intellectual Property Rights*), as of December 31, 2020 and 2019; and 3,333 shares held by an unrelated third-party consultant as of December 31, 2020, upon the exercise for cash at $1.50 per share of a corresponding number of stock options issued under the Lucid Diagnostics Inc. 2018 Equity Plan in January 2020 (as such equity plan is discussed in Note 10, *Stock-Based Compensation*).

As of December 31, 2020 and 2019, Lucid Diagnostics Inc. is a consolidated majority-owned subsidiary of the Company, and a corresponding noncontrolling interest (NCI) is included as a separate component of consolidated stockholders' equity in the consolidated balance sheet as of December 31, 2020 and 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, 2020 and 2019.

Solys Diagnostics Inc.

As of December 31, 2020 and 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, 2020 and 2019, along with the recognition of a net loss attributable to the NCI in the consolidated statement of operations in the years ended December 31, 2020 and 2019.

Note 13 — Income Taxes

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

	Year Ended December 31,	
	2020	2019
Current		
Federal, State and Local	$ —	$ —
Deferred		
Federal	(4,571)	(3,342)
State and Local	(4,147)	(4,808)
	(8,718)	(8,150)
Less: Valuation allowance reserve	8,718	8,150
	$ —	$ —

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,	
	2020	2019
U.S. federal statutory rate	21.0%	21.0%
U.S. state and local income taxes, net of federal benefit	9.9%	14.2%
Permanent differences	(5.8)%	(3.5)%
Other	(0.8)%	15.5%
Valuation allowance	(24.3)%	(47.2)%
Effective tax rate	—%	—%

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,	
	2020	2019
Deferred Tax Assets		
Net operating loss	$ 21,836	$ 14,060
Non-deductible interest expense	517	357
Debt issue costs	205	285
Stock-based compensation expense	1,901	1,213
Patent licenses	14	14
Research and development tax credit carryforwards	396	396
Accrued expenses	552	371
Section 195 deferred start-up costs	24	28
Deferred tax assets	$ 25,445	$ 16,724
Deferred Tax Liabilities		
Depreciation	(19)	(16)
Deferred Tax Liabilities	$ (19)	$ (16)
Deferred tax assets, net of deferred tax liabilities	25,426	16,708
Less: valuation allowance	(25,426)	(16,708)
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 13 — 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, 2020 and 2019.

The Company has total estimated federal and state net operating loss ("NOL") carryforward of approximately $63 million and $40.0 million as of December 31, 2020 and 2019, respectively, which is available to reduce future taxable income, of which approximately $13.8 million have statutory expiration dates commencing in 2035, and approximately $49.2 million which do not have a statutory 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 than 50% ownership change, as computed under such IRC Section 382). The State and Local NOL carryforwards of approximately $63.0 million have statutory expiration dates commencing in 2035. The Company has total estimated research and development ("R&D") tax credit carryforward of approximately $0.4 million as of December 31, 2020 which are available to reduce future tax expense and have statutory expiration dates commencing in 2035.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted in response to the pandemic resulting from the outbreak of a novel strain of a coronavirus designated as the "Severe Acute Respiratory Syndrome Coronavirus 2" - or "SARS-CoV-2". The pandemic resulting from SARS-CoV-2 is commonly referred to by its resulting illness of "coronavirus disease-2019" ("COVID-19"), and is referred to herein as the COVID-19 pandemic.

Among other provisions, the CARES Act increases the limitation on the allowed business interest expense deduction from 30 percent to 50 percent of adjusted taxable income for tax years beginning January 1, 2019 and 2020 and allows businesses to immediately expense the full cost of Qualified Improvement Property, retroactive to tax years beginning on or after January 1, 2018. Additionally, the CARES Act permits net operating loss carryovers ("NOLs") and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. While the Company is currently evaluating the impact of these CARES Act provisions, it is not expected, at this time, to have a material impact on the consolidated income tax provision.

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 2017 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 14 — 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,	
	2020	2019
Numerator		
Net loss - before noncontrolling interest	$ (35,888)	$ (17,268)
Net loss attributable to noncontrolling interest	1,612	811
Net loss - as reported, attributable to PAVmed Inc.	$ (34,276)	$ (16,457)
Series B Convertible Preferred Stock dividends – earned[1]	$ (287)	$ (270)
Net loss attributable to PAVmed Inc. common stockholders	$ (34,563)	$ (16,727)
Denominator		
Weighted average common shares outstanding, basic and diluted[2]	47,432,115	30,197,458
Loss per share		
Basic and diluted		
Net loss - as reported, attributable to PAVmed Inc.	$ (0.72)	$ (0.54)
Net loss attributable to PAVmed Inc. common stockholders	$ (0.73)	$ (0.55)

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

	December 31,	
	2020	2019
PAVmed Inc. 2014 Equity Plan stock options and restricted stock awards	8,215,195	5,903,529
Unit purchase options - as to shares of common stock	53,000	53,000
Unit purchase options - as to shares underlying Series Z Warrants	53,000	53,000
Series Z Warrants	16,814,939	16,815,039
Series W Warrants	381,818	381,818
Series B Convertible Preferred Stock[3]	1,228,075	1,158,209
Total	26,746,027	24,364,595

(1) The Series B 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 period presented.

(2) Basic weighted-average number of shares of common stock outstanding for the years ended December 31, 2020 and 2019 include the shares of the Company issued and outstanding during the years ended December 31, 2020 and December 31, 2019, 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) 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.

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of March 12, 2021, 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 discussion is not complete, and 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 20,000,000 shares of preferred stock, par value $0.001, and 150,000,000 shares of common stock, par value $0.001.

Series B Convertible Preferred Stock

On March 23, 2018, we filed the PAVmed Inc. Certificate of Designation of Preferences, Rights, and Limitations of Series B Convertible Preferred Stock ("PAVmed Inc. Series B Convertible Preferred Stock Certificate of Designation"). As of March 12, 2021, there were 1,252,273 shares of Series B Convertible Preferred Stock issued and outstanding.

Common Stock

As of March 12, 2021, there were 82,460,720 shares of our common stock issued and outstanding, and, as of such date, we also had issued and outstanding:

(i) Stock Options to purchase 7,023,529 shares of our common stock at a weighted average exercise price of $2.55 per share, under the PAVmed Inc. 2014 Long-Term Incentive Equity Plan ("PAVmed Inc. 2014 Equity Plan"); and 1,778,406 shares of our common stock reserved for issuance, but not subject to outstanding awards under the PAVmed Inc. 2014 Equity Plan; and 360,673 shares of our common stock reserved for issuance under the PAVmed Inc. Employee Stock Purchase Plan ("PAVmed Inc. ESPP");
(ii) Common Stock Purchase Warrants to purchase 16,422,915 shares of our common stock at a weighted average exercise price of $1.68 per share;
(iii) Unit Purchase Options ("UPO") 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 Series Z Warrant entitling the holder to purchase one share of our common stock at an exercise price of $1.60 per share;
(iv) Series B Convertible Preferred Stock of 1,252,273 shares, convertible into a corresponding number of shares of our common stock;

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 issued pursuant to the PAVmed Inc. Series B Convertible Preferred Stock Certificate of Designation, 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, as discussed herein below.

The Series B Convertible Preferred stock is senior to our common stock with respect to dividends and assets distributed in liquidation. In this regard, 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 share of common stock of PAVmed Inc. 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 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.

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, as of March 12, 2021. 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 16,041,097 Series Z Warrants outstanding, as of March 12, 2021. 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 21.1

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 Incorporated May 8, 2018
Solys Diagnostics Inc. (84-3484870) - *Majority-Owned*	Delaware Incorporated October 7, 2019

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 Nos. 333-253384, 333-248709, 333-229372, 333-227718, 333-222234, 333-221406, 333-235335, 333-216963, 333-214288], Form S-8 [File No.333-248529] of our report dated March 15, 2021, with respect to our audits of the consolidated financial statements of PAVmed Inc and Subsidiaries as of December 31, 2020 and 2019 and for the two years in the period ended December 31, 2020, which report is included in this Annual Report on Form 10-K of PAVmed Inc. for the year ended December 31, 2020.

/s/ Marcum LLP

Marcum LLP
New York, NY
March 15, 2021

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: March 15, 2021

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: March 15, 2021

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, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lishan Aklog, M.D., Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

Date: March 15, 2021

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, 2020 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: March 15, 2021

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