UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ 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 filed	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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 ☒

As of June 30, 2021, 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 $470.2 million, based on 73,467,278 shares of common stock held by non-affiliates and a last reported sales price per share of the registrant's common stock of $6.40 on such date.

As of March 29, 2022 there were87,667,406 shares of the registrant's Common Stock, par value $0.001 per share, issued (with such number of shares inclusive of shares of common stock underlying granted but unvested restricted stock options).

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2022 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, 2021.

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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.

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 medical technology 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. From inception on June 26, 2014, thru 2020, the Company's activities were technology-focused on advancing its lead products towards regulatory approval and pre-commercialization, protecting its intellectual property, and building its corporate infrastructure and management team. Beginning in 2020 through 2021 our activities and efforts are best described as transition years focused mainly on infrastructure expansion including personnel, systems, and facilities. Additionally, the focus increasingly involved building out the commercial foundation including reimbursement with CMS and private payor engagement, sales operations, clinical services and Lucid Test Centers. For the years 2022 and beyond, the central focus will be predominantly on commercial expansion and execution including the acceleration of EsoGuard commercialization and the transition of NextFlo, EsoCure, Veris, and the next generation of CarpX from pre-commercial activities to commercial adoption.

The Company operates in one segment as a medical device company with four operating divisions which include Medical Devices, Diagnostics, Digital Health, and Emerging Innovations. As resources permit, we will continue to explore internal and external innovations that fulfill our project selection criteria without limiting ourselves to any target specialty or condition. In addition to activities ongoing at the parent company level, the Company also has ongoing operations conducted in three majority owned subsidiaries: Lucid Diagnostics, Inc. ("Lucid Diagnostics" or "LUCID") incorporated in May 2018, Veris Health, Inc. ("Veris") founded in May 2021 with the acquisition of Oncodisc, Inc and its digital health technologies, and Solys Diagnostics, Inc. ("Solys Diagnostics" or "SOLYS") incorporated in October 2019.

On October 14, 2021, Lucid Diagnostics completed an initial public offering ("IPO") of its common stock under an effective registration statement on Form S-1 (SEC File No. 333-259721), wherein a total of 5.0 million IPO shares of common stock of Lucid Diagnostics Inc. were issued, with such total IPO shares inclusive of 571,428 shares issued to PAVmed Inc., at an IPO offering price of $14.00 per share, resulting in gross proceeds to Lucid Diagnostics Inc. of $70.0 million, before underwriting fees of $4.9 million, and approximately $0.7 million of offering costs incurred by Lucid Diagnostics Inc.

PAVmed Inc. and its subsidiaries have proprietary rights to the trademarks used herein, including, among others, PAVmed™, Lucid Diagnostics™, LUCID™, Veris Health™, VERIS™, Oncodisc™, Solys Diagnostics™, SOLYS™, 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 are in various phases of development, regulatory clearances, approvals, and commercialization, including:

- The EsoCheck device received 510(k) marketing clearance from the U.S. Food and Drug Administration ("FDA"), in June 2019 and European CE Mark Certification in May 2021 as an esophageal cell collection device; and, EsoGuard has been established as a Laboratory Developed Test ("LDT"), completed European CE Mark Certification in June 2021, 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. ("RDx"), headquartered in Irvine, California. On February 25, 2022, Lucid Diagnostics new, wholly owned subsidiary, LucidDx Labs Inc. ("LucidDx Labs") acquired from ResearchDx, Inc. ("RDx"), a CLIA-certified, CAP-accredited clinical laboratory operator located in Irvine, CA, certain licenses and other related assets necessary for LucidDx Labs to operate its own new CLIA-certified, CAP-accredited clinical laboratory located in Lake Forest, CA. In August 2021, Lucid Diagnostics launched a strategic partnership with direct-to-consumer telemedicine company UpScriptHealth to support our commercialization efforts. Also in August 2021, we tested our first patients referred by primary care physicians ("PCPs") in three Lucid Test Centers opened in the Phoenix metropolitan area.

- 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) in April 2020, with the first commercial procedure successfully performed in December 2020. In May 2021 European CE Mark Certification was received for CarpX.
- I n May 2021, we formed Veris Health, which is our newest majority-owned subsidiary. In connection with it formation, Veris Health acquired Oncodisc Inc ("Oncodisc"), a digital health company with ground breaking tools to improve personalized cancer care through remote patient monitoring. Oncodisc's core technologies include the first intelligent implantable vascular healthcare platform that provides patients and physicians with new tools to improve outcomes and optimize the delivery of cost-effective care through remote monitoring and data analytics. Its vascular access port contains biologic sensors capable of generating continuous data on key physiologic parameters known to predict adverse outcomes in cancer patients undergoing treatment. Wireless communication to the patient's smartphone and its cloud-based digital healthcare platform efficiently and effectively delivers actionable real time data to patients and physicians. The technologies are the subject of multiple patent applications and one allowed patent awaiting final issuance.

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

- ***Diagnostics*** - EsoGuard Esophageal DNA Test, EsoCheck Esophageal Cell Collection Device; and EsoCure Esophageal Ablation Device with Caldus Technology;
- ***Medical Devices*** - 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;
- ***Digital Health*** – Veris cancer healthcare platform and implantable intelligent vascular port combining remote monitoring and data analytics;
- ***Emerging Medical Devices –*** *NextVent* single-use ventilators; FlexMO medical circulatory support cannulas; Veris Cardiac Monitor; *DisappEAR* resorbable pediatric ear tubes; *Solys* Noninvasive glucose monitoring;

Diagnostics

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. 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 dysplastic BE and related pre-cursors to EAC in patients with chronic gastroesophageal reflux ("GERD").

EsoGuard is a bisulfite-converted next-generation sequencing (NGS) DNA assay performed on surface esophageal cells collected with EsoCheck. It quantifies methylation at 31 sites on two genes, Vimentin (VIM) and Cyclin A1 (CCNA1). The assay was evaluated in a 408-patient multicenter case-control study published in Science Translational Medicine and showed greater than 90% sensitivity and specificity at detecting esophageal precancer and all conditions along the BE-EAC spectrum, including on samples collected with EsoCheck (Moinova, et al. Sci Transl Med. 2018 Jan 17;10(424): eaao5848). EsoGuard is commercially available in the U.S. as a Laboratory Developed Test (LDT) performed at our CLIA-certified laboratory partner, ResearchDx Inc. ("RDx"), which does business as "PacificDx". Cell samples, including those collected with EsoCheck, as discussed below, are sent to RDx, for testing and analyses using our proprietary EsoGuard NGS DNA assay.

EsoCheck is an FDA 510(k) and CE Mark cleared noninvasive swallowable balloon capsule catheter device capable of sampling surface esophageal cells in a less than five-minute office. It consists of a vitamin pill-sized rigid plastic capsule tethered to a thin silicone catheter from which a soft silicone balloon with textured ridges emerges to gently swab surface esophageal cells. When vacuum suction is applied, the balloon and sampled cells are pulled into the capsule, protecting them from contamination and dilution by cells outside of the targeted region during device withdrawal. We believe this proprietary Collect+Protect™ technology makes EsoCheck the only noninvasive esophageal cell collection device capable of such anatomically targeted and protected sampling.

In December 2019, we secured "gapfill" determination for the EsoGuard PLA code 0114U through the United States Department of Health and Human Services ("HHS") Centers for Medicare and Medicaid Services ("CMS") Clinical Laboratory Fee Schedule ("CLFS") process, which has allowed us to engage directly with Medicare contractor Palmetto GBA, LLC and its MolDx Program on CMS payment and coverage. In October 2020, CMS granted EsoGuard final Medicare payment determination of $1,938.01, effective January 1, 2021. We are still awaiting Medicare local coverage determination from MolDx, which we understand is working to clear a significant backlog of reviews.

We are also aggressively pursuing EsoGuard U.S. private payor payment and coverage. We recently held our initial advisory board meetings with medical directors of major insurers to obtain feedback and guidance on the type of clinical data that will be helpful in securing payment and coverage. Although the claim cycle can be prolonged during the early commercialization of a new test, PacificDx is starting to receive out-of-network private insurance payments on our behalf.

Our initial EsoGuard commercialization efforts focused on gastroenterology (GI) physicians who have generally embraced our message that EsoGuard has the potential to expand the funnel of BE-EAC patients who will need long term EGD surveillance and, potentially, treatment with endoscopic esophageal ablation. We have previously relied upon a hybrid sales model with full-time sales management and approximately fifty independent sales representatives. We significantly expanded our full-time commercial team in 2021 and are actively recruiting full-time territory managers and sales representatives nationwide. Our Lucid Vice President of Sales and three Area Sales Directors ("ASD") oversee a growing number of Sales Representatives, Market Development Mangers ("MDM") and Clinical Specialists. EsoGuard testing has accelerated as pandemic-related healthcare facility limitations have eased.

Our EsoGuard commercialization efforts span multiple channels including targeting primary care physicians and consumers in addition to GI physicians. To assure sufficient testing capacity and geographic coverage, as part of this expansion, we are building our own network of Lucid Test Centers, staffed by Lucid-employed clinical personnel, where patients can undergo the EsoCheck procedure and have the sample sent for EsoGuard testing, starting with three test centers launched in the Phoenix metropolitan area. We have expanded our test centers to include Salt Lake City, Utah, Henderson, Nevada, and Denver, Colorado. We are currently expanding into Portland, Oregon, Seattle, Washington, and Boise, Idaho.

We have also established an EsoGuard Telemedicine Program, in partnership with UpScript, LLC, an independent third-party telemedicine provider, that accommodates EsoGuard self-referrals from direct-to-consumer marketing.

Our active clinical research and development program seeks to expand the clinical evidence of our products' efficacy to support our ongoing regulatory, reimbursement and commercial efforts, including an FDA PMA submission for approval of EsoGuard and EsoCheck as an in vitro diagnostics ("IVD") device, as currently, EsoGuard and EsoCheck are permitted to be marketed separately, but not in combination. We are actively enrolling patients in two international multicenter clinical trials to support FDA PMA approval of EsoGuard, used with EsoCheck, as an IVD indicated to detect NDBE. ESOGUARD-BE-1 is a screening study which will enroll approximately 500 to 900 male GERD patients over 50 years of age with one other risk factor. ESOGUARD-BE-2 is a case control study which will enroll approximately 500 male GERD patients with a previous diagnosis of NDBE, LGD, HGD, or EAC, along with normal controls.

In February 2020, we received FDA "Breakthrough Device Designation" for EsoGuard as an in-vitro diagnostic medical device ("IVD"). 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. The Centers for Medicare and Medicaid Services and the United States Congress continue to work to provide an expedited coverage pathway for emerging technologies.

We have received ISO 13485:2016 certification for Lucid's quality management system and received CE Mark certification for EsoCheck in May 2021 which allows it to be marketed in CE Mark European countries, which include the European Economic Area (the EU, Norway, Iceland, and Lichtenstein), Switzerland, and, until July 1, 2023, the United Kingdom. In June 2021, we completed the European Directive 98/79/EC for In-Vitro Diagnostic Medical Devices ("IVDD") CE Mark certification for EsoGuard after Lucid and its European Union ("EU") authorized representative completed the Commission of the European Union ("EC") declaration of conformity procedure, including the associated technical documentation, ensuring and declaring EsoGuard meets the essential requirements of the IVDD.

EsoCure

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 have also completed an acute and survival animal study of EsoCure™ Esophageal Ablation Device, demonstrating successful direct thermal balloon catheter ablation of esophageal lining through working channel of standard endoscope. We plan to conduct additional development work and animal testing of EsoCure to support a future FDA 510(k) submission.

In March 2022, both the PAVmed and Lucid board of directors have approved entering into an intercompany license between PAVmed and Lucid such that Lucid will be granted the rights to commercialize EsoCure for the treating dysplastic Barrett's Esophagus, including a royalty arrangement whereby Lucid will pay PAVmed a 5% royalty on all EsoCure sales up to $100 million per calendar year, and 8% above that threshold. Lucid will obligated to fund ongoing development costs and cumulative patent expenses. EsoCure will become part of an integrated suite of Lucid products addressing BE-EAC. Furthermore, should PAVmed acquire businesses or commercial products or develop technologies that may be partially or wholly synergistic with Lucid's lead products and therefore provide the opportunity to create value, Lucid may also seek to negotiate an arms-length commercial license from PAVmed to market the relevant commercial products that may originate from PAVmed's development or acquisition initiatives. To that end, In March 2022, both the PAVmed and Lucid board of directors have approved entering into a purchase and sale of the CapNostics, LLC assets from PAVmed to Lucid as well as transferring the consulting agreement with the previous principal owner of CapNostics, LLC. The transfer price is $2.1 million for the assets, the same purchase price paid by PAVmed's subsidiary.

Medical Devices

CarpX

CarpX is a minimally invasive surgical device for use in the treatment of carpal tunnel syndrome which received FDA 510(k) marketing clearance in April 2020, with the first commercial procedure successfully performed in December 2020. After an initial slowdown in commercialization related to COVID, more recently we have recruited new sales leadership and have recently trained eight new surgeons to perform the CarpX procedure with four more scheduled to undergo training in the coming months. Our limited-release commercialization efforts thru 2022 are focused on engaging key opinion hand surgeons designed to solicit input for ergonomic improvements to the device, procedure development and surgical-time optimization, and ease of use. Concurrently, we are presently working on improvements to the device that will released in stages over the next

several quarters.

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 presently have a National Sales Director, one Sales Representative, and one Clinical Specialist that are overseeing our CarpX commercial efforts. As we broaden adoption of the device beyond key opinion leaders. we intend to commercialize 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 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 received CE Mark certification for CarpX in May 2021 which allows it to be marketed in CE Mark European countries, which include the European Economic Area (the EU, Norway, Iceland, and Lichtenstein), Switzerland, and, until July 1, 2023, the United Kingdom.

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 have initiated 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. In March of 2022, the First-In-Human implantations of PortIO devices were successfully performed at the Clinica Porto Azul in Barranquilla, Colombia.

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 may seek a long-term strategic partnership or acquiror with respect to NextFlo, as we continue to have periodic discussions continue with large strategic partners to license the NextFlo technology for disposable infusion pumps. Notwithstanding, we continue to advance the technology towards self-commercialization. We have initiated design freeze verification testing in preparation for final verification and validation testing of NextFlo IV Infusion Set, to support FDA 510(k) submission and clearance targeted for the second half of 2022.

We recently hired a director of sales who will focus on all aspects of NextFlo's commercial launch including and not limited to creating and executing the sales strategy, hiring/mentoring the commercial launch team, and collaborating with internal resources on product development and marketing. Target customers include Acute Inpatient Care, Outpatient Care, Infusion Centers, Home Infusions, Outpatient Pharmacy, EMS, and the Department of Defense.

Digital Health

Veris

In May 2021, we formed Veris Health, which is our newest majority majority-owned subsidiary, focused on digital health technology. In connection with its formation, Veris Health acquired Oncodisc, a digital health company with groundbreaking tools to improve personalized cancer care through remote patient monitoring.

Oncodisc was founded by experienced physician entrepreneurs, James Mitchell, M.D., who joins Veris Health as its full-time Chief Medical Officer, and Andrew Thoreson, M.D., who will serve as a Veris Health consultant. Oncodisc's core technologies include the first intelligent implantable vascular access port with biologic sensors and wireless communication, combined with an oncologist-designed remote digital healthcare platform that provides patients and physicians with new tools to improve outcomes and optimize the delivery of cost-effective care through remote monitoring and data analytics.

Oncodisc was founded in 2018 by Mitchell, a radiation oncologist, and Thoreson, an interventional radiologist, who previously co-founded Redsmith, Inc., an interventional catheter company whose technology was acquired by C.R. Bard Inc., now BD Inc. (NYSE: BDX). Oncodisc received a National Science Foundation ("NSF") Small Business Innovation Research ("SBIR") grant award to support its early work and completed both the MedTech Innovator Accelerator and UCSF Rosenman Institute Accelerator programs.

Its groundbreaking vascular access port contains biologic sensors capable of generating continuous data on key physiologic parameters known to predict adverse outcomes in cancer patients undergoing treatment. Wireless communication to the patient's smartphone and its cloud-based digital healthcare platform efficiently and effectively delivers actionable real time data to patients and physicians. The technologies are the subject of multiple patent applications and one issued patent.

The planned Veris Health business model seeks to generate 100% recurring revenue through oncology practice and hospital-based subscriptions. These entities would purchase seats on the platform and pay a monthly remote monitoring charge to drive revenues from remote patient monitoring and device implantation under existing CPT codes, as well as established CMS Oncology Care Model (OCM) bonuses and CMS Quality Reporting Program incentives. Veris Health also anticipates strong demand for its intelligent implantable vascular access port and remote monitoring platform from oncology biotherapeutic companies to support clinical trials of their novel immunotherapy and chemotherapy agents with continuous physiologic data and transformative analytics.

In addition to targeting the oncology market, Veris plan to expand into cardiovascular diseases, end-stage renal disease, and lung disorders like COPD. We have already initiated R&D efforts around an enhanced implantable cardiac monitor capable of detecting cardiac arrhythmias and other physiologic parameters critical for high-risk cardiac patients. Future devices will combine novel sensing technology with seamless communication, engaging user interface design, and data analytics driving actionable clinical insights for patients with congestive heart failure. These technologies will then be expanded for high-risk kidney disease and pulmonary patients.

Emerging Medical Devices

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: *NextVent* (single use ventilators); FlexMO (medical circulatory support cannulas); Veris Cariac monitor;*DisappEAR* (resorbable pediatric ear tubes); and *Solys* (Noninvasive glucose monitoring). 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.

Diagnostics

Our majority owned subsidiary, Lucid Diagnostics, Inc. (Nasdaq: LUCD) is a commercial-stage medical diagnostics technology company focused on the millions of patients with gastroesophageal reflux disease (GERD), also known as chronic heartburn, acid reflux or simply reflux, who are at risk of developing esophageal precancer and cancer, specifically highly lethal esophageal adenocarcinoma (EAC).

We believe that our lead products, the EsoGuard® Esophageal DNA Test performed on samples collected with the EsoCheck® Esophageal Cell Collection Device, constitute the first and only commercially available diagnostic test capable of serving as a widespread screening tool to prevent EAC deaths, through early detection of esophageal precancer in at-risk GERD patients. The technologies were highlighted in the NCI's Annual Plan and Budget Proposal for FY2020 to Congress as one of the year's significant advances in cancer prevention. We believe EsoGuard could have as great an impact in preventing EAC deaths as widespread Pap test screening has had in preventing cervical cancer deaths.

In just over three years since our inception, we have advanced the technologies underlying EsoGuard and EsoCheck from the academic research laboratory to commercial products within scalable business model. EsoGuard is commercialized in the U.S. as a Laboratory Developed Test (LDT) and was granted final Medicare payment determination of $1,938.01, effective January 1, 2021. EsoCheck is commercialized in the U.S. as a 510(k)-cleared esophageal cell collection device. EsoGuard, used with EsoCheck, was granted FDA Breakthrough Device designation and is the subject of two large, actively enrolling, international multicenter PMA clinical trials.

Gastroesophageal reflux disease (GERD), a pathologic condition in which stomach fluid, including acid, inappropriately refluxes into the lower esophagus, is ubiquitous and can lead to highly lethal esophageal adenocarcinoma (EAC). Our opportunity is to prevent EAC deaths through the early detection of esophageal precancer and cancer in millions of at-risk GERD patients.

In 2021, approximately 20,000 U.S. GERD patients are projected to be diagnosed with EAC and approximately 16,000 will die from it. Over 80% of EAC patients will die within five years of diagnosis, making it the second most lethal cancer in the U.S. The U.S. incidence of EAC has increased 500% over the past four decades, while the incidences of other common cancers have declined or remained flat. In nearly all cases, EAC silently progresses until it manifests itself with new symptoms of advanced disease. EAC is nearly always invasive at diagnosis, and, unlike other common cancers, mortality rates are high even in its earlier stages.

Up to 50 million, or one in four, U.S. adults have weekly GERD symptoms. Although symptoms can be ameliorated with medications, including proton pump inhibitors (PPIs) such as Nexium® and Prilosec®, medications do not prevent progression to esophageal precancer or cancer.

Barrett's Esophagus (BE) is an esophageal precancer and complication of GERD characterized by pathologic transformation of surface esophageal cells. Dysplastic BE is a late esophageal precancer characterized by further premalignant pathologic transformation called dysplasia. All EAC is believed to arise from BE as the culmination of pathologic changes along the BE-EAC precancer-cancer spectrum—from nondysplastic BE (NDBE), to low-grade dysplastic BE (LGD), high-grade dysplastic BE (HGD) and finally EAC. Dysplastic BE can be cured with endoscopic esophageal ablation which reliably halts progression to EAC.

The subgroup of long-standing or severe GERD patients at-risk for BE and progression to EAC is well defined in clinical practice guidelines, including the American College of Gastroenterology (ACG) BE Guidelines. Risk factors include age over 50 years, male gender, White race, obesity, smoking history and a family history of BE-EAC. The ACG BE Guidelines recommend screening for patients with a five-year history of, or severe, GERD and three or more risk factors. The highest risk symptomatic GERD cohort recommended for screening consists of the estimated 13 million U.S. men over 50 with one additional risk factor. An estimated 60% of at-risk GERD patients are Medicare beneficiaries.

Unfortunately, for a variety of reasons, less than 10% of at-risk GERD patients who are recommended for screening undergo traditional invasive upper gastrointestinal endoscopy (EGD). We believe that the profound tragedy of an EAC diagnosis is that likely death could have been prevented if the at-risk GERD patient had been screened and then undergone surveillance and curative endoscopic esophageal ablation of dysplastic BE.

Since mortality rates are high even in early stage EAC, preventing EAC deaths requires detection and intervention at the precancer stage. Most of the necessary elements for such an early detection program are already well established—an at-risk population (at-risk GERD patients), a precancer (BE), and an intervention which can halt progression to EAC (endoscopic esophageal ablation). The only missing element for such an early detection program is a widespread screening tool that can detect BE prior to EAC.

Gastroesophageal reflux disease (GERD), a pathologic condition in which stomach fluid, including acid, inappropriately refluxes into the lower esophagus, is ubiquitous and can lead to highly lethal esophageal adenocarcinoma (EAC). Our opportunity is to prevent EAC deaths through the early detection of esophageal precancer and cancer in millions of at-risk GERD patients.

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We believe EsoGuard, used with EsoCheck, constitutes that missing element—the first and only commercially available diagnostic test capable of serving as a widespread screening tool to prevent EAC deaths through early detection of esophageal precancer and cancer in at-risk GERD patients.

EsoGuard is a bisulfite-converted next-generation sequencing (NGS) DNA assay performed on surface esophageal cells collected with EsoCheck. It quantifies methylation at 31 sites on two genes, Vimentin (VIM) and Cyclin A1 (CCNA1). The assay was evaluated in a 408-patient multicenter case-control study published in Science Translational Medicine, and showed greater than 90% sensitivity and specificity at detecting esophageal precancer and all conditions along the BE-EAC spectrum, including on samples collected with EsoCheck (Moinova, *et al. Sci Transl Med.* 2018 Jan 17;10(424): eaao5848). Large ongoing clinical trials seek to replicate these results, including a prospective screening study of at-risk GERD patients. EsoGuard is commercially available in the U.S. as a Laboratory Developed Test (LDT) performed at our CLIA-certified laboratory partner, ResearchDx Inc. dba PacificDx.

EsoCheck is an FDA 510(k) and CE Mark cleared noninvasive swallowable balloon capsule catheter device capable of sampling surface esophageal cells in a less than five-minute office. It consists of a vitamin pill-sized rigid plastic capsule tethered to a thin silicone catheter from which a soft silicone balloon with textured ridges emerges to gently swab surface esophageal cells. When vacuum suction is applied, the balloon and sampled cells are pulled into the capsule, protecting them from contamination and dilution by cells outside of the targeted region during device withdrawal. We believe this proprietary Collect+Protect™ technology makes EsoCheck the only noninvasive esophageal cell collection device capable of such anatomically targeted and protected sampling. The sample is sent by overnight express mail to our third-party CLIA-certified laboratory partner for EsoGuard testing.

Current Status of EsoGuard and EsoCheck

Regulatory

In June 2019, we received FDA 510(k) clearance to market EsoCheck in the U.S. as a device indicated for use in the collection and retrieval of surface cells of the esophagus in adults. In December 2019, our CLIA-certified laboratory partner, completed documentation of EsoGuard analytical validity allowing us to commercialize it as a Laboratory Developed Test (LDT). In May 2021, we received CE Mark certification for EsoCheck, and in June 2021, we completed CE Mark self-certification for EsoGuard, indicating both may be marketed in CE Mark European countries.

EsoGuard's status as a commercially available LDT is dependent on the FDA exercising enforcement discretion for LDTs. Notwithstanding the fact that FDA has exercised such discretion despite indicating through non-binding communications and documents it might consider no longer doing so, and the fact that HHS recently forbade FDA from requiring premarket review of LDTs absent a formal rulemaking process, pending legislation seeking to revamp the regulatory framework of diagnostic tests keeps the regulatory landscape for LDTs such as EsoGuard uncertain. To mitigate that risk long-term, we have decided to pursue FDA PMA approval for EsoGuard, as an IVD. In October 2019, we participated in a FDA pre-submission meeting and received feedback on a proposed initial indication for use and the design of our two international multi-center clinical studies to support a PMA application for FDA approval of EsoGuard on samples collected with EsoCheck. We expect to complete enrollment by the end of 2022 and submit our PMA by early 2023.

Manufacturing & Logistics

EsoCheck is currently manufactured for us by our partner Sage Product Development Inc. on a line that can produce over ten thousand units per year. In July 2021 we entered into an agreement to transfer the EsoCheck manufacturing line to high-volume manufacturer Coastline International Inc. The initial term of the agreement expires on September 1, 2023, subject to automatic renewal for successive two-year terms unless either party notifies the other of intent to terminate the agreement no less than 90 days prior to the initial termination date or the expiration of any successive term. The agreement, as amended, provides per unit pricing for up to 250,000 units per year, a non-recurring charge to cover the costs associated with the transfer process, and a detailed timeline that allows for the flexibility to move production to Coastline later in 2022 as test volumes increase. The manufacturing line is being designed to allow capacity to be scaled to over one million units per year. Our EsoGuard Specimen Kits are manufactured for us by our partner ResearchDx and can be transferred to a higher volume manufacturer whenever demand dictates. The warehousing, logistics, fulfillment and customer support of our products is managed for us by our partner HealthLink International, a leading third-party logistics company.

Reimbursement

In December 2019, we secured "gapfill" determination for EsoGuard's PLA code 0114U through the CMS CLFS process. This allowed us to engage directly with Medicare contractor Palmetto GBA and its MolDx Program on CMS payment and coverage. In October 2020, CMS granted EsoGuard final Medicare payment determination of $1,938.01, effective January 1, 2021. We are still awaiting Medicare local coverage determination from MolDx, which we understand is working to clear a significant backlog of reviews.

We are also aggressively pursuing EsoGuard U.S. private payor payment and coverage. We recently held our first advisory board meeting with medical directors of major insurers to obtain feedback and guidance on the type of clinical data that will be helpful in securing payment and coverage. Although the claim cycle can be prolonged during the early commercialization of a new test, PacificDx has received out-of-network private insurance payments on our behalf.

Commercialization

Our initial EsoGuard commercialization efforts on gastroenterology (GI) physicians who have generally embraced our message that EsoGuard has the potential to expand the

funnel of BE-EAC patients who will need long-term EGD surveillance and, potentially, treatment with endoscopic esophageal ablation. At the outset of our commercialization, we utilized a hybrid sales model with full-time sales management but have since transitioned and significantly expanded our full-time commercial team in 2021 and are actively recruiting full-time territory market develop managers and sales representatives nationwide. EsoGuard testing has begun accelerating as pandemic-related healthcare facility limitations have eased.

We are now expanding EsoGuard commercialization to target primary care physicians (PCPs). The vast majority of at-risk GERD patients are cared for by PCPs and never see a gastroenterologist. To assure sufficient testing capacity and geographic coverage during this expansion, we are building our own network of Lucid Test Centers, where Lucid-employed clinical personnel will perform the EsoCheck procedure for EsoGuard testing. We have hired personnel and leased medical office space and have launched three pilot Lucid Test Centers in the Phoenix metropolitan area and added centers in Utah, Colorado, and Nevada. We are presently focused on adding Centers in Oregon, Washington, and Idaho. Additionally, we have established an EsoGuard Telemedicine Program, in partnership with an independent third-party telemedicine provider, that can accommodate EsoGuard self-referrals from direct-to-consumer marketing. In July 2021, we entered into an agreement with UpScript, LLC ("UpScript") to develop and operate a web-based platform to allow individuals access to licensed physicians and healthcare professionals in order to engage in a telemedicine consult. UpScript will develop, operate, and maintain a Lucid website for individuals to request a Laboratory Test and access physicians and other healthcare professionals that are each qualified by law for professional services they are providing. The Lucid website will have the ability to transmit the requests from individuals and return a test order, if authorized. UpScript will transmit any such test order to the CLIA-certified laboratory directed by Lucid in order arrange for the performance of the specimen collection with the EsoCheck and performance of the laboratory test (EsoGuard).

Clinical Research & Development

Our active clinical research and development program seeks to expand the clinical evidence of our products' efficacy to support our ongoing regulatory, reimbursement and commercial efforts. We are actively enrolling patients in two international multicenter clinical trials to support FDA PMA approval of EsoGuard, used with EsoCheck, as an IVD indicated to detect NDBE. ESOGUARD-BE-1 is a screening study which will enroll approximately 500 to 900 male GERD patients over 50 years of age with one other risk factor. ESOGUARD-BE-2 is a case control study which will enroll approximately 500 male GERD patients with a previous diagnosis of NDBE, LGD, HGD, or EAC, along with normal controls. Approximately one-half of the U.S. sites and one European site are actively enrolling. We expect to complete enrollment in both trials by the end of 2022 or the early part of 2023 and submit our PMA to FDA by mid-2023.

Our Growth Strategy

We believe EsoGuard's total addressable U.S. market opportunity exceeds $25 billion based on an effective Medicare payment of $1,938 and the over 13 million U.S. male at-risk GERD patients recommended for screening by clinical practice guidelines. We believe that EsoGuard, used with EsoCheck, as the first and only commercially available test capable of serving as a widespread BE-EAC screening tool, has the potential to become the standard of care to detect esophageal precancer in at-risk GERD patients.

Expand EsoGuard Commercialization Across Multiple Channels

The first pillar of our overall growth strategy is to expand EsoGuard commercialization across multiple channels, targeting primary care physicians (PCPs) and consumers in addition to GI physicians. We continue to accelerate the expansion of our sales and marketing team targeting these multiple channels.

We have the opportunity to educate PCPs that GERD can lead to EAC, and that, for the first time, they can refer their at-risk GERD patients for testing using a non-endoscopic alternative to EGD. We believe our Lucid Test Centers will play a critical role in significantly growing EsoGuard testing from PCP referrals. After advancing the pilot program in Phoenix, we are steadily expanding our Lucid Test Centers to other metropolitan areas, first in Western U.S. states and then nationwide.

We believe that direct-to-consumer (DTC) education and marketing will help drive our long-term growth. We believe that educating consumers on the link between GERD and BE-EAC, and the availability of a simple noninvasive test to detect esophageal precancer, will encourage those at risk to consider EsoGuard testing. We have launched an EsoGuard Telemedicine Program with DTC marketing in Phoenix and will expand it to other metropolitan areas once we demonstrate an acceptable return on investment.

Expand Our Clinical Evidence to Support Commercialization, Reimbursement and Regulatory Efforts

The second pillar of our growth strategy is to aggressively expand the clinical evidence for our products to support our commercialization, reimbursement and regulatory efforts, as well as to secure recommendations in clinical practice guidelines, an important value creation milestone. We are currently undertaking multiple ongoing and future clinical trials to build this evidence.

We seek to accelerate completion of our ongoing ESOGUARD-BE-1 and ESOGUARD-BE-2 clinical trials to support FDA PMA approval of EsoGuard, used with EsoCheck, as an IVD. We will then work with FDA, pursuant to our Breakthrough Device designation, to extend the ESOGUARD-BE-1 to enroll sufficient patients to support an expanded indication to detect dysplastic BE, a substantial but potentially highly rewarding undertaking. Finally, we are planning several EsoGuard/EsoCheck clinical utility studies, including a large registry and a study using electronic medical record screening to assess an EsoGuard-driven strategy to find BE-EAC disease in at-risk GERD patients.

Expand Our Manufacturing and Laboratory Testing Capacity

We are in the process of scaling our operational capacity, enhance efficiency and improve operating margins as demand for our products grows. We will complete transfer of EsoCheck manufacturing to a high-volume partner in 2022, which will provide sufficient long-term manufacturing capacity and substantially lower per-unit cost of goods. We anticipated doing the same for EsoGuard Specimen Kit manufacturing as demand dictates. Although the CLIA-certified laboratory at ResearchDX has sufficient capacity to meet EsoGuard testing for the medium-term, we believe it is in our long-term interest to secure our own CLIA-certified laboratory, to increase capacity further, streamline billing and claims management, and decrease per-test cost of goods. On February 25. 2022, Lucid Diagnostics new, wholly owned subsidiary, LucidDx Labs Inc. acquired from ResearchDx, Inc., a CLIA-certified, CAP-accredited clinical laboratory operator located in Irvine, CA, certain licenses and other related assets necessary for LucidDx Labs to operate its own new CLIA-certified, CAP-accredited clinical laboratory located in Lake Forest, CA.

Expand Our Product Portfolio

We seek to expand our product portfolio with at least two highly synergistic technologies under development—BE-EAC progression markers and PAVmed's EsoCure device —that would create a fully integrated suite of products to address the diagnosis, monitoring and treatment of BE-EAC. We have the opportunity to license and develop biomarkers with the potential to discriminate between NDBE and dysplastic BE on samples collected with EsoCheck, which we believe would revolutionize NDBE surveillance. When dysplastic BE is identified, endoscopic esophageal ablation is indicated to cure the BE and halt progression to EAC. EsoCure has certain key features which give it the potential, once cleared and clinically available, to unseat the dominant RF ablation technology. We intend to pursue these and any other technologies which synergize with our lead products, improve our competitive position or otherwise provide the opportunity to create value. In March of 2022, both the PAVmed and Lucid boards approved entering into an intercompany license agreement for Lucid to formally license EsoCure.

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 is enrolling GERD patients without a prior diagnosis of BE or EAC who satisfy ACG BE screening guidelines. The case control study is enrolling patients with a previous diagnosis of non-dysplastic BE, dysplastic BE (both low and high-grade) or EAC. In both studies, EsoGuard is comparing 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 the Centers for Medicare and Medicaid Services and the United States Congress continue to work to provide an expedited coverage pathway for emerging technologies.

Pursuant to our Breakthrough Device discussions with FDA, we intend to extend enrollment in the ESOGUARD-BE-1 screening study until it is sufficiently powered to support expansion to the above proposed indication for use to include detection of dysplastic BE. FDA indicated that although they would have preferred to a study powered for HGD, they understood that the study size would be impracticable and that they would be open to including LGD. It also indicated that it would consider study designs with some enrichment and, potentially, interim analysis and approval to mitigate sample size. We will be working with FDA to finalize an extension of our current screening study to support such an expanded dysplastic BE indication once FDA resumes Breakthrough Device meetings for IVDs, which are currently on hold as the branch works to clear a Covid-19 pandemic related backlog. This study will be a substantial, capital-intensive, but potentially highly rewarding undertaking. Although the study size is yet to be determined and will depend on negotiations with FDA, it will be in the thousands.

EsoGuard Clinical Utility Studies

Demonstrating EsoGuard clinical utility requires providing evidence that it has a meaningful impact on the clinical care of patients undergoing the procedure. It does not require demonstrating the performance of the assay, *i.e.*, the negative and positive predictive values. Our PMA trials are designed and powered to do so. Clinical utility studies need to demonstrate that patients with a positive EsoGuard test undergoes confirmatory EGD which leads to a specific intervention, *e.g.*, implementation of an NDBE surveillance program or ablation of dysplastic BE. Ideally, the near-term EGD rate of EsoGuard negative patients should be low. In other words, EsoGuard testing should be able to triage patient to EGD vs. no EGD, with EGD positive patients receiving an intervention, which would not have happened if the patient had not been triaged by EsoGuard.

Demonstrating EsoGuard's clinical utility is very important for a variety of purposes, including, importantly, for private payor payment and coverage. Our recent advisor board meeting with medical directors of private insurers confirmed this. They strongly indicated that one of the most important factors in their future decision to grant payment and coverage will be demonstrating that physicians order the test and, when they do, that clinical utility can be demonstrated.

Clinical utility studies are also important for general EsoGuard commercialization to physician who want to know that it can "find disease". A recent U.K. study from Dr. Fitzgerald's team is a good example. They published a large study of GERD patients in a primary care setting who underwent screening with Cytosponge/TFF-3 and showed that they were able to identify patients with BE and the occasional EAC. This was not a performance study with routine EGD so the authors could not say how many BE-EAC patients were missed, which was likely non-trivial given the published data on suboptimal Cytosponge/TFF-3 performance. However, the study was useful in convincing U.K. authorities to initiate mobile testing centers around the country.

We shortly will launch an EsoGuard Registry study as our primary study to demonstrate clinical utility. Every patient undergoing EsoCheck testing will be asked to provide informed consent for us to collect limited post-procedural data from the patient's physician on care received after EsoGuard testing, most importantly whether they underwent EGD and, if so, what the results showed.

We are also in discussions with a large academic medical center to initiate a clinical utility study in which investigators would use the network-wide electronic medical record to systematically identify at-risk GERD patients, offer them EsoGuard testing and compare them to historical controls also identified from the database. The study would seek to demonstrate that an EsoGuard-guided strategy identifies more BE-EAC patient than historical practice.

Finally, we are helping investigators at a VA medical center launch a Department of Defense supported study to compare the positive predictive value of EsoGuard followed by EGD compared to EGD alone and the relative costs of each strategy. The study would seek to demonstrate that EsoGuard increases the positive rate of EGD, an important measure of the clinical utility of a noninvasive diagnostic test.

Eosinophilic Esophagitis Using EsoCheck

We are exploring additional EsoCheck applications beyond our core focus of BE-EAC. The application with the greatest potential may be the monitoring of patients with Eosinophilic Esophagitis (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. Several anti-inflammatory biologics are being evaluated to treat EoE. 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 noninvasive diagnostic device have proven unsuccessful.

In March 2020, we entered into a clinical trial research agreement with the University of Pennsylvania to perform a pilot study to assess whether EsoCheck can detect the eosinophils characteristic of active EoE and potentially serve as a less-invasive, more efficient, and cost-effective alternative to endoscopic biopsies in the management of EoE patients. The study, entitled "*Pilot Study of EsoCheck Compared to Biopsies and Brush Cytology During Endoscopy for Evaluation of Eosinophilic Esophagitis*", was led by Gary W. Falk, M.D., an internationally renowned expert on esophageal disease with specific experience and expertise in the management of EoE. The study, which has been completed, was a prospective cross-sectional pilot feasibility study of ten patients with suspected or established EoE scheduled for a clinically indicated upper endoscopy. The patients underwent esophageal sampling using EsoCheck, with the sample sent for traditional cytologic analysis, followed by EGD, including brushings and biopsies. The study results have yet to be published but preliminary reports indicate that EsoCheck is able to detect a meaningful number of eosinophils in patients with active disease. We have already initiated discussions with Dr. Falk to lead a larger multicenter follow-up study powered to document EsoCheck's sensitivity and specificity in detecting active EoE, compared to EGD with brushings and biopsy.

EsoGuard and EsoCheck Intellectual Property

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

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

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

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

EsoGuard and EsoCheck Specific Government Regulation

HIPAA and Other Privacy Laws

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HIPAA") established comprehensive protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or "Covered Entities": health plans, healthcare clearinghouses, and healthcare providers that conduct certain healthcare transactions electronically. Covered Entities and their business associates must have in place administrative, physical, and technical standards to guard against the misuse of individually identifiable health information. We perform activities that may implicate HIPAA, such as providing clinical laboratory testing services and entering 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 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 several 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 Diagnostics business. There were no material capital expenditures for environmental control facilities in the years ended December 31, 2021 and 2020.

Medical Devices

CarpX - Percutaneous Device to Treat Carpal Tunnel Syndrome

The Market

Carpal Tunnel Syndrome ("CTS") is the most common cumulative trauma disorder and accounts for over half of all occupational injuries. The carpal tunnel is an anatomic compartment in the wrist through which tendons and the median nerve pass. Cumulative trauma leads to inflammation which manifests itself clinically through its compressive effect on the median nerve, resulting in motor and sensory dysfunction in the hand. A survey published in the Journal of the American Medical Association reported 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.

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. All 20 patients underwent successful CarpX procedures.

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. More recently we have recruited new sales leadership and have recently trained eight new surgeons to perform the CarpX procedure with four more scheduled to undergo training in the coming months. Our limited-release commercialization efforts thru 2022 are focused on engaging key opinion hand surgeons designed to solicit input for ergonomic improvements to the device, procedure development and surgical-time optimization, and ease of use. Concurrently, we are presently working on improvements to the device that will released in stages over the next several quarters. We presently have a National Sales Director, one Sales Representative, and one Clinical Specialist that are overseeing our CarpX commercial efforts. As we broaden adoption of the device beyond key opinion leaders. we intend to commercialize 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 have received ISO 13485:2016 certification for PAVmed's quality management system and received CE Mark certification for CarpX in May 2021 which allows it to be marketed in CE Mark European countries, which include the European Economic Area (the EU, Norway, Iceland, and Lichtenstein), Switzerland, and, until July 1, 2023, the United Kingdom.

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 have initiated 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. In March of 2022, the First-In-Human implantations of PortIO devices were successfully performed at the Clinica Porto Azul in Barranquilla, Colombia.

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.

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 An initial FDA 510(k) submission for the NextFlo IV Infusion Set is planned for the second half of 2022.

We recently hired a director of sales who will focus on all aspects of NextFlo's commercial launch including and not limited to creating and executing the sales strategy, hiring/mentoring the commercial launch team, and collaborating with internal resources on product development and marketing. Target customers include Acute Inpatient Care, Outpatient Care, Infusion Centers, Home Infusions, Outpatient Pharmacy, EMS, and the Department of Defense.

Digital Health

Veris Health - implantable vascular healthcare platform

Device development continues in parallel with software platform development, with integration of the software and hardware teams ensuring end-to-end functionality. Device R&D is led by the internal PAVmed technical team, leveraging consultants with expertise in active implantable devices, medical hardware, and firmware. In Q4 2021, Veris successfully completed feasibility animal testing of multiple device prototypes. Design freeze on the initial Veris intelligent implantable device is expected by the end of 2022, followed by filing for 510(k) clearance with FDA. Veris has also initiated regulatory and commercial strategies for the European Union.

In addition to targeting the oncology market, Veris plan to expand into cardiovascular diseases, end-stage renal disease, and lung disorders like COPD. We have already initiated R&D efforts around an enhanced implantable cardiac monitor capable of detecting cardiac arrhythmias and other physiologic parameters critical for high-risk cardiac patients. Future devices will combine novel sensing technology with seamless communication, engaging user interface design, and data analytics driving actionable clinical insights for patients with congestive heart failure. These technologies will then be expanded for high-risk kidney disease and pulmonary patients.

We are currently recruiting a Veris Chief Commercial Officer to assist with further developing the sales strategy and hiring the commercial launch team to lay the groundwork with customer targets including major cancer centers and oncology practices. We are planning a limited commercial release of the first product to key accounts with wearable connected devices when the software is completed, currently expected in the six months ended Dec 31, 2022.

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.

Recent Events

Financing Transactions Generally

PAVmed Inc and Subsidiaries financing transactions in the year ended December 31, 2021, resulted in approximately $117.0 million of gross proceeds, before placement agent fees and expenses and offering costs, including $62.0 gross proceeds resulting from the issue of shares of Lucid Diagnostics Inc. common stock at an offering price of $14.00 per share in an IPO on October 14, 2021, with such gross proceeds of $62.0 million not including the purchase by PAVmed Inc. of 571,428 shares of Lucid Diagnostics Inc. common stock at the $14.00 IPO offering price.

PAVmed ATM Facility

In December 2021, we filed Form S-3 registration statement (File No. 333-261814) with the SEC (a "Shelf Registration") and a base prospectus to provide future financing for the Company in either common stock, shares of preferred stock, warrants, debt securities or units of one or more classes of securities not to exceed $275 million. Also included in the registration statement is a prospectus supplement (the "ATM Prospectus") for an "at-the-market offering" for up to $50 million of our common stock that may be offered and sold under a Controlled Equity Offering Agreement between us and Cantor Fitzgerald & Co.

PAVmed Inc. March 2022 Notes

Subsequent to December 31, 2021, on March 31, 2022, we entered into a Securities Purchase Agreement ("March 2022 SPA") with an accredited institutional investor , for the sale of up to $50,000,000 in initial principal amount of Senior Secured Convertible Promissory Notes (the "March 2022 Notes"), in a registered direct offering (the "Offering"), for a purchase price equal to $1,000 for each $1,100 in principal amount of March 2022 Notes.

Pursuant to the SPA we executed the agreements for an initial closing for the sale of$27.5 million in principal amount of March 2022 Notes, of which the Investor funded and the Company received cash proceeds of $24.9 million on April 5, 2022, after deduction of lender fees. Subject to certain conditions being met or waived, from time to time after such time that stockholder approval for an increase in our authorized shares from 150 million to 250 million is obtained, but before March 31, 2024, one or more additional closings for up to the remaining principal amount of March 2022 Notes may occur, upon five trading days' notice by us to the investor. The aggregate principal amount of March 2022 Notes that may be offered in the additional closings may not be more than $22.5 million. The investor's obligation to purchase the notes at each additional closing is subject to certain conditions set forth in the March 2022 SPA (including minimum price and volume thresholds, maximum ratio of debt to market capitalization, and minimum market capitalization), which may be waived by the Required Holders (as defined in the March 2022 SPA). Under the March 2022 SPA, the investor will be required to purchase March 2022 Notes in the additional closings if such conditions are met or waived. In addition, from and after March 31, 2023, the investor may by written notice to us elect to require us to issue up to $22.5 million in initial principal amount of March 2022 Notes, so long as in doing so it would not cause the ratio of (a) the outstanding principal amount of the March 2022 Notes (including the additional March 2022 Notes), accrued and unpaid interest thereon and accrued and unpaid late charges to (b) our average market capitalization over the prior ten trading days, to exceed 25%. If we fail to complete the sale of the additional Notes contemplated by any such written notice, or if the investor is unable to deliver any such notice prior to March 31, 2024 as a result of the limitation described in the preceding sentence, then we will be obligated to pay a break-up fee to the investor at such time in an aggregate amount equal to $1.35 million.

We will not pay any selling commission to any party in connection with the Offering, although we will pay a financial advisory fee equal to 1.8% of the gross proceeds from the Offering to an independent financial advisor. The Company estimates that the net cash proceeds will be approximately $20.4 million from the additional closings of the Offering, after deducting the estimated expenses of the Offering, assuming the sale of all of the March 2022 Notes.

The March 2022 Notes have a voluntary fixed conversion price of $5.00 per share, a stated interest rate of 7.875% per annum, and a maturity of 24 months (subject to extension in certain circumstances). The March 2022 Notes will be secured by all our existing and future assets (including those of our significant subsidiaries, other than Lucid and its subsidiaries), but including only 9.99% of Lucid's outstanding common stock held by us, pursuant to a security agreement by and between the Company and the Investor.

Recent Events - continued

PAVmed March 2022 Notes *- continued*

On the date six months after the issuance of a March 2022 Note, on the 1st and 10th trading day of each calendar month thereafter, and on the maturity date (each an "Installment Date"), the Company will make an amortization payment on the March 2022 Note in an amount equal to the initial principal balance of the note divided by the total number of such amortization payments (such that the entire initial principal balance will be repaid by the maturity date), plus any amounts that have been deferred or accelerated to the applicable installment date, plus all accrued and unpaid interest and any late charges (the "Installment Amount"). Each amortization payment will be satisfied in shares of the Company's common stock, subject to certain customary equity conditions (including minimum price and volume thresholds) at 100% of the Installment Amount or otherwise (or at our election, in whole or in part) in cash at 115% of the Installment Amount. The conversion price for any Installment Amount so converted will be based on the then current market price, but not more than the fixed conversion price then in effect and not less than a floor price.

The Offering was made pursuant to the Company's existing shelf registration statement on Form S-3 (Registration No. 333-261814), which was filed with theSEC on December 21, 2021 and declared effective by the SEC on January 7, 2022. A prospectus supplement relating to the Offering, together with the accompanying base prospectus included in the registration statement, was filed with the SEC on April 4, 2022.

Lucid Equity Facility

Subsequent to December 31, 2021, on March 28, 2022, Lucid Diagnostics, Inc. entered into a committed equity facility with an affiliate of Cantor Fitzgerald ("Cantor"). Under the terms of the facility, Cantor has committed to purchase up to $50 million of Lucid Diagnostics Inc. common stock from time to time at the request of Lucid Diagnostics Inc. While there are distinct differences, the facility is structured similarly to a traditional at-the-market equity facility, insofar as it allows Lucid Diagnostics Inc. to raise primary equity capital on a periodic basis at prices based on the existing market price.

Lucid Laboratory Asset Acquisition

Subsequent to December 31, 2021, on February 25, 2022, Lucid Diagnostics, Inc., through its wholly-owned subsidiary LucidDx Labs, Inc., entered into an asset purchase agreement ("RDx APA") with ResearchDx, Inc. ("RDx"), an unrelated third-party. Under the RDx APA, LucidDx Labs Inc. acquired certain licenses and other related assets necessary to operate a CLIA-certified, CAP-accredited commercial clinical laboratory. The RDx APA acquired assets, along with other LucidDx Labs Inc. purchased and leased property and equipment, are being used to commence laboratory operations to perform the EsoGuard® Esophageal DNA assay, inclusive of DNA extraction, next generation sequencing ("NGS") and specimen storage. Prior to consummation of the RDx APA, RDx provided such laboratory services at its owned CLIA-certified, CAP-accredited laboratory. Under the RDx APA, LucidDx Labs Inc. will pay RDx an aggregate purchase price of up to $6.2 million for the acquired assets. Concurrent with the RDx APA, LucidDx Labs Inc. and RDx also entered into a management services agreement ("RDx MSA"), with a term of three years, and a total of approximately $1.8 million of quarterly

payments.

Intellectual Property

Our business will depend on our ability to create or acquire proprietary medical device technologies to commercialize. We intend to vigorously protect our proprietary technologies' intellectual property rights in patents, trademarks and copyrights, as available through registration in the United States and internationally. We currently have applied for or own 72 patents across 10 families of products. Patent protection and other proprietary rights are thus essential to our business. Our policy is to aggressively file patent applications to protect our proprietary technologies including inventions and improvements to inventions. We seek patent protection, as appropriate, on:

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

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

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

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

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

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

Key U.S. Regulation

FDA Regulation

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

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

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

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

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

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

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

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

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 Technology

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

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

Post-Approval Regulation of Medical Devices

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

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

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

Manufacturing cGMP Requirements

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

Other U.S. Regulation

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

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

Physician Payment Sunshine Act

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

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

Federal Anti-Kickback Statute

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

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

Federal False Claims Act

The False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the False Claims Act. Several pharmaceutical, device and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus 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, as of March 29, 2022, we have 89 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"), our Chief Operating Officer ("COO") 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 Information

We were incorporated in Delaware on June 26, 2014. Our corporate headquarters 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.

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.

Risk Factor Summary

Our business is subject to numerous risks and uncertainties that you should consider before investing in our common stock. These risks are described more fully below and include, but are not limited to, risks relating to the following:

Risks Related to Financial Position and Capital Resources

- We have incurred operating losses since our inception and may not be able to achieve profitability.
- Servicing our indebtedness may require a significant amount of cash, and the restrictive covenants contained in our indebtedness could adversely affect our business plan, liquidity, financial condition, and results of operations.
- The accounting method for convertible debt securities that may be settled in cash, such as the March 2022 Notes, is the subject of recent changes that could have a material effect on our reported financial results.

Risks Related to 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.
- Since we have a limited operating history and have not generated significant revenues, you will have little basis upon which to evaluate our ability to achieve our business objective.
- 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 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.
- 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.
- 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.
- Our products may never achieve market acceptance.
- Recommendations, guidelines and quality metrics issued by various organizations may significantly affect payers' willingness to cover, and healthcare providers' willingness to prescribe, our products.
- 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.
- We will be dependent on third-party manufacturers since we will not initially directly manufacture our products.
- 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.
- Our future performance will depend in part on the success of products we have not yet developed.
- Our products and services may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming our business.
- 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.
- Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.
- We may not be able to protect or enforce our intellectual property rights, which could impair our competitive position.
- 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.
- 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.

- Our business may suffer if we are unable to manage our 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 ability to be successful will be totally dependent upon the efforts of our key personnel.
- 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.
- 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.
- Any future products we may develop may not be approved for sale in the U.S. or in any other country.
- Our business may be adversely affected by health epidemics and or pandemics, including the pandemic resulting from the SARS-CoV-2 and the resulting illness of COVID-19.
- 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.
- 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.

Risks Relating 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.
- Even if we receive regulatory approval for any product we may develop, we will be subject to ongoing regulatory requirements 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.
- Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.
- Healthcare reform measures could hinder or prevent our products' commercial success.
- If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.
- If required, clinical trials necessary to support a 501(k) notice or a 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.
- The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.
- Our medical products may in the future be subject to product recalls that could harm our reputation, business and financial results.
- If our 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 claims.
- If the effectiveness and safety of our devices are not supported by long-term data, our future revenues could decline.
- If we are found to be promoting the use of its devices for unapproved or "off-label" uses or engaging in other noncompliant activities, we may be subject to recalls, seizures, fines, penalties, injunctions, adverse publicity, prosecution, or other adverse actions, resulting in damage to its reputation and business.
- We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

- Our failure or our 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.

Risks Associated with Ownership of Our Common Stock

- We may issue shares of our common stock 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 management and their affiliates control a substantial interest in us and thus may influence certain actions requiring a stockholder vote.
- There can be no assurance that our common stock will continue to trade on the Nasdaq Capital Market or another national securities exchange.
- 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.
- Our stock price may be volatile, and purchasers of our securities could incur substantial losses.
- Our outstanding warrants and other convertible securities may have an adverse effect on the market price of our common stock.
- We do not intend to pay any dividends on our common stock at this time.
- We are subject to evolving corporate governance and public disclosure expectations and regulations that impact compliance costs and risks of noncompliance.
- 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.
- 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.
- 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.
- 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.

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 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.

Servicing our indebtedness may require a significant amount of cash, and the restrictive covenants contained in our indebtedness could adversely affect our business plan, liquidity, financial condition, and results of operations.

We may be required to repay or redeem, or to pay interest on, the March 2022 Notes or any future permitted indebtedness incurred by us or our subsidiaries, in cash. Despite our right to pay the interest and principal balance of the March 2022 Notes by issuing shares of our common stock, we may be required to repay such indebtedness in cash, if we do not meet certain customary equity conditions (including minimum price and volume thresholds) or in certain other circumstances. For example, we may be required to repay the outstanding principal balance and accrued but unpaid interest, along with a premium, upon the occurrence of certain changes of control or an event of default.

Our ability to make payments of the principal of, to pay interest on, or to redeem our indebtedness in cash, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We have not generated material revenue from operations to date, and our business may not generate cash flow from operations in the future sufficient to service our indebtedness and make necessary capital expenditures. In addition, the March 2022 Notes contain, and any future indebtedness may contain, restrictive covenants, including financial covenants. These payment obligations and covenants could have important consequences on our business. In particular, they could:

- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness;
- limit, among other things, our ability to borrow additional funds and otherwise raise additional capital, and our ability to conduct acquisitions, joint, ventures or similar arrangements, as a result of our obligations to make such payments and comply with the restrictive covenants in the indebtedness;
- limit our flexibility in planning for, or reacting to, changes in our businesses and the industries in which we operate;
- increase our vulnerability to general adverse economic and industry conditions; and
- place us at a competitive disadvantage compared to our competitors that have lower fixed costs.

The debt service requirements of any other permitted indebtedness we incur or issue in the future, as well as the restrictive covenants contained in the governing documents for any such indebtedness, could intensify these risks.

If we are unable to make the required cash payments, there could be a default under one or more of the instruments governing our indebtedness. Any such default or acceleration may further result in an event of default and acceleration of our other indebtedness. In such event, or if a default otherwise occurs under our indebtedness, including as a result of our failure to comply with the financial or other covenants contained therein, the holders of our indebtedness could require us to immediately repay the outstanding principal and interest on such indebtedness in cash, in some cases subject to a premium. Furthermore, the holders of our secured indebtedness could foreclose on their security interests in our assets.

If we are required to make payments under our indebtedness in cash and are unable to generate sufficient cash flow from operations, we may be required to sell assets, or we may seek to refinance the remaining balance, by either refinancing with the holder of the indebtedness, by raising sufficient funds through a sale of equity or debt securities or

by obtaining a credit facility. No assurances can be given that we will be successful in making the required payments under our indebtedness, or in refinancing our obligations on favorable terms, or at all. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. A failure to refinance could have a material adverse effect on our liquidity, financial position, and results of operations. Should we refinance, it could be dilutive to shareholders or impose onerous terms on us.

The accounting method for convertible debt securities that may be settled in cash, such as the March 2022 Notes, is the subject of recent changes that could have a material effect on our reported financial results.

In May 2008, the Financial Accounting Standards Board ("FASB") issued FASB Staff Position No. APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement), which has subsequently been codified as Accounting Standards Codification 470-20, Debt with Conversion and Other Options, or "ASC 470-20." Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the March 2022 Notes) that may be settled entirely or partially in cash in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the March 2022 Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the March 2022 Notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the March 2022 Notes to their face amount over the term of the March 2022 Notes. We will report lower net income in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results, and the market price of our common stock.

In addition, under certain circumstances, convertible debt instruments (such as the March 2022 Notes) that may be settled entirely or partially in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the March 2022 Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the March 2022 Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of our common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the March 2022 Notes, then our diluted earnings per share would be adversely affected.

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 significant 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 significant 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.

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 commercialize 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.

Our products may never achieve market acceptance.

To date, we have not generated significant 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.

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 Lake Forest, CA. 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 we fail 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.

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.

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.

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

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

We also rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology. We seek to protect our know-how and other unpatented proprietary technology, as trade secrets or otherwise, with confidentiality agreements and/or intellectual property assignment

agreements with our team members, independent distributors and consultants. However, such agreements may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that our competitors discover or independently develop similar or identical designs or other proprietary information. Our trade secrets may be vulnerable to disclosure or misappropriation by employees, contractors and other persons.

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

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

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

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

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

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

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

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

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.

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 products 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.

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 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. 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 United States, 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.

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.

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

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

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

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

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

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

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

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

We intend to seek distribution and marketing partners 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.

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

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

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

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

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

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

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits payments or the provision of anything of value to foreign officials for the purpose of obtaining or keeping business;
- the federal False Claims Act, or FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

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

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

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

If required, clinical trials necessary to support a 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.

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

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

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

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

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

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

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

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

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

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

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

- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase order or recommendation of, any item or service for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services not provided as claimed and which may apply to entities like the Company to the extent that the Company's interactions with customers may affect their billing or coding practices;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established new federal crimes for knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services, as well as leading to regulations imposing certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

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

For example, 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, 2021, our management and their affiliates collectively owned 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.

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.

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

As of December 31, 2021, there were 86,367,845 shares of our common stock issued and outstanding, and, as of such date, we also had issued and outstanding:

(i) stock options to purchase 8,720,198 shares of our common stock at a weighted average exercise price of $3.39 per share, with such total number inclusive of both stock options granted under the PAVmed Inc. 2014 Long-Term Incentive Equity Plan ("PAVmed Inc. 2014 Equity Plan");and 1,160,573 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 626,081 shares of our common stock reserved for issuance under the PAVmed Inc. Employee Stock Purchase Plan ("PAVmed Inc. ESPP")

(ii) Series Z Warrants to purchase 11,937,455 shares of our common stock at an exercise price of $1.60 per share; and Series W Warrants to purchase 377,873 shares of our common stock at an exercise price of $5.00 per share, with all such Series W Warrants expiring unexercised subsequent to December 31, 2021, as of January 29, 2022;

(iii) Series B Convertible Preferred Stock of 1,113,919 shares, convertible into the same number of shares of our common stock.

In addition, the March 2022 Notes with a principal amount of $27.5 million are convertible into 5,500,000 shares of our common stock (assuming the March 2022 Notes were converted in full on such date at the initial fixed conversion price of $5.00 per share). The number of shares of our common stock underlying the March 2022 Notes may increase if we conduct additional closings under the March 2022 SPA, pursuant to which we may issue March 2022 Notes with up to an additional $22,500,000 of principal amount. Furthermore, the number of shares of common stock to be issued under the March 2022 Notes may be substantially greater than the estimate set forth in this paragraph, if we pay the interest and the installments of principal in shares of our common stock, because in such cases (and in certain other cases as described elsewhere in this Annual Report on Form 10-K) the number of shares issued will be determined based on the then current market price (but in any event not more than fixed conversion price per share or less than a floor price specified in the notes). We cannot predict the market price of our common stock at any future date, and therefore, we are unable to accurately forecast or predict the total amount of shares that ultimately may be issued under these notes. In addition, the number of shares issued under these notes may be substantially greater if we voluntarily lower the conversion price, which we are permitted to do pursuant to the terms thereof.

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

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

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

We are subject to evolving corporate governance and public disclosure expectations and regulations that impact compliance costs and risks of noncompliance.

We are subject to changing rules and regulations promulgated by a number of governmental and self-regulatory organizations, including the SEC and Nasdaq, as well as evolving investor expectations around corporate governance and environmental and social practices and disclosures. These rules and regulations continue to evolve in scope and complexity, and many new requirements have been created in response to laws enacted by the U.S. and foreign governments, making compliance more difficult and uncertain. The increase in costs to comply with such evolving expectations, rules and regulations, as well as any risk of noncompliance, could adversely impact us.

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 a smaller reporting 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.

If we experience material weaknesses inn our internal control over financial reporting 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.

Although our management determined that our internal control over financial reporting was effective as of December 31, 2021, we may experience material weaknesses in our internal control over financial reporting in the future. Any necessary remediation efforts would place a significant burden on management and add increased pressure to our financial resources and processes. If we were are unable to successfully remediate any 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.

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 a short-term office space rental agreement in Pennsylvania. We also have lease agreements for our Lucid Test Centers in various locations in Arizona, Colorado and Nevada that in the aggregate approximate 2,155 square feet. 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.

Effective with the respective lease commencement dates, subsequent to December 31, 2021, the Company and its subsidiaries have entered into additional lease agreements to expand its operations for a research and development facility in Massachusetts with 7,375 square feet, a CLIA laboratory in California with 21,019 square feet, an office space in Pennsylvania with 4,300 square feet, a light manufacturing facility in Utah with 22,288 square feet, and additional Lucid Testing Center's (LTC's) with an aggregate of approximately 2,000 square feet.

Item 3. Legal Proceedings

On November 2, 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 did not seek any specific monetary damages. The Company did not believe it was clear the prior approval of these matters was invalid or otherwise ineffective. However, to avoid any uncertainty and 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 Settlement Term Sheet Agreement, dated January 28, 2021, 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 approval by the Court.

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 Kingswood Capital Markets, a "division" of Benchmark Investments, Inc. On December 16, 2021, the court granted PAVmed's motion to dismiss the case for lack of subject matter jurisdiction. On February 7, 2022, Benchmark Investments LLC, which claimed to be affiliated with Benchmark Investments, Inc., filed a new complaint in the Supreme Court of the State of New York, New York County, asserting claims similar to those in the federal action, and adding to its allegations that financings conducted by the Company in January 2021 and February 2021 also violated the Company's engagement letter with Kingswood Capital Markets. 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.

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 equity is traded on the Nasdaq Capital Market under the symbols: "PAVM." with respect to our common stock; "PAVMZ" and "PAVMW" with respect to each of our Series Z Warrants and Series W Warrants, respectively. Subsequent to December 31, 2021 the Series W Warrants issued and outstanding as of December 31, 2021, expired unexercised on January 29, 2022.

Holders

As of March 29, 2022, there were 87,667,406 shares of our common stock outstanding. Our shares of common stock are held by an estimated 17,000 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, amongst and other factors deemed 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 years ended December 31, 2021 and 2020, respectively, at each of the respective holders' election, a total of 210,448 and 25,000 shares of Series B Convertible Preferred Stock were converted into the same number of shares of common stock of PAVmed Inc.

During the year ended December 31, 2021, the Company's board-of-directors declared an aggregate of approximately $288 of Series B Convertible Preferred Stock dividends, earned as of December 31, 2020, March 31, 2021, June 30, 2021, and September 30, 2021, which have been settled by the issue of an additional aggregate 96,292 shares of Series B Convertible Preferred Stock. 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 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.

Subsequent to December 31, 2021, in January 2022, the Company's board-of-directors declared a Series B Convertible Preferred Stock dividend earned as of December 31, 2021 and payable as of January 1, 2022, of approximately $67, which will be settled by the issue of an additional 22,291 shares of Series B Convertible Preferred Stock (with such dividend not recognized as a dividend payable as of December 31, 2021, as the Company's board of directors had not declared such dividends payable as of such date).

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, 2021.

Item 6. [Reserved]

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 Subsidiaries.

Overview

PAVmed Inc and Subsidiaries, referred to herein as "PAVmed" or the "Company" is comprised of PAVmed Inc. and its wholly-owned subsidiary and its majority-owned subsidiaries, inclusive of Lucid Diagnostics, Inc. ("Lucid Diagnostics" or "LUCID"), Veris Health, Inc. ("Veris Health" or "VERIS"), and Solys Diagnostics, Inc. ("Solys Diagnostics" or "SOLYS").

The Company is a highly differentiated, multi-product, commercial-stage medical technology 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 the inception of PAVmed Inc. 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 technology company, with the following lines-of-business: "Medical Devices", "Diagnostics", "Digital Health", and "Emerging Innovations". The Company has ongoing operations conducted through PAVmed Inc. and its majority-owned subsidiaries of Lucid Diagnostics, Veris Health, and Solys Diagnostics.

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 and European CE Mark Certification in May 2021 as an esophageal cell collection device; and, EsoGuard has been established as a Laboratory Developed Test ("LDT"), completed European CE Mark Certification in June 2021, and was launched commercially in December 2019.

- 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) in April 2020.

- In May 2021, we formed Veris Health, which is our newest majority-owned subsidiary. In connection with its formation, Veris Health acquired Oncodisc Inc ("Oncodisc"), a digital health company with ground breaking tools to improve personalized cancer care through remote patient monitoring. Oncodisc's core technologies include the first intelligent implantable vascular healthcare platform that provides patients and physicians with new tools to improve outcomes and optimize the delivery of cost-effective care through remote monitoring and data analytics. Its vascular access port contains biologic sensors capable of generating continuous data on key physiologic parameters known to predict adverse outcomes in cancer patients undergoing treatment. Wireless communication to the patient's smartphone and its cloud-based digital healthcare platform efficiently and effectively delivers actionable real time data to patients and physicians. The technologies are the subject of multiple patent applications and one allowed patent awaiting final issuance.

As discussed in Item 1 Business Background and Overview:

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

- Medical Devices - 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;

- Digital Health - Veris cancer healthcare platform and implantable intelligent vascular port combining remote monitoring and data analytics; and,

- Emerging Innovations - NextVent single-use ventilators; FlexMO medical circulatory support cannulas; Veris Cardiac Monitor; *DisappEAR* resorbable pediatric ear tubes; *Solys* Noninvasive glucose monitoring.

Financing

The Company's financing transactions in the year ended December 31, 2021, resulted in approximately $117.0 million of gross proceeds, before placement agent fees and expenses and offering costs, inclusive of $62.0 gross proceeds resulting from the issue of shares of Lucid Diagnostics Inc. common stock at an offering price of $14.00 per share in an IPO on October 14, 2021, with such gross proceeds of $62.0 million not including the purchase by PAVmed Inc. of 571,428 shares of Lucid Diagnostics Inc. common stock at the $14.00 IPO offering price.

In the year ended December 31, 2021 a total of 4,877,484 PAVmed Inc. Series Z Warrants ("PAVMZ") 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 December 2021, PAVmed Inc. filed Form S-3 registration statement (File No. 333-261814) with the SEC (a "Shelf Registration") and a base prospectus to provide future financing for the Company in either common stock, shares of preferred stock, warrants, debt securities or units of one or more classes of securities not to exceed $275 million. Also included in the registration statement is a prospectus supplement (the "ATM Prospectus") for an "at-the-market offering" for up to $50 million of our common stock that may be offered and sold under a Controlled Equity Offering Agreement between us and Cantor Fitzgerald & Co.

Subsequent to December 31, 2021, on March 31, 2022, PAVmed Inc. entered into a Securities Purchase Agreement ("SPA") with an accredited institutional investor ("investor") in a private placement, pursuant to which PAVmed Inc. agreed to sell, and the investor agreed to purchase, up to $50.0 million in initial principal amount of Secured Promissory Notes. The purchase price of the Secured Promissory Notes is $1,000 for each $1,100 in principal amount of the notes, representing an original issue discount of $100 per $1,100 in principal amount of the notes. A further discussion of the SPA dated March 31, 2022 can be found herein below under Liquidity and Capital Resources - *Financings Subsequent to December 31, 2021- PAVmed Inc - Private Placement - Securities Purchase Agreement*

Subsequent to December 31, 2021, in March 2022, Lucid Diagnostics, Inc. entered into a committed equity facility with an affiliate of Cantor. Under the terms of the facility, Cantor has committed to purchase up to $50 million of Lucid Diagnostics Inc. common stock from time to time at the request of Lucid Diagnostics Inc. While there are distinct differences, the facility is structured similarly to a traditional at-the-market equity facility, insofar as it allows Lucid Diagnostics Inc. to raise primary capital on a periodic basis at prices based on the existing market price.

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. 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 United States, 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

Revenue

Revenue is recognized with respect to the EsoGuard Commercialization Agreement, dated August 1, 2021, between the Company's majority-owned subsidiary, Lucid Diagnostics Inc., and ResearchDX Inc. ("RDx"), CLIA certified commercial laboratory service provider.

Cost of revenue

The cost of revenue recognized with respect to the revenue recognized under the EsoGuard Commercialization Agreement is inclusive of: a royalty fee incurred under the Amended CWRU License Agreement; employee related costs of employees engaged in the administration to patients of the EsoCheck cell sample collection procedure (principally at the LUCID Test Centers); the EsoCheck devices and EsoGuard mailers (cell sample shipping costs) distributed to medical practitioners locations and the LUCID Test Centers; and LUCID Test Centers operating expenses, including rent expense and supplies.

Sales and marketing expenses

Sales and marketing expenses consist primarily of salaries and related costs for employees engaged in sales and marketing activities, as well as advertising and promotion expenses. We anticipate our sales and marketing 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 as we execute on our business strategy.

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, employees involved in third-party payor reimbursement contract negotiations and 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 with the growth and expansion of our business operations objectives. 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 chief medical officer and engineering personnel;
- costs associated with regulatory filings;
- patent license fees;
- cost of laboratory supplies and acquiring, developing, and manufacturing preclinical prototypes;
- product design engineering studies; and
- rental expense for facilities maintained solely for research and development purposes.

We plan to incur research and development expenses for the foreseeable future as we continue the development of our 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, non-invasive glucose monitoring and digital health 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; gain on PPP loan forgiveness; and interest expense recognized in connection with one of our convertible notes.

Year ended December 31, 2021 versus December 31, 2020

Revenue

In the year ended December 31, 2021, revenue was $0.5 million as compared to no revenue in the corresponding period in the prior year. The $0.5 million increase principally relates to our EsoGuard Commercialization Agreement, dated August 1, 2021, which resulted in revenue recognition of $0.1 million per month beginning August 2021.

Cost of revenue

In the year ended December 31, 2021, cost of revenue was approximately $0.6 million as compared to no cost of revenue in the corresponding period in the prior year. The $0.6 million increase principally relates to costs associated with our commercialization agreement that started in August 2021.

Sales and marketing expenses

In the year ended December 31, 2021, sales and marketing costs were approximately $8.9 million, compared to $2.8 million for the corresponding period in the prior year. The net increase of $6.1 million was principally related to:

- approximately $3.7 million increase in compensation related costs principally related to an increase in headcount and severance expense incurred for 2 former employees;
- approximately $0.9 million increase in stock based compensation from RSA grants to Lucid and PAVmed employees and non-employees, and an increase in stock options granted corresponding with the increase in the number of employees; and
- approximately $1.5 million increase in outside professional services related to EsoCheck, EsoGuard and consulting and professional services fees.

General and administrative expenses

In the year ended December 31, 2021, general and administrative costs were approximately $25.6 million, compared to $9.6 million for the corresponding period in the prior year. The net increase of $16.0 million was principally related to:

- approximately $2.2 million increase in compensation related costs principally related to an increase in headcount;
- approximately $8.5 million increase in stock based compensation from RSA grants to Lucid and PAVmed employees and non-employees, and an increase in stock options granted corresponding with the increase in the number of employees; and
- approximately $4.2 million in consulting services related to patents, regulatory compliance, legal processes for contract review, transition of PR and IR firms, and public company expenses; and
- approximately $1.1 million in general business expenses.

Research and development expenses

In the year ended December 31, 2021, research and development costs were approximately $19.8 million as compared to $11.0 million for the corresponding period in the prior year. The net increase $8.9 million was principally related to:

- approximately $7.8 million increase in development costs, particularly in clinical trial activities and outside professional and consulting fees with respect to EsoCheck, EsoCure, CarpX, NextFlo, Port IO, a glucose monitoring project, and a digital health project;
- approximately $0.7 million increase in compensation related costs and related to expanded clinical and engineering staff; and
- approximately $0.4 million increase in stock based compensation from RSA grants to Lucid and PAVmed employees and non-employees, and an increase in stock options granted corresponding with the increase in the number of employees.

Other Income and Expense

Debt forgiveness

In the year ended December 31, 2021, our PPP loan related to the CARES Act of $0.3 million was forgiven by the Small Business Administration. No principal or interest payments were ever made and accordingly we recorded a gain of $0.3 million.

Change in fair value of convertible debt

In the year ended December 31, 2021, the non-cash income (expense) recognized for the change in the fair value of our convertible notes was approximately $1.7 million, as compared to $6.0 million of other expense for the year ended December 31, 2020. The change in the fair value adjustment of the convertible notes is principally related to each of the convertible notes being repaid-in-full during the year ended December 31, 2021, as discussed herein below under “Other Income and Expense - Loss from Extinguishment of Debt”.

See *Note 12, Financial Instruments Fair Value Measurements*, and *Note 13, 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, 2021, a debt extinguishment loss in the aggregate of approximately $3.7 million was recognized in connection with the convertible notes, as discussed below.

- 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 of our common stock, with a fair value of approximately $1,723 (with such fair value measured as the respective conversion date quoted closing price of our common stock), resulting in the recognition of a loss from extinguishment of debt of approximately $760 in the six months ended June 30, 2021; and,
- On January 30, 2021, we paid in cash a $350 partial principal repayment of the Senior Convertible Note dated April 30, 2020 (“April 2020 Senior Convertible Note”); and on March 2, 2021, we made a cash payment of approximately $14,466, resulting in the repayment-in-full on such date of both the April 2020 Senior Convertible Note and the Senior Secured Convertible Note dated August 6, 2021, resulting in the recognition of a loss from extinguishment of debt of approximately $2,955 in the six months ended June 30, 2021.

In the prior year ended December 31, 2020, a loss from extinguishment of debt of approximately $6.5 million was recognized, with such loss resulting from the difference

between: the face value principal repayments and the corresponding payments of the interest thereon; as compared to the fair value of the shares of our common stock issued upon conversion of such convertible note, with such fair value measured as the respective issue date closing quoted price per share of our common stock.

See our consolidated financial statements *Note 13, Debt*, for additional information with respect to the convertible notes.

Income Taxes

The Company has total estimated federal and state net operating loss ("NOL") carryforward of approximately $104.1 million and $63.0 million as of December 31, 2021 and 2020, respectively, which is available to reduce future taxable income, of which approximately $13.8 million have statutory expiration dates commencing in 2036, and approximately $90.3 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 103.9 million have statutory expiration dates commencing in 2036. The Company has total estimated research and development ("R&D") tax credit carryforward of approximately 0.4 million as of December 31, 2021 which are available to reduce future tax expense and have statutory expiration dates commencing in 2036.

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. The Company evaluated the impact of these CARES Act provisions and determined they did not have a material impact on the consolidated income tax provision.

See our consolidated financial statements *Note 18, 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, 2021, 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, 2021.

Common Stock

Year Ended December 31, 2021

- On January 5, 2021, a total of 6,000,000 shares of common stock of PAVmed Inc. were issued for gross proceeds of approximately $13,434, before a placement agent fee and expenses of approximately $951, and offering costs incurred by the Company of approximately $71. 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).
- On February 23, 2021, a total of 9,782,609 shares of common stock of PAVmed Inc. were issued for proceeds of approximately $41,566, before offering costs incurred by the Company of approximately $290. 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).
- In January 2021, 667,668 shares of PAVmed Inc. 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 13, *Debt*.
- During the year ended December 31, 2021, 210,448 shares of PAVmed Inc. common stock were issued upon conversion of the same number of shares of Series B Convertible Preferred Stock. See Note 15, *Preferred Stock*, for a discussion of the Series B Convertible Preferred Stock.
- During the year ended December 31, 2021, an aggregate of 4,881,429 shares of PAVmed Inc. common stock were issued upon exercise of common stock purchase warrants, including 4,877,484 with respect to Series Z Warrants; and 3,945 with respect to Series W Warrants.
- During the year ended December 31, 2021, 621,164 shares of PAVmed Inc. common stock were issued upon exercise of stock options for cash of approximately $980. See Note 14, *Stock-Based Compensation*, for a discussion of the PAVmed Inc. 2014 Equity Plan.
- During the year ended, the PAVmed Inc. Employee Stock Purchase Plan purchased 234,592 shares of common stock of the Company. See Note 14, *Stock-Based Compensation*, for a discussion of the PAVmed Inc. Employee Stock Purchase Plan.

Year Ended December 31, 2020

- During 2020, a total of 10,647,500 shares of PAVmed Inc. common stock 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 PAVmed Inc. 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 13, *Debt*.
- In 2020, 306,555 shares of PAVmed Inc. common stock were purchased by employees through participation in the PAVmed Inc. Employee Stock Purchase Plan, as discussed in Note 14, *Stock-Based Compensation.*

Debt

During the year ended December 31, 2021, the Company repaid-in-full all of the outstanding principal balances of our convertible notes, as discussed herein above under

"*Other Income and Expense - Loss from Extinguishment of Debt*". See our consolidated financial statements Note 13, Debt, for additional information with respect to prior year debt funding.

Other Financings

On October 14, 2021, Lucid Diagnostics Inc. completed an initial public offering ("IPO") of its common stock under an effective registration statement on Form S-1 (SEC File No. 333-259721), wherein a total of 5.0 million shares of common stock were issued, inclusive of 571,428 issued to PAVmed Inc., at an IPO offering price of $14.00 per share, resulting gross proceeds to Lucid Diagnostics Inc. of $70.0 million, before underwriting fees of $4.9 million, and approximately $0.7 million of offering costs incurred by Lucid Diagnostics Inc. (Lucid Diagnostics Inc. is a majority-owned subsidiary of PAVmed Inc., and PAVmed Inc. has a controlling financial interest in Lucid Diagnostics Inc., both before and after the Lucid Diagnostics Inc. IPO. In this regard, PAVmed Inc. held 81.8477% and 79.9796% of Lucid Diagnostics Inc. common stock issued and outstanding before and after the Lucid Diagnostics Inc. IPO, respectively, with such percentages computed excluding the common shares underlying unvested restricted stock awards granted under the Lucid Diagnostics Inc. Long-Term Equity Incentive Plan.)

Lucid Diagnostics Inc - Committed Equity Facility

Subsequent to December 31, 2021, in March 2022, Lucid Diagnostics, Inc. entered into a committed equity facility with an affiliate of Cantor. Under the terms of the facility, Cantor has committed to purchase up to $50 million of Lucid Diagnostics Inc. common stock from time to time at the request of Lucid Diagnostics Inc. While there are distinct differences, the facility is structured similarly to a traditional at-the-market equity facility, insofar as it allows Lucid Diagnostics Inc. to raise primary equity capital on a periodic basis at prices based on the existing market price.

Financings Subsequent to December 31, 2021

PAVmed Inc - Private Placement - Securities Purchase Agreement

Subsequent to December 31, 2021, on March 31, 2022, we entered into the March 2022 SPA with an accredited institutional investor , for the sale of up to $50.0 million in initial principal amount of March 2022 Notes, in a registered direct offering (which we refer to as the Offering), for a purchase price equal to $1,000 for each $1,100 in principal amount of March 2022 Notes

Pursuant to the SPA we executed the agreements for an initial closing for the sale of $27.5 million in principal amount of March 2022 Notes, of which the Investor funded and the Company received cash proceeds of $24.9 million on April 5, 2022, after deduction of lender fees. Subject to certain conditions being met or waived, from time to time after such time that stockholder approval for an increase in our authorized shares from 150 million to 250 million is obtained, but before March 31, 2024, one or more additional closings for up to the remaining principal amount of March 2022 Notes may occur, upon five trading days' notice by us to the investor. The aggregate principal amount of March 2022 Notes that may be offered in the additional closings may not be more than $22.5 million. The investor's obligation to purchase the notes at each additional closing is subject to certain conditions set forth in the March 2022 SPA (including minimum price and volume thresholds, maximum ratio of debt to market capitalization, and minimum market capitalization), which may be waived by the Required Holders (as defined in the March 2022 SPA). Under the March 2022 SPA, the investor will be required to purchase March 2022 Notes in the additional closings if such conditions are met or waived. In addition, from and after March 31, 2023, the investor may by written notice to us elect to require us to issue up to $22.5 million in initial principal amount of March 2022 Notes, so long as in doing so it would not cause the ratio of (a) the outstanding principal amount of the March 2022 Notes (including the additional March 2022 Notes), accrued and unpaid interest thereon and accrued and unpaid late charges to (b) our average market capitalization over the prior ten trading days, to exceed 25%. If we fail to complete the sale of the additional Notes contemplated by any such written notice, or if the investor is unable to deliver any such notice prior to March 31, 2024 as a result of the limitation described in the preceding sentence, then we will be obligated to pay a break-up fee to the investor at such time in an aggregate amount equal to $1.35 million.

We will not pay any selling commission to any party in connection with the Offering, although we will pay a financial advisory fee equal to 1.8% of the gross proceeds from the Offering to an independent financial advisor. We estimate that the net cash proceeds will be approximately $20.4 million from the additional closings of the Offering, after deducting the estimated expenses of the Offering, assuming the sale of all of the March 2022 Notes.

The March 2022 Notes have a voluntary fixed conversion price of $5.00 per share, a stated interest rate of 7.875% per annum, and a maturity of 24 months (subject to extension in certain circumstances). The March 2022 Notes will be secured by all our existing and future assets (including those of our significant subsidiaries, other than Lucid and its subsidiaries), but including only 9.99% of Lucid's outstanding common stock held by us, pursuant to a security agreement by and between the Company and the Investor.

On the date six months after the issuance of a March 2022 Note, on the 1st and 10th trading day of each calendar month thereafter, and on the maturity date (each an "Installment Date"), the Company will make an amortization payment on the March 2022 Note in an amount equal to the initial principal balance of the note divided by the total number of such amortization payments (such that the entire initial principal balance will be repaid by the maturity date), plus any amounts that have been deferred or accelerated to the applicable installment date, plus all accrued and unpaid interest and any late charges (the "Installment Amount"). Each amortization payment will be satisfied in shares of the Company's common stock, subject to certain customary equity conditions (including minimum price and volume thresholds) at 100% of the Installment Amount or otherwise (or at our election, in whole or in part) in cash at 115% of the Installment Amount. The conversion price for any Installment Amount so converted will be based on the then current market price, but not more than the fixed conversion price then in effect and not less than a floor price. The March 2022 Notes also may be repaid in shares of our common stock, at price per share of our common stock based on the then current market price, but not more than the fixed conversion price then in effect and not less than a floor price, upon the occurrence of certain events of default. We may be required to repay the March 2020 Notes, in cash, at a premium to the outstanding principal balance, upon the occurrence of an event of default or upon a Change of Control (as defined in the March 2020 Notes).

We will be subject to certain customary affirmative and negative covenants regarding the rank of the March 2022 Notes, the incurrence of indebtedness, the existence of liens, the repayment of indebtedness and the making of investments, the payment of cash in respect of dividends, distributions or redemptions, the transfer of assets, the maturity of other indebtedness, and transactions with affiliates, among other customary matters. We also will be subject to financial covenants requiring that (i) the amount of our available cash equal or exceed $8.0 million at all times, (ii) the ratio of (a) the outstanding principal amount of the March 2022 Notes, accrued and unpaid interest thereon and accrued and unpaid late charges to (b) our average market capitalization over the prior ten trading days, not exceed 30%, and (iii) that our market capitalization shall at no time be less than $75 million. The March 2022 Notes include certain customary events of default.

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.

Revenue Recognition

The Company recognizes revenue under the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*, ("ASC 606"). At its inception, an arrangement is accounted for under the provisions of ASC 606 as a contract with a customer when there is: a legally enforceable contract between the parties; the rights of the parties are identified; the arrangement has commercial substance; and collectability of the contract consideration is deemed probable. To determine revenue recognition for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

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.

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 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.

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, 2021 and 2020.

Financial Instruments - Derivatives

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.

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").

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.

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:

- 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, 2021 and 2020;

- 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, 2021; 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. Prior to the Lucid Diagnostics Inc. IPO, 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. After its IPO, 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 is its quoted closing price per share.

Leases

The Company adopted FASB ASC Topic 842, *Leases*, ("ASC 842") effective December 31, 2021, with such adoption not having an effect on the Company's consolidated financial statements. All significant lease agreements and contractual agreements with embedded lease agreements are accounted for under the provisions of ASC 842, wherein, if the contractual arrangement: involves the use of a distinct identified asset; provides for the right to substantially all the economic benefits from the use of the asset throughout the contractual period; and, provides for the right to direct the use of the asset. A lease agreement is accounted for as either a finance lease (generally with respect real estate) or an operating lease (generally with respect to equipment). Under both a finance lease and an operating lease, the Company recognizes as of the lease commencement date a lease right-of-use ("ROU") asset and a corresponding lease payment liability.

A lease ROU asset represents the Company's right to use an underlying asset for the lease term, and the lease liability represents its contractual obligation to make lease payments. The lease ROU asset is measured at the lease commencement date as the present value of the future lease payments plus initial direct costs incurred. The Company recognizes lease expense of the amortization of the lease ROU asset for an operating lease on a straight-line basis over the lease term; and for financing leases on a straight-line basis unless another basis is more representative of the pattern of economic benefit. The lease liability is measured at the lease commencement date with the discount rate generally based on the Company's incremental borrowing rate (to the extent the lease implicit rate is not known nor determinable), with interest expense recognized using the interest method for financing leases.

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, 2021 and 2020.

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, 2021, 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, 2021 and December 31, 2020 or recognized during the years ended December 31, 2021 and 2020. The Company is not aware of any issues under review to potentially result in significant payments, accruals, or material deviations from its position.

Recent Accounting Standards Updates Adopted

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, by eliminating the beneficial conversion and cash conversion accounting models previously contained in ASC 470-20 that required separate accounting for embedded conversion features. ASU 2020-06 also simplified the assessment of a financial instrument settlement to determine whether a contract is an entity's own equity qualifies for equity classification by removing certain conditions from ASC 815-4-25. 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 did not 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 did not have an effect on the Company's consolidated financial statements.

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, 2021. 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, 2021.

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.

Changes to Internal Controls Over Financial Reporting

There have 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, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

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 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

Item 11. Executive Compensation

The information required by this Item 11 is incorporated by reference to our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

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 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

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 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 is incorporated by reference to our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

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 (PCAOB ID#688)
Consolidated Balance Sheets
Consolidated Statements of Operations
Consolidated Statements of Changes in 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 Z Warrant Certificate (5)
4.4	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)
4.5	Form of Senior Secured Convertible Note (15)
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)

Exhibit No.	Description
10.4.1	Securities Purchase Agreement between PAVmed Inc. and the purchasers of the Series A Preferred Stock Units (2)
10.4.2	Registration Rights Agreement between PAVmed Inc. and the purchasers of the Series A Preferred Stock Units (2)
10.5*	Amended and Restated Employment Agreement between PAVmed Inc. and Lishan Aklog, M.D. (9)
10.6*	Amended and Restated Employment Agreement between PAVmed Inc. and Dennis M. McGrath (9)
10.7*	Employment Agreement between PAVmed Inc. and Brian J. deGuzman, M.D. (4)
10.8	Employment Agreement between PAVmed Inc. and Shaun O'Neil (18)
10.9	PAVmed Inc. Fourth Amended and Restated 2014 Long-Term Incentive Equity Plan (10)(12)
10.10	PAVmed Inc. Employee Stock Purchase Plan (10)(12)
10.10.1	Common Stock Purchase Agreement, dated as of March 28, 2022, by and between CF Principal Investments LLC and Lucid Diagnostics Inc.(14)
10.10.2	Registration Rights Agreement, dated as of March 28, 2022, by and between CF Principal Investments LLC and Lucid Diagnostics Inc.(14)
10.11.1	Asset Purchase Agreement, dated as of February 25, 2022, by and among LucidDx Labs Inc., Lucid Diagnostics Inc. and ResearchDx, Inc. (17)
10.11.2	Management Services Agreement, dated as of February 25, 2022, by and among LucidDx Labs Inc. and ResearchDx, Inc. (17)
10.11.3	Form of Securities Purchase Agreement (15)

10.11.4	Form of Security Agreement (15)
10.11.5	Form of Voting Agreement (15)
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	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

(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.
(14)	Incorporated by reference to Lucid Diagnostic Inc.'s Current Report on Form 8-K filed on April 1, 2022.
(15)	Incorporated by reference to the Registrant's Current Report on Form 8-K filed April 4, 2022
(16)	Incorporated by reference to the Registrant's Definitive Proxy Statement on Schedule 14A filed April 30, 2021
(17)	Incorporated by reference to Lucid Diagnostic Inc.'s Current Report on Form 8-K filed on March 3, 2022).
(18)	Incorporated by reference to the Registrant's Current Report on Form 8-K filed February 24, 2022.

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

Item 16. Form 10-K Summary

None

SIGNATURES

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

PAVmed Inc.

April 5, 2022

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)*	April 5, 2022
/s/ Dennis M. McGrath Dennis M. McGrath	President Chief Financial Officer *(Principal Financial and Accounting Officer)*	April 5, 2022
/s/ Michael J. Glennon Michael J. Glennon	Vice Chairman Director	April 5, 2022
/s/ Debra J. White Debra J. White	Director	April 5, 2022
/s/ James L. Cox, M.D.	Director	April 5, 2022

James L. Cox, M.D.		
/s/ Ronald M. Sparks Ronald M. Sparks	Director	April 5, 2022
/s/ Timothy Baxter Timothy Baxter	Director	April 5, 2022
/s/ Joan B. Harvey Joan B. Harvey	Director	April 5, 2022

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.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of PAVmed Inc. and Subsidiaries (the "Company") as of December 31, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, 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 provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
(continued)

Valuation of Lucid Diagnostics Inc. (LUCD) common stock prior to its IPO

Critical Audit Matter Description

The Company estimates the fair value of LUCD common stock for purpose of share based compensation utilizing valuation models with unobservable inputs. Unlike Level 1 and 2 inputs, Level 3 inputs are unobservable, supported by little or no market activity and are significant to the conclusion of fair value of LUCD common stock.

Subjective and challenging judgment is required by management to determine the assumptions and valuation methodology to conclude on material Level 3 inputs that result in the conclusion of fair value of LUCD common stock. Auditing management's models to determine the fair value was complex and required judgment, particularly when evaluating inputs such as discount rates, probability of event occurring, estimated IPO value, number of common equivalent shares, projections, guideline companies, weighting of the income approach and market approach, public company multiples, and multiples of revenue. These assumptions are affected by potential future outcomes, market and industry factors as well as estimates of the LUCD's future growth.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures to address this critical audit matter included the following:

- We obtained an understanding of the design of controls associated with the Company's process to establish a valuation methodology and determine assumptions used in valuation models to conclude on fair value. For example, we gained an understanding of management's review controls over the significant assumptions described above as well as over the data used in the valuation models.

- With assistance from our valuation specialists, we evaluated the reasonableness of the valuation methodology and significant assumptions; tested inputs for reasonableness, including discount rates, guideline companies, weighting of the income approach and market approach, public company multiples and multiples of revenue; and corroborated with audit evidence from external sources or comparisons to other companies in the industry.

- We gained an understanding of the Company's process used to develop projections and tested inputs including probability of event occurring, estimated IPO value, and number of common equivalent shares for reasonableness. Further, we evaluated audit evidence from events or transactions occurring after the measurement date for comparison to management's estimate.

/s/ Marcum LLP

Marcum llp

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

New York, NY
April 5, 2022

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

	December 31, 2021	December 31, 2020
Assets:		
Current assets:		
Cash	$ 77,258	$ 17,256
Accounts receivable	200	—
Prepaid expenses, deposits, and other current assets	5,179	1,685
Total current assets	82,637	18,941
Fixed assets, net	1,585	82
Intangible assets, net	2,029	—
Other assets	725	755
Total assets	$ 86,976	$ 19,778
Liabilities, Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 3,299	$ 2,966
Accrued expenses and other current liabilities	4,259	2,325
CARES Act Paycheck Protection Program note payable	—	300
Senior Secured Convertible Notes - at fair value	—	10,060
Senior Convertible Note - at fair value	—	4,600
Total liabilities	7,558	20,251
Commitments and contingencies (Note 11)		
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 1,113,919 at December 31, 2021 and 1,228,075 shares at December 31, 2020	2,419	2,537
Common stock, $0.001 par value. Authorized, 150,000,000 shares; 86,367,845 and 63,819,935 shares outstanding as of December 31, 2021 and December 31, 2020, respectively	86	64
Additional paid-in capital	198,071	87,570
Accumulated deficit	(138,910)	(88,275)
Total PAVmed Inc. Stockholders' Equity	61,666	1,896
Noncontrolling interests	17,752	(2,369)
Total Stockholders' Equity (Deficit)	79,418	(473)
Total Liabilities and Stockholders' Equity	$ 86,976	$ 19,778

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except number of shares and per share amounts)

	Year Ended December 31,	
	2021	2020
Revenue	$ 500	$ —
Cost of revenue	585	—
Gross profit (loss)	(85)	—
Operating expenses:		
Sales and marketing	8,895	2,789
General and administrative	25,566	9,599
Research and development	19,847	10,963
Total operating expenses	54,308	23,351
Loss from operations	(54,393)	(23,351)
Other income (expense):		
Interest expense	—	(53)
Change in fair value - Senior Secured Convertible Notes and Senior Convertible Note	1,682	(5,327)
Offering costs - Senior Secured Convertible Note and Senior Convertible Note	—	(660)
Debt extinguishments loss - Senior Secured Convertible Notes	(3,715)	(6,497)
Debt forgiveness	300	—
Other income (expense), net	(1,733)	(12,537)
Loss before provision for income tax	(56,126)	(35,888)
Provision for income taxes	—	—
Net loss before noncontrolling interests	(56,126)	(35,888)
Net loss attributable to the noncontrolling interests	5,779	1,612
Net loss attributable to PAVmed Inc.	(50,347)	(34,276)
Less: Series B Convertible Preferred Stock dividends earned	(283)	(287)
Net loss attributable to PAVmed Inc. common stockholders	$ (50,630)	$ (34,563)
Per share information:		
Net loss per share attributable to PAVmed Inc. - basic and diluted	$ (0.65)	$ (0.72)
Net loss per share attributable to PAVmed Inc. common stockholders – basic and diluted	$ (0.65)	$ (0.73)
Weighted average common shares outstanding, basic and diluted	77,515,767	47,432,115

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, 2021
(in thousands except number of shares and per share data)

	PAVmed Inc. Stockholders' Equity (Deficit)							
	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Non controlling	
	Shares	Amount	Shares	Amount	Capital	Deficit	Interest	Total
Balance - December 31, 2020	1,228,075	$ 2,537	63,819,935	$ 64	$ 87,570	$ (88,275)	$ (2,369)	$ (473)
Dividends declared - Series B Convertible Preferred Stock	96,292	288	—	—	—	(288)	—	—
Conversions - Series B Convertible Preferred Stock	(210,448)	(406)	210,448	—	406	—	—	—
Issue common stock - registered offerings, net	—	—	15,782,609	16	53,688	—	—	53,704
Vest - restricted stock awards vests	—	—	150,000	—	—	—	—	—
Exercise - Series Z warrants	—	—	4,877,484	5	7,799	—	—	7,804
Exercise - Series W warrants	—	—	3,945	—	20	—	—	20
Conversions - Senior Secured Convertible Note	—	—	667,668	1	1,722	—	—	1,723
Exercise - stock options	—	—	621,164	—	979	—	—	979
Purchase - Employee Stock Purchase Plan	—	—	234,592	—	436	—	—	436
Issue common stock of majority-owned subsidiary	—	—	—	—	—	—	—	—
Impact of subsidiary equity transactions[(1)]	—	—	—	—	39,576	—	16,760	56,336
Issue of common stock of majority-owned subsidiary	—	—	—	—	—	—	6	6
Stock-based compensation - PAVmed Inc.	—	—	—	—	5,410	—	—	5,410
Stock-based compensation - majority-owned subsidiary	—	—	—	—	465	—	9,134	9,599
Net loss	—	—	—	—	—	(50,347)	(5,779)	(56,126)
Balance - December 31, 2021	1,113,919	$ 2,419	86,367,845	$ 86	$ 198,071	$ (138,910)	$ 17,752	$ 79,418

(1) Primarily represents the impact of the Lucid Diagnostics Inc. IPO. See Note 17, *Noncontrolling Interest* for further information.

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 number of shares and per share data)

	PAVmed Inc. Stockholders' Deficit							
	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Non controlling	
	Shares	Amount	Shares	Amount	Capital	Deficit	Interest	Total
Balance - 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
Net Loss	—	—	—	—	—	(34,276)	(1,612)	(35,888)
Balance - 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 STATEMENTS OF CASH FLOWS
(in thousands, except number of shares and per share data)

	Year Ended December 31,	
	2021	2020
Cash flows from operating activities		
Net loss - before noncontrolling interest ("NCI")	$ (56,126)	$ (35,888)
Adjustments to reconcile net loss - before NCI to net cash used in operating activities		
Depreciation expense	80	23
Amortization expense	146	—
Stock-based compensation	15,009	2,044
In-process R&D charge	133	—
Change in fair value - Senior Secured Convertible Notes and Senior Convertible Note	(1,682)	5,327
Debt extinguishment loss - Senior Secured Convertible Notes and Senior Convertible Note	3,715	6,497
Debt forgiveness	(300)	—
Changes in operating assets and liabilities:		
Accounts receivable	(200)	—
Prepaid expenses and other current assets	(3,458)	(1,336)
Accounts payable	174	501
Accrued expenses and other current liabilities	1,918	918
Net cash flows used in operating activities	(40,591)	(21,914)
Cash flows from investing activities		
Purchase of equipment	(1,469)	(55)
Acquisitions, net of cash acquired	(2,247)	—
Net cash flows used in investing activities	(3,716)	(55)
Cash flows from financing activities		
Proceeds - issue of common stock - initial public offering - majority-owned subsidiary common stock	62,000	—
Payment - offering costs - initial public offering - majority-owned subsidiary common stock	(5,665)	—
Proceeds – issue of common stock – registered offerings	55,016	16,032
Payment – offering costs – registered offerings	(1,312)	(100)
Proceeds – issue of Senior Secured Convertible Notes	—	13,300
Proceeds – issue of Senior Convertible Note	—	3,700
Proceeds – Cares Act Paycheck Protection Program Loan	—	300
Payment – repayment of Senior Convertible Note and Senior Secured Convertible Note	(14,816)	—
Payment – Senior Convertible Note and Senior Secured Convertible Note – non-installment payments	(154)	(600)
Proceeds – exercise of Series Z warrants	7,804	—
Proceeds – exercise of Series W warrants	20	—
Proceeds – exercise of Series S warrants	—	12
Proceeds – exercise of stock options	980	—
Proceeds – issue common stock – Employee Stock Purchase Plan	436	357
Proceeds – exercise of stock options issued under equity incentive plan of majority owned subsidiary	—	5

Net cash flows provided by financing activities	104,309	33,006
Net increase (decrease) in cash	60,002	11,037
Cash, beginning of period	17,256	6,219
Cash, end of period	$ 77,258	$ 17,256

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(amounts in these accompanying notes are presented in thousands, except number of shares and per-share amounts.)

Note 1 — The Company

Description of the Business

PAVmed Inc and Subsidiaries, referred to herein as "PAVmed" or the "Company" is comprised of PAVmed Inc. and its wholly-owned subsidiary and its majority-owned subsidiaries, inclusive of Lucid Diagnostics, Inc. ("Lucid Diagnostics" or "LUCID"), Veris Health, Inc. ("Veris Health" or "VERIS"), and Solys Diagnostics, Inc. ("Solys Diagnostics" or "SOLYS").

The Company is 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 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:

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, NextFlo, EsoCure and digital health technologies acquired by the Company's majority-owned subsidiary Veris Health Inc.

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

Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), and applicable rules and regulations of the United States Securities and Exchange Commission ("SEC"), and include the accounts of the Company and its wholly-owned and majority-owned subsidiaries. All significant intercompany transactions and balances have been eliminated in consolidation. The Company holds a majority-ownership interest and has controlling financial interest in each of: Lucid Diagnostics Inc., Veris Health Inc., and Solys Diagnostics Inc., with the corresponding noncontrolling interest included as a separate component of consolidated stockholders' equity (deficit), including the recognition in the consolidated statement of operations of a net loss attributable to the noncontrolling interest based on the respective minority-interest equity ownership of each majority-owned subsidiary. See Note 17, *Noncontrolling Interest*, for a discussion of each of the majority-owned subsidiaries noted above. The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions.

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

Use of Estimates

In preparing the consolidated financial statements in conformity with U.S. GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets, inclusive of acquired intangible assets and the determination of corresponding carrying value reserve, if any, and liabilities and the disclosure of contingent losses, as of the date of the consolidated financial statements, as well as the reported amounts of revenue and expenses during the reporting period. Significant estimates in these consolidated financial statements include those related to the estimated fair value of stock-based equity awards, financial instruments recognized as liabilities, debt obligations, and common stock purchase warrants. Other significant estimates include the provision or benefit for income taxes and the corresponding valuation allowance on deferred tax assets. Additionally, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. On an ongoing basis, the Company evaluates its estimates and assumptions. The Company bases its estimates on historical experience and on various other assumptions believed to be reasonable. Due to inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates.

Financial Condition

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

The Company has financed its operations principally through 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 companies that devote substantially all of their efforts to the commercialization of their initial product and services and ongoing research and development activities and conducting 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, with the cash on-hand as of the date hereof and other debt and equity committed sources of financing, the Company expects to be able to fund its operations for one year from the date of the issue of the Company's consolidated financial statements included herein in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. See Note 20, *Subsequent Events*, for a discussion of the committed sources of financing noted above.

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

Significant Accounting Policies - continued

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 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.

Revenue Recognition

The Company recognizes revenue under the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*, ("ASC 606"). At its inception, an arrangement is accounted for under the provisions of ASC 606 as a contract with a customer when there is: a legally enforceable contract between the parties; the rights of the parties are identified; the arrangement has commercial substance; and collectability of the contract consideration is deemed probable. To determine revenue recognition for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. See Note 4, *Revenue from Contracts with Customers*, for further information regarding revenue recognition.

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

Significant Accounting Policies - continued

Fixed Assets

Fixed assets are stated at cost and depreciated using the straight-line method over the assets' estimated useful lives. Additions and improvements are capitalized, including direct and indirect costs incurred to validate equipment and bring to working conditions. The costs for maintenance and repairs are expensed as incurred.

Leases

The Company adopted FASB ASC Topic 842, *Leases*, ("ASC 842") effective December 31, 2021, with such adoption not having an effect on the Company's consolidated financial statements.

All significant lease agreements and contractual agreements with embedded lease agreements are accounted for under the provisions of ASC 842, wherein, if the contractual arrangement: involves the use of a distinct identified asset; provides for the right to substantially all the economic benefits from the use of the asset throughout the contractual period; and, provides for the right to direct the use of the asset. A lease agreement is accounted for as either a finance lease (generally with respect real estate) or an operating lease (generally with respect to equipment). Under both a finance lease and an operating lease, the Company recognizes as of the lease commencement date a lease right-of-use ("ROU") asset and a corresponding lease payment liability.

A lease ROU asset represents the Company's right to use an underlying asset for the lease term, and the lease liability represents its contractual obligation to make lease payments. The lease ROU asset is measured at the lease commencement date as the present value of the future lease payments plus initial direct costs incurred. The Company recognizes lease expense of the amortization of the lease ROU asset for an operating lease on a straight-line basis over the lease term; and for financing leases on a straight-line basis unless another basis is more representative of the pattern of economic benefit.

The lease liability is measured at the lease commencement date with the discount rate generally based on the Company's incremental borrowing rate (to the extent the lease implicit rate is not known nor determinable), with interest expense recognized using the interest method for financing leases.

Certain leases may include options to extend or terminate the agreement. The Company does not assume renewals in determination of the lease term unless the renewals are deemed to be reasonably certain at lease commencement. As well, an option to terminate is considered unless it is reasonably certain the Company will not exercise the option. The Company elected the practical expedient to not recognize a lease ROU asset and lease payment liability for leases with a term of twelve months or less ("short-term leases"), resulting in the aggregate lease payments being recognized on a straight line basis over the lease term. The Company's leases with a commencement date prior to January 1, 2022 were short-term leases and therefore did not require recording a ROU asset or lease liability at December 31, 2021. Additionally, the Company elected the practical expedient to not separate lease and non-lease components. See Note 9, *Leases.*

Intangible Assets

Purchased intangible assets are recorded at cost and depreciated using the straight-line method over the assets' estimated useful life. See Note 6, Acquisitions, for further information with respect to purchased intangible assets.

Impairment - Long Lived Assets

The Company reviews its long-lived assets, including intangible assets with finite lives, for recoverability whenever events or changes in circumstances indicate the carrying amount of the assets may not be fully recoverable. The Company evaluates assets for potential impairment by comparing estimated future undiscounted net cash flows to the carrying amount of the asset. If the carrying amount of the assets exceeds the estimated future undiscounted cash flows, impairment is measured based on the difference between the carrying amount of the assets and fair value which is generally an expected present value cash flow technique. The assessment and determination of the existence of an impairment indicator comprises measurable operating performance criteria as well as qualitative factors deemed relevant and appropriate to such evaluation.

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

Significant Accounting Policies - 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 ("PAVmed Inc. 2014 Equity Plan") and the Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan ("Lucid Diagnostics Inc. 2018 Equity Plan").

The Company accounts for stock-based compensation in accordance with the provisions of FASB ASC Topic 718, Stock Compensation ("ASC 718").

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.

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:

- 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, 2021 and 2020;

- 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, 2021; 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 and restricted stock awards granted under the PAVmed Inc. 2014 Equity Plan is its quoted closing price per share.

On October 14, 2021, Lucid Diagnostics Inc. completed an initial public offering ("IPO") of its common stock under an effective registration statement on Form S-1 (SEC File No. 333-259721), wherein a total of 5.0 million IPO shares of common stock of Lucid Diagnostics Inc. were issued, with such total IPO shares inclusive of 571,428 shares issued to PAVmed Inc. The price per share of Lucid Diagnostics Inc. common stock used in the computation of estimated fair value of stock options and restricted stock awards granted under the Lucid Diagnostics Inc. 2018 Equity Plan is as follows: (i) for the period October 14, 2021 to December 31, 2021 it is its quoted closing price per share; and (ii) for the period January 1, 2021 to October 14, 2021, it was estimated using a probability-weighted average expected return methodology ("PWERM"), which involves the determination of equity value under various exit scenarios and an estimation of the return to the common stockholders under each scenario; and (iii) as of December 31, 2020, it was estimated using a discounted cash flow analysis 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 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, 2021 and December 31, 2020, 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, 2021 and 2020.

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

Significant Accounting Policies - continued

Financial Instruments - Derivatives

The Company evaluates its financial instruments to determine if the financial instrument itself or if any embedded components of a financial instrument 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.

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.

Note 2 — Summary of Significant Accounting Policies and Recent Accounting Standards Updates - 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, 2021 and 2020.

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, 2021, 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, 2021 and December 31, 2020 or recognized during the years ended December 31, 2021 and 2020. 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's designation as an "emerging growth company" or "EGC" under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), expired during 2021. As an EGC, the company had irrevocably elected to adopt new or revised accounting standards using the effective date applicable to private companies. With the expiry of its EGC designation, effective December 31, 2021, the Company adopted the previously deferred accounting standards in accordance with the effective date applicable to non-EGC public companies, as such effective dates are applicable to SEC smaller reporting company requirements.

Recent Accounting Standards Updates Adopted

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, by eliminating the beneficial conversion and cash conversion accounting models previously contained in ASC 470-20 that required separate accounting for embedded conversion features. ASU 2020-06 also simplified the assessment of a financial instrument settlement to determine whether a contract is an entity's own equity qualifies for equity classification by removing certain conditions from ASC 815-4-25. 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 did not 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 did not have an effect on the Company's consolidated financial statements.

Effective December 31, 2021, the Company adopted FASB ASC Topic 842, Leases, ("ASC 842"). ASC 842 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 Company's adoption of ASC 842 did not have an effect on the Company's consolidated financial statements. See Note 9, *Leases*.

Note 3 — Patent License Agreement – Case Western Reserve University

Overview

The Company, through its majority-owned subsidiary Lucid Diagnostics Inc., entered into a patent license agreement with Case Western Reserve University ("CWRU"), captioned the Amended and Restated License Agreement and dated August 23, 2021 ("Amended CWRU License Agreement"). The Amended CWRU License Agreement is a successor to and replaced in its entirety the previous CWRU License Agreement, dated May 12, 2018, between Lucid Diagnostics Inc. and CWRU. The Amended 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.

The Amended CWRU License Agreement (as did the predecessor 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 "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 Fee was $273. On the August 23, 2021 effective date of the Amended CWRU License Agreement, the remaining balance of $223 became payable, and such amount was paid in September 2021. Additionally, also in September 2021, the Company paid a $10 amendment fee in connection with the Amended CWRU License Agreement. Additionally, the Amended CWRU License Agreement provides for each of patent fees reimbursement payments; milestone payments; and royalty payments - each as discussed below.

Patent Fees Reimbursement

Lucid Diagnostics Inc. is responsible for reimbursement of certain CWRU billed patent fees. See Note 5,*Related Party Transactions*, for patent fee reimbursement payments paid to CWRU in the years ended December 31, 2021 and 2020.

Milestones

The (predecessor) CWRU License Agreement contained milestones, including regulatory milestones with respect to the FDA 501(k) submission of EsoCheck and the FDA clearance of EsoCheck, respectively regulatory submissions and clearances; which were achieved in accordance with the requisite contractual due dates, for which a $75

research and development expense was recognized and paid with respect to the achievement of the regulatory milestone related to FDA clearance of EsoCheck. The CWRU License Agreement was amended effective February 12, 2021, 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 $100 payment to CWRU in consideration for such changes to the commercialization milestone ("CWRU License Agreement Amendment Fee"), with such fee recognized as general and administrative expense as of December 31, 2020 and paid in February 2021. The regulatory milestone related to FDA PMA submission of a licensed product ("PMA Milestone") is included in the Amended CWRU License Agreement, and is the sole remaining unachieved milestone, for which a $200 milestone payment would be payable to CWRU upon its achievement.

Note 3 — Patent License Agreement – Case Western Reserve University - continued

Royalty Fee

Under the Amended CWRU License Agreement, the Company is required to pay a royalty fee to CWRU with respect to the "Licensed Products" (as defined in the CWRU License Agreement) of a percentage of "Net Sales", as defined in the Amended CWRU License Agreement, as follows: 5.0% of Net Sales up to $100.0 million per year; and 8.0% of Net Sales of $100.0 million or greater per year, with such amounts subject-to a minimum annual royalty fee.

The base minimum annual royalty fee is $50 commencing January 1 following the first anniversary of the "First Commercial Sale" of a "Licensed Product" (as such terms are defined in the Amended CWRU License Agreement). The minimum annual royalty fee increases to each of: $ 150 if the annual "Net Sales" (as defined in the Amended CWRU License Agreement) exceed $25.0 million up to $50.0 million; $300 if annual Net Sales exceed $50.0 million up to $100.0 million; and $600 if annual Net Sales exceed $100.0 million. The Company recognized a 5.0% royalty fee payment liability as of December 31, 2021 with respect to the revenue recognized under the EsoGuard Commercialization Agreement, dated August 1, 2021, between Lucid Diagnostics Inc. and Research Dx Inc.

Additionally, the Company is required to pay a royalty fee on (sub-license) "Other Proceeds" (as defined in the Amended CWRU License Agreement) of: 30% of sub-license proceeds to extent the sub-license proceeds are realized prior to the first commercial Sale of a Licensed Product; or 15% of sub-license proceeds to extent the sub-license proceeds are realized after the first commercial Sale of a Licensed Product.

Consulting Agreements with Physician Inventors - Intellectual Property - CWRU License Agreement

Lucid Diagnostics Inc. entered into consulting agreements with each of the three physician inventors of the intellectual property licensed under the Amended CWRU License Agreement ("Physician Inventors"), with each such consulting agreement providing for compensation on a contractual rate per hour for consulting services provided, and an expiration date of May 12, 2024, upon each of the respective the agreements' renewal effective May 12, 2021. Additionally, each of the Physician Inventors have been granted stock options and restricted stock awards under the Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan; and stock options under the PAVmed Inc. 2014 Long-Term Incentive Equity Plan. See Note 5, *Related Party Transactions*, with respect to the consulting fee expense and stock based compensation expense recognized with respect to the Physician Inventors consulting agreements and stock options and restricted awards discussed above; and Note 14, *Stock-Based Compensation*, for information regarding each of the "Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan" and the separate "PAVmed Inc. 2014 Long-Term Incentive Equity Plan".

Note 4 - Revenue from Contracts with Customers

Revenue is recognized when the satisfaction of the performance obligation occurs, which is when the delivery of product and /or the provision of service is rendered, and is measured as the amount of estimated consideration expected to be realized. In the year ended December 31, 2021, the Company recognized revenue under the EsoGuard Commercialization Agreement, dated August 1, 2021, as discussed below.

EsoGuard Commercialization Agreement

The Company, through its majority-owned subsidiary, Lucid Diagnostics Inc., entered into the EsoGuard Commercialization Agreement, dated August 1, 2021, with its Commercial Laboratory Improvements Act ("CLIA") certified commercial laboratory service provider, ResearchDX Inc. ("RDx"), an unrelated third-party. The EsoGuard Commercialization Agreement is on a month-to-month basis, and may be terminated by either party thereto, with or without cause, upon forty-five (45) days prior written notice.

On February 25, 2022, the EsoGuard Commercialization Agreement was terminated in conjunction with the execution of an Asset Purchase Agreement between Lucid Dx Labs Inc., a wholly-owned subsidiary of Lucid Diagnostics Inc. and RDx, as such agreement is further discussed in Note 20, *Subsequent Events*.

Revenue Recognized

In the year ended December 31, 2021, the Company recognized total revenue of $500, which represents the minimum fixed monthly fee of $100 to be paid by RDx for the delivery of services under the EsoGuard Commercialization Agreement for the period from the agreement inception date of August 1, 2021 to December 31, 2021. The monthly fee was deemed to be collectible for such period as RDx has timely paid the applicable respective monthly fee.

Cost of Revenue

The cost of revenue recognized with respect to the revenue recognized under the EsoGuard Commercialization Agreement for the year ended December 31, 2021 totaled $585, inclusive of employee related costs of employees engaged in the delivery of the administration to patients of the EsoCheck cell sample collection procedure; EsoCheck devices and EsoGuard mailers (cell sample shipping costs) distributed to medical practitioners' locations and the Lucid Test Centers; Lucid Test Centers operating expenses, including rent expense and supplies; and royalty fees incurred under the Amended CWRU License Agreement.

Note 5 —Related Party Transactions

Case Western Reserve University and Physician Inventors - CWRU License Agreement

Case Western Reserve University ("CWRU") and each of the three physician inventors of the intellectual property licensed under the CWRU License Agreement ("Physician Inventors") each hold equity ownership minority interests in Lucid Diagnostics Inc. The expenses incurred with respect to the CWRU License Agreement and the three Physician Inventors, as classified in the accompanying consolidated statement of operations for the periods indicated are summarized as follows:

	For the year ended December 31,

	2021	2020
Cost of Revenue		
CWRU – Royalty Fee	$ 25	$ —
General and Administrative Expense		
CWRU – License Agreement - Amendment Fee - Milestone III	10	100
Stock-based compensation expense – Physician Inventors' restricted stock awards	910	—
Research and Development Expense		
CWRU License Agreement - reimbursement of patent legal fees	195	250
EsoCheck devices provided to CWRU	—	15
Fees - Physician Inventors' consulting agreements	29	83
Stock-based compensation expense – Physician Inventors' stock options	169	23
Total Related Party Expenses	$ 1,338	$ 471

Lucid Diagnostics Inc. entered into consulting agreements with each of the three Physician Inventors, with each such consulting agreement providing for compensation on a contractual rate per hour for consulting services provided, and an expiration date of May 12, 2024, upon the agreements' renewal effective May 12, 2021. Additionally, as discussed below, each of the Physician Inventors have been granted stock options under the PAVmed Inc. 2014 Long-Term Incentive Equity Plan, and stock options and restricted stock awards under the Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan.

Under each of their respective (initial) consulting agreements with Lucid Diagnostics Inc., the three Physician Inventors were each granted 25,000 stock options under the PAVmed Inc. 2014 Equity Plan, with a grant date of May 12, 2018, an exercise price of $ 1.59 per share of common stock of PAVmed Inc., vesting ratably on a quarterly basis commencing June 30, 2018 and ending March 31, 2021, and a contractual period of ten years from the date of grant. As of March 31, 2021, such stock options were fully vested and exercisable. Each of the Physician Inventors were granted 50,000 stock options under the PAVmed Inc. 2014 Equity Plan, with a grant date of June 21, 2021, an exercise price of $6.41 per share of common stock of PAVmed Inc., vesting ratably on a quarterly basis commencing June 30, 2021 and ending March 31, 2024, and a contractual period of ten years from the date of grant.

On March 1, 2021, restricted stock awards were granted under the Lucid Diagnostics Inc. 2018 Equity Plan to each of the three Physician Inventors, with such restricted stock awards having a single vesting date of March 1, 2023, with the fair value of such restricted stock awards recognized as stock-based compensation expense ratably on a straight-line basis over the vesting period, which is commensurate with the service period. The restricted stock awards are subject to forfeiture if the requisite service period is not completed.

See Note 14, *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 17, *Noncontrolling Interest*, for a discussion of Lucid Diagnostics Inc. and the corresponding noncontrolling interests.

Note 5 —Related Party Transactions - continued

Other Related Party Transactions

Lucid Diagnostics Inc. previously entered into a consulting agreement with Stanley N. Lapidus, effective June 2020 with such consulting agreement providing for compensation on a contractual rate per hour for consulting services provided. In July 2021, Mr. Lapidus was appointed as Vice Chairman of the Board of Directors of Lucid Diagnostics Inc. Lucid Diagnostics Inc. recognized as general and administrative expense of $21 and $7 in the years ended December 31, 2021 and 2020, respectively, in connection with the consulting agreement.

Veris Health Inc. entered into a consulting agreement with Andrew Thoreson, M.D. effective June 2021 with such consulting agreement providing for compensation on a contractual rate per hour for consulting services provided. Veris Health Inc. recognized general and administrative expense of $ 54 in the year ended December 31, 2021 in connection with the consulting agreement.

Note 6 — Acquisitions

Oncodisc Inc.

On May 28, 2021, Veris Health Inc., a majority-owned subsidiary of PAVmed Inc., acquired all of the outstanding common stock of Oncodisc Inc. ("Oncodisc") for total purchase consideration of approximately $261, consisting of: the issue of 1,564,514 shares of common stock of Veris Health Inc., with such shares having an estimated fair value of approximately $6; and cash paid of approximately $255. Additionally, the cash acquired was approximately $108 and liabilities assumed were approximately $50. The acquisition of Oncodisc was accounted for by Veris Health Inc as an asset acquisition. Veris Health Inc. has allocated the preliminary purchase price based upon the respective fair values as of the date of acquisition as follows:

Acquisition - Oncodisc Inc.	**Amount**
Cash Acquired	$ 108
Intangible asset - in process R&D	133
Intangible asset - assembled workforce	70
Liabilities assumed	(50)
Total net assets acquired	$ 261

The intangible asset recognized for the in-process research and development ("IPRD") of $133 was determined to have no alternative future use and was recognized as a current period research and development expense. The intangible asset recognized for the assembled workforce of approximately $70, which is included in "Intangible assets, net" on the accompanying consolidated balance sheet, has an expected useful life of one year, and is being recognized on a ratable basis over such period, which commenced in June 2021. See Note 17, *Noncontrolling Interest*, for a discussion of Veris Health Inc. and the corresponding noncontrolling interests.

CapNostics, LLC.

On October 5, 2021, PAVmed Subsidiary Corporation, a majority-owned subsidiary of PAVmed Inc., acquired the membership interest of CapNostics, LLC ("CapNostics") for total (gross) purchase consideration of approximately $2.1 million of cash paid at the closing of the transaction. The acquisition of CapNostics was accounted for as an asset acquisition. The intangible asset recognized for the defensive technology of approximately $2.1 million, which is included in "Intangible assets, net" on the accompanying consolidated balance sheet, has an expected useful life of five years, and is being recognized on a ratable basis over such period, which commenced in October 2021. The

Company has allocated the preliminary purchase price based upon the respective fair values as of the date of acquisition as follows:

Acquisition - CapNostics, LLC	Amount
Cash Acquired	$ 5
Other current assets	6
Intangible asset - defensive technology	2,104
Liabilities assumed	(10)
Total net assets acquired	$ 2,105

Amortization - Acquired Intangible Assets

Amortization expense of the acquired intangible assets discussed above was $146 for the year ended December 31, 2021 (there was no such amortization expense for the prior year ended December 31, 2020), and is included in general and administrative expenses in the accompanying consolidated statements of operations. The scheduled future amortization expense of such acquired intangible assets is as follows: $449 for the year 2022; $420 for each of the years 2023, 2024, and 2025; and $319 for the year 2026.

Note 7 — Prepaid Expenses, Deposits, and Other Current and Non-Current Assets

Current Assets

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

	December 31, 2021	December 31, 2020
Advanced payments to service providers and suppliers	$ 2,084	$ 507
Prepaid insurance	1,856	61
Deposits	713	262
EsoCheck cell collection supplies	434	779
EsoGuard mailer supplies	59	55
CarpX devices	33	21
Total prepaid expenses, deposits and other current assets	$ 5,179	$ 1,685

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 (the "EsoGuard CRO Agreement"). 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. The Company incurred an on-account deposit of $725 and $755 as of December 31, 2021 and 2020, respectively, with the deposit classified as a non-current asset in the line item captioned "Other assets" on the accompanying consolidated balance sheets as of December 31, 2021 and 2020. See Note 11, *Commitment and Contingencies*, for a discussion of the EsoGuard CRO Agreement.

Note 8 — Fixed Assets

Fixed assets, less accumulated depreciation, consisted of the following as of:

	Estimated Useful Life	December 31, 2021	December 31, 2020
Computer and office equipment	2-5 years	$ 426	$ 51
Laboratory equipment	3-7 years	1,161	88
Furniture and fixtures	3-5 years	96	—
Leasehold improvements	(1)	2	—
Assets under construction	n/a	38	—
Total Fixed Assets		1,723	139
Less Accumulated Depreciation		(138)	(57)
Total Fixed Assets, net		$ 1,585	$ 82

(1) Lesser of remaining lease term or estimated useful life.

The assets under construction presented above are with respect to the establishment of a Company-owned CLIA-certified, CAP-accredited commercial clinical laboratory. The total fixed assets is inclusive of $99 of accounts payable and $16 of accrued expenses and other current liabilities in the accompanying consolidated balance sheet as of December 31, 2021. Depreciation expense of $80 and $23 for the years ended December 31, 2021 and 2020, respectively, is included in general and administrative expenses in the accompanying consolidated statements of operations.

Note 9 — Leases

As of December 31, 2021,the Company only had short-term leases, inclusive of: an 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, with such rental agreement able to be cancelled with two months written notice; and two other month-to-month office space rental agreements, each of which have an April 30, 2022 termination date. The total rent expense incurred under month-to-month rental agreements was $191 and $189, for the years ended December 31, 2021 and 2020, respectively.

In addition to the short-term leases as of December 31, 2021 noted above, the Company entered into additional lease agreements, each with commencement dates subsequent to December 31, 2021, classified as operating leases and short-term leases, including for each of: a research and development facility; a commercial clinical laboratory; a light manufacturing facility; additional Lucid Test Centers; and for office space.

As of December 31, 2021, with respect to short-term leases: the total future lease payments of both the (existing) short-term leases effective as of December 31, 2021 plus the (new) short-term leases (i.e. the new short-term leases with commencement dates subsequent to December 31, 2021), are $178 in 2022 and $9 in 2023.

As of December 31, 2021, with respect to operating leases: the total future lease payments of the (new) operating leases (i.e. the new operating leases with commencement dates subsequent to December 31, 2021), are as follows:

2022	$ 1,359
2023	1,592
2024	1,560
2025	696
2026	712
Thereafter	277
Total lease payments	6,196

Note 10 — Accrued Expenses and Other Current Liabilities

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

	December 31, 2021	December 31, 2020
Compensation and Employee Benefits	$ 3,151	$ 1,777
CWRU License Agreement fee	—	223
CWRU License Agreement Amendment fee	—	100
CWRU Amended License Agreement - Royalty fee	25	—
Operating expenses	1,083	171
EsoGuard mailer supplies	—	22
CarpX devices	—	32
Total accrued expenses and other current liabilities	$ 4,259	$ 2,325

The “Compensation and Employee Benefits” includes: discretionary bonus payments to employees; unused employee vacation time; and employee payroll deductions related to the PAVmed Inc. Employee Stock Purchase Plan (“PAVmed Inc. ESPP”). See Note 14, *Stock-Based Compensation*, for additional information on the PAVmed Inc. ESPP.

See Note 3, *Patent License Agreement - Case Western Reserve University*, for a discussion of the CWRU License Agreement.

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

Note 11 — Commitment and Contingencies

Clinical Trials - Agreement with Clinical Research Organization

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

On November 2, 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 did not seek any specific monetary damages. The Company did not believe it was clear the prior approval of these matters was invalid or otherwise ineffective. However, to avoid any uncertainty and 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 Settlement Term Sheet Agreement, dated January 28, 2021, 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 approval by the Court.

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 Kingswood Capital Markets, a “division” of Benchmark Investments, Inc. On December 16, 2021, the court granted PAVmed’s motion to dismiss the case for lack of subject matter jurisdiction. On February 7, 2022, Benchmark Investments LLC, which claimed to be affiliated with Benchmark Investments, Inc., filed a new complaint in the Supreme Court of the State of New York, New York County, asserting claims similar to those in the federal action, and adding to its allegations that financings conducted by the Company in January 2021 and February 2021 also violated the Company’s engagement letter with Kingswood Capital Markets. 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 12 — Financial Instruments Fair Value Measurements

Recurring Fair Value Measurements

The fair value hierarchy table for the reporting dates noted 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

(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 year ended December 31, 2020.

Convertible notes are accounted for under the fair value option ("FVO") election, wherein, each of the convertible notes were initially measured at their respective 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.

There were no fair value measurements as of December 31, 2021 as each of the convertible notes were previously repaid-in-full in the three months ended March 31, 2021, as discussed herein below in Note 13, *Debt*. The estimated fair value of each of the convertible notes as of December 31, 2020, 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, and were therefore classified within the Level 3 category, as the fair value 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.

The estimated fair value of each of the convertible notes as of December 31, 2020, 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%	50.20%	27.20%
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	70.00%	70.00%	70.00%
Risk free rate	0.09%	0.11%	0.12%
Dividend yield	—%	—%	—%

The estimated fair values reported utilized the Company's common stock price along with certain Level 3 inputs, as discussed above, 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 13 — Debt

Convertible Notes

All of the convertible notes, as such convertible notes are discussed below, were repaid-in-full during the three months ended March 31, 2021. The fair value and face value principal of outstanding convertible notes at December 31, 2020 were 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

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

The "November 2019 Senior Convertible Notes" remaining unpaid outstanding face value principal of approximately $956 as of December 31, 2020 was repaid-in-full as of January 5, 2021, with the remaining principal balance, along with the payment of interest thereon of approximately $7, 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), resulting in the recognition of a loss from extinguishment of debt of approximately $760.

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

The "April 2020 Senior Convertible Note" unpaid outstanding face value principal of approximately $4,111 as of December 31, 2020 was repaid-in-full in March 2021, as discussed herein below. In the years ended December 31, 2021 and 2020, approximately $52 and $215, respectively, of non-installment payments were paid in cash.

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

The "August Senior Convertible Note" unpaid outstanding face value principal of approximately $7,750 as of December 31, 2020 was repaid-in-full in March 2021, as discussed herein below. In the years ended December 31, 2021 and 2020, approximately $102 and $246, respectively, of non-installment payments were paid in cash.

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

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. The Company recognized a debt extinguishment loss of approximately $2,955 in the year ended December 31, 2021 in connection with the repayments of the April 2020 Senior Convertible Note and the August 2020 Senior Convertible Note.

Note 13 — Debt - continued

Convertible Notes - continued

A reconciliation of the fair value of the convertible notes for the year ended December 31, 2021 is as follows:

	November 2019 Senior Secured Convertible Notes	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, 2020	$ 1,270	$ 4,600	$ 8,790	$ 14,660	$ —
Installment repayments – common stock	(956)	—	—	(956)	—
Non-installment payments – common stock	(7)	—	—	(7)	—
Non-installment payments – cash	—	(52)	(102)	(154)	—
Change in fair value	(307)	(437)	(938)	(1,682)	1,682
Principal repayments - cash	—	(4,111)	(7,750)	(11,861)	—
Fair Value at December 31, 2021[1]	$ —	$ —	$ —	$ —	
Other Income (Expense) - Change in fair value – year ended December 31, 2021[1]					$ 1,682

(1) As discussed above, all remaining convertible notes were previously repaid during the three months ended March 31, 2021.

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

	December 2018 Senior Secured Convertible Note	November 2019 Senior Secured Convertible Notes	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)

The Senior Convertible Notes presented above were 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 12, Financial Instruments Fair Value Measurements, for a further discussion of fair value assumptions.

Note 13 — 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". Through the life of the PPP Loan, the Company made no principal or interest payments. The Company submitted its PPP Loan forgiveness application on April 21, 2021 and the forgiveness application was approved on June 9, 2021. Upon PPP Loan forgiveness, the Company recognized a gain of $300 in its consolidated statements of operations in the year ended December 31, 2021.

Note 14 — 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") is designed to enable PAVmed Inc. to offer employees, officers, directors, and consultants, as defined, an opportunity to acquire shares of common stock of PAVmed Inc. 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 PAVmed Inc. board of directors.

A total of 11,951,081 shares of common stock of PAVmed Inc. are reserved for issuance under the PAVmed Inc. 2014 Equity Plan, with 1,160,573 shares available for grant as of December 31, 2021. The share reservation is not diminished by a total of 600,854 PAVmed Inc. stock options and restricted stock awards granted outside the PAVmed Inc. 2014 Equity Plan as of December 31, 2021.

PAVmed Inc. 2014 Equity Plan - Stock Options

Stock options issued and outstanding under the PAVmed Inc. 2014 Equity Plan and including PAVmed stock options granted outside the plan is as follows:

	Number of Stock Options	Weighted Average Exercise Price	Remaining Contractual Term (Years)	Intrinsic Value[2]
Outstanding stock options at December 31, 2019	5,203,529	$ 2.58	8.1	$ 394
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
Outstanding stock options at December 31, 2020	6,798,529	$ 2.55	7.3	$ 2,558
Granted[1]	2,900,000	$ 4.90		
Exercised	(621,164)	$ 1.58		
Forfeited	(357,167)	$ 2.82		
Outstanding stock options at December 31, 2021	8,720,198	$ 3.39	6.8	$ 3,516
Vested and exercisable stock options at December 31, 2021	6,228,106	$ 2.88	5.7	$ 3,245

(1) Stock options granted under the PAVmed Inc. 2014 Equity Plan generally vest ratably over twelve quarters, with the vesting 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, 2021 and 2020 and the exercise price of the underlying PAVmed Inc. stock options, to the extent such quoted price is greater than the exercise price.

Note 14 — Stock-Based Compensation - continued

PAVmed Inc. 2014 Long-Term Incentive Equity Plan - continued

PAVmed Inc. 2014 Equity Plan - Restricted Stock Awards

On April 1, 2021, a total of 300,000 restricted stock awards were granted to employees under the PAVmed Inc. 2014 Equity Plan, with such restricted stock awards having a single vesting date of April 1, 2024. The (April 1, 2021) restricted stock awards fair value of approximately $1.5 million, which was measured using the grant date quoted closing price per share of PAVmed Inc. common stock, is recognized as stock-based compensation expense ratably on a straight-line basis over the vesting period, which is commensurate with the service period. The restricted stock awards are subject to forfeiture if the requisite service period is not completed.

On December 15, 2021, a total of 100,000 restricted stock awards were granted to consultants outside of the PAVmed Inc. 2014 Equity Plan, with such restricted stock awards having a single vesting date of December 15, 2023. The (December 15, 2021) restricted stock awards fair value of approximately $0.3 million, which was measured using the grant date quoted closing price per share of PAVmed Inc. common stock, is recognized as stock-based compensation expense ratably on a straight-line basis over the vesting period, which is commensurate with the service period. The restricted stock awards are subject to forfeiture if the requisite service period is not completed.

A total of 1,650,000 restricted stock awards were previously granted under the PAVmed Inc. 2014 Equity Plan, with such restricted stock awards having an aggregate fair value of approximately $2.7 million, which was measured using the respective grant date quoted closing price per share of PAVmed Inc. common stock, with the fair value recognized as stock-based compensation expense ratably on a straight-line basis over the vesting period, which is commensurate with the service period. The vesting of the previously granted restricted stock awards is as follows: 233,334 vested on March 15, 2020; 466,666 vesting on March 15, 2022; 450,000 vesting ratably on an annual basis over a three year period with the initial annual vesting date on May 1, 2021; and 500,000 restricted stock awards having a single vesting date of May 1, 2023. The restricted stock awards are subject to forfeiture if the requisite service period is not completed.

Subsequent to December 31, 2021, as of March 29, 2022, additional stock-based equity grants of 3.1 million stock options with a weighted average exercise price of $1.67 were granted under the PAVmed Inc 2014 Equity Plan.

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 5,644,000 shares of common stock of Lucid Diagnostics Inc. are reserved for issuance under the Lucid Diagnostics Inc. 2018 Equity Plan, with 2,752,615 shares available for grant as of December 31, 2021, with the share reservation not diminished by a total of 473,300 Lucid Diagnostics Inc. stock options and restricted stock awards granted outside the Lucid Diagnostics Inc. 2018 Equity Plan.

Note 14 — Stock-Based Compensation - continued

Lucid Diagnostics Inc. 2018 Equity Plan - Stock Options

Stock options issued and outstanding under the Lucid Diagnostics Inc. 2018 Equity Plan and including Lucid Diagnostics options granted outside the plan is as follows:

	Number of Stock Options		Weighted Average Exercise Price	Remaining Contractual Term (Years)
Outstanding stock options at December 31, 2019	1,403,945	$	0.61	9.0
Granted[(1)]	—	$	—	
Exercised	(4,703)	$	1.06	
Forfeited	—	$	—	
Outstanding stock options at December 31, 2020	1,399,242	$	0.61	8.0
Vested and exercisable stock options at December 31, 2020	1,085,288	$	0.58	7.9
Outstanding stock options at December 31, 2020	1,399,242	$	0.61	8.0
Granted[(1)]	20,000	$	9.08	
Exercised	—	$	—	
Forfeited	—	$	—	
Outstanding stock options at December 31, 2021	1,419,242	$	0.60	7.0
Vested and exercisable stock options at December 31, 2021	1,337,417	$	0.61	7.0

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

Lucid Diagnostics Inc. 2018 Equity Plan – Restricted Stock Awards

As of December 31, 2021, a total of1,897,795 restricted stock awards were granted under the Lucid Diagnostics Inc. 2018 Equity Plan, summarized as follows:

On March 1, 2021, a total of 1,467,440 restricted stock awards were granted under the Lucid Diagnostics Inc. 2018 Equity Plan to employees of PAVmed Inc., a member of the board of directors of Lucid Diagnostics Inc. (who is also a member of the board of directors of PAVmed Inc.), and to each of the three physician inventors of the intellectual property licensed under the CWRU License Agreement, with such restricted stock awards having a single vesting date of March 1, 2023, and an aggregate grant date fair value of approximately $18.9 million, measured as discussed below, with such aggregate estimated fair value recognized as stock-based compensation expense ratably on a straight-line basis over the vesting period, which is commensurate with the service period. The restricted stock awards are subject to forfeiture if the requisite service period is not completed.

In April 2021, a total of 91,715 restricted stock awards were granted under the Lucid Diagnostics Inc 2018 Equity Plan, inclusive of such restricted stock awards granted to an employee of PAVmed Inc. and a consultant, with such restricted stock awards having a single vesting date in April 2023, and an aggregate grant date fair value of approximately $1.2 million, measured as discussed below, with such aggregate estimated fair value recognized as stock-based compensation expense ratably on a straight-line basis over the vesting period, which is commensurate with the service period. The restricted stock awards are subject to forfeiture if the requisite service period is not completed. As of December 31, 2021, a total of 7,055 restricted stock awards have been forfeited.

In July 2021, a total of 84,660 restricted stock awards were granted under the Lucid Diagnostics Inc 2018 Equity Plan, inclusive of such restricted stock awards granted to member of the board of directors of Lucid Diagnostics Inc. with such restricted stock awards having a single vesting date in July 2023, and an aggregate grant date fair value of approximately $1.1 million, measured as discussed below, with such aggregate estimated fair value recognized as stock-based compensation expense ratably on a straight-line basis over the vesting period, which is commensurate with the service period. The restricted stock awards are subject to forfeiture if the requisite service period is not completed.

Note 14 — Stock-Based Compensation - continued

Lucid Diagnostics Inc. 2018 Equity Plan – Restricted Stock Awards - continued

In September 2021, 169,320 restricted stock awards were granted under the Lucid Diagnostics Inc 2018 Equity Plan to a member of the board of directors of Lucid Diagnostics Inc., with such restricted stock award vesting ratably over a two year period with vesting dates of each of September 15, 2022 and 2023, and an aggregate grant date fair value of approximately $2.3 million, measured as discussed below, with such aggregate estimated fair value recognized as stock-based compensation expense ratably on a straight-line basis over the vesting period, which is commensurate with the service period. The restricted stock awards are subject to forfeiture if the requisite service period is not completed.

On October 14, 2021, 84,660 restricted stock awards were granted under the Lucid Diagnostics Inc 2018 Equity Plan, to a member of the board of directors of Lucid Diagnostics Inc., with such restricted stock awards having a single vesting date of October 14, 2023, and an aggregate grant date fair value of approximately $1.0 million, measured as the grant date closing price of Lucid Diagnostics Inc common stock, with such aggregate estimated fair value recognized as stock-based compensation expense ratably on a straight-line basis over the vesting period, which is commensurate with the service period. The restricted stock awards are subject to forfeiture if the requisite service period is not completed.

On December 15, 2021, 50,000 restricted stock awards were granted outside of the Lucid Diagnostics Inc 2018 Equity Plan, with such restricted stock award having a single vesting date on December 15, 2023, and an aggregate grant date fair value of approximately $0.3 million, measured as the grant date closing price of Lucid Diagnostics Inc common stock, with such aggregate estimated fair value recognized as stock-based compensation expense ratably on a straight-line basis over the vesting period, which is commensurate with the service period. The restricted stock awards are subject to forfeiture if the requisite service period is not completed.

Subsequent to December 31, 2021, as of March 29, 2022, additional stock-based equity grants under the Lucid Diagnostics Inc. 2018 Equity Plan included each of1.8 million stock options with a weighted average exercise price of approximately $4.16 per share and the same vesting and contractual term as discussed above; and a total of 320,000 restricted stock awards with a weighted average grant date fair value of $4.52 per share of Lucid Diagnostics Inc. common stock, with single vesting date ofthree years from date of grant.

The price per share of Lucid Diagnostics Inc. common stock used in the computation of estimated fair value of stock options and restricted stock awards granted under the Lucid Diagnostics Inc. 2018 Equity Plan is as follows: (i) from October 14, 2021 to December 31, 2021 it is its quoted closing price per share on date of grant; and (ii) for the period January 1, 2021 to October 13, 2021, it was estimated using a probability-weighted average expected return methodology ("PWERM"), which involves the determination of equity value under various exit scenarios and an estimation of the return to the common stockholders under each scenario, wherein, the estimated fair value was based upon an analysis of future values, assuming various outcomes, based upon the probability-weighted present value of expected future investment returns, considering each of the possible future outcomes available to Lucid Diagnostics Inc.; and (iii) as of December 31, 2020, it was estimated using a discounted cash flow analysis applied to a multi-year forecast of its future cash flows.

The PWERM principally involved (i) the identification of scenarios and related probabilities; (ii) determine the equity value under each scenario; and (iii) determine the common stock shareholders' return in each scenario. The two scenarios identified were an initial public offering ("IPO") of Lucid Diagnostics Inc. common stock ("IPO

scenario"); and, to continue on as a private company ("stay private scenario"). With respect to the IPO scenario, the valuation of the Lucid Diagnostics Inc. common stock was computed using assumptions, including dates of the IPO, to calculate an estimated pre-money valuation; and, with respect to the stay private scenario, an income approach was used, wherein a risk-adjusted discount rate is applied to projected future cash flows. For the awards during 2021, a relative weighting ranged from 75%-97.5% for to the IPO scenario and the relative weighting ranged from 2.5%-25% for the stay private scenario.

Note 14 — Stock-Based Compensation - continued

Consolidated Stock-Based Compensation Expense

The consolidated stock-based compensation expense recognized by each of PAVmed Inc. and Lucid Diagnostics Inc. 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,	
	2021	2020
Sales and marketing expenses	$ 1,177	$ 278
General and administrative expenses	12,799	1,304
Research and development expenses	1,033	462
Total stock-based compensation expense	$ 15,009	$ 2,044

Stock-Based Compensation Expense Recognized by Lucid Diagnostics Inc.

As noted, the consolidated stock-based compensation expense presented above is inclusive of stock-based compensation expense recognized by Lucid Diagnostics Inc., inclusive of each of: stock options granted under the PAVmed Inc. 2014 Equity Plan to the three physician inventors of the intellectual property underlying the CWRU License Agreement ("Physician Inventors") (as discussed above in Note 5, *Related Party Transactions*); and stock options and restricted stock awards granted to employees of PAVmed Inc. and non-employee consultants under the Lucid Diagnostics Inc. 2018 Equity Plan.

The stock-based compensation expense recognized by Lucid Diagnostics Inc. 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,	
	2021	2020
Lucid Diagnostics Inc 2018 Equity Plan – sales and marketing expenses	$ 8	$ —
Lucid Diagnostics Inc 2018 Equity Plan – general and administrative expenses	9,073	—
Lucid Diagnostics Inc 2018 Equity Plan – research and development expenses	66	52
PAVmed Inc 2014 Equity Plan - sales and marketing expenses	202	—
PAVmed Inc 2014 Equity Plan - general and administrative expenses	38	—
PAVmed Inc 2014 Equity Plan - research and development expenses	212	13
Total stock-based compensation expense – recognized by Lucid Diagnostics Inc	$ 9,599	$ 65

The consolidated 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 (Years)
PAVmed Inc. 2014 Equity Plan		
Stock Options	$ 7,559	1.8
Restricted Stock Awards	$ 2,021	1.2
Lucid Diagnostics Inc. 2018 Equity Plan		
Stock Options	$ 100	0.6
Restricted Stock Awards	$ 16,000	1.3

Note 14 — Stock-Based Compensation - continued

Stock-based compensation expense recognized with respect to stock options granted under the PAVmed Inc. 2014 Equity Plan was based on a weighted average estimated fair value of such stock options of $3.46 per share and $1.27 per share during the years ended December 31, 2021 and 2020, respectively, calculated using the following weighted average Black-Scholes valuation model assumptions:

	Year Ended December 31,	
	2021	2020
Expected term of stock options (in years)	5.6	5.8
Expected stock price volatility	76.0%	73.0%
Risk free interest rate	1.0%	0.5%
Expected dividend yield	—%	—%

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 $5.13 per share during the year ended December 31, 2021. There were no stock-based awards granted under the Lucid Diagnostics Inc. 2018 Equity Plan during the year ended December 31, 2020. The stock-based compensation was calculated using the following weighted average Black-Scholes valuation model assumptions:

	Year Ended December 31,	
	2021	2020
Expected term of stock options (in years)	5.7	0.0
Expected stock price volatility	70.0%	—%
Risk free interest rate	1.3%	—%

Expected dividend yield	—%	—%

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. A total of 203,480 shares and 154,266 shares of common stock of the Company were purchased for proceeds of approximately $304 and $126, on the ESPP purchase dates of March 31, 2021 and 2020, respectively. A total of 31,112 shares and 152,289 shares of common stock of the Company were purchased for proceeds of approximately $131 and $231, on the ESPP purchase dates of September 30, 2021 and 2020, respectively. The PAVmed Inc. ESPP has a total reservation of 1,250,000 shares of common stock of PAVmed Inc. of which 626,081 shares are available-for-issue remaining as of December 31, 2021.

Lucid Diagnostics, Inc Employee Stock Purchase Plan ("ESPP")

The Lucid Diagnostics Inc. Employee Stock Purchase Plan ("Lucid Diagnostics Inc. ESPP"), adopted by the Company's board of directors effective November 9. 2021, provides eligible employees the opportunity to purchase shares of Lucid Diagnostics 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 Lucid Diagnostics Inc. common stock at the beginning or end of each six month share purchase period. The Lucid Diagnostics Inc. ESPP share purchase dates are March 31 and September 30. The initial ESPP purchase date will be September 30, 2022.

The Lucid Diagnostics Inc. ESPP has a total reservation of 500,000 shares of common stock of PAVmed Inc. of which 500,000 shares are available-for-issue remaining as of December 31, 2021.

Note 15 — Preferred Stock

The Company is authorized to issue 20 million shares of its Series B Convertible 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, 2021 and 2020, there were 1,113,919 and 1,228,075 shares of Series B Convertible Preferred Stock (classified in permanent equity) issued and outstanding, respectively.

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, 2021, the Company's board-of-directors declared an aggregate of approximately $288 of Series B Convertible Preferred Stock dividends, earned as of December 31, 2020, March 31, 2021, June 30, 2021, and September 30, 2021, which have been settled by the issue of an additional aggregate 96,292 shares of Series B Convertible Preferred Stock.

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 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.

Subsequent to December 31, 2021, in January 2022, the Company's board-of-directors declared a Series B Convertible Preferred Stock dividend earned as of December 31, 2021 and payable as of January 1, 2022, of approximately $67, which will be settled by the issue of an additional 22,291 shares of Series B Convertible Preferred Stock (with such dividend not recognized as a dividend payable as of December 31, 2021, as the Company's board of directors had not declared such dividends payable as of such date).

In the year ended December 31, 2021 and 2020, at the election of the holders, a total of 210,448 and 25,000 shares of Series B Convertible Preferred Stock, respectively, were converted into the same number of shares of common stock of the Company.

Note 16 — Common Stock and Common Stock Purchase Warrants

Common Stock

The Company is authorized to issue up to 150 million shares of its common stock, par value of $0.001 per share. There were 86,367,845 and 63,819,935 shares of common stock issued and outstanding as of December 31, 2021 and December 31, 2020, respectively.

Year Ended December 31, 2021

- On January 5, 2021, a total of 6,000,000 shares of common stock of the Company were issued for gross proceeds of approximately $13,434, before a placement agent fee and expenses of approximately $951, and offering costs incurred by the Company of approximately $71. 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).

- On February 23, 2021, a total of 9,782,609 shares of common stock of the Company were issued for proceeds of approximately $41,566, before offering costs incurred by the Company of approximately $290. 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).

- 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 13, *Debt.*

- During the year ended December 31, 2021, 210,448 shares of common stock of the Company were issued upon conversion of the same number of shares of Series B Convertible Preferred Stock. See Note 15, *Preferred Stock*, for a discussion of the Series B Convertible Preferred Stock.

- During the year ended December 31, 2021, an aggregate of 4,881,429 shares of common stock of the Company were issued upon exercise of common stock purchase warrants, including 4,877,484 with respect to Series Z Warrants; and 3,945 with respect to Series W Warrants.

- During the year ended December 31, 2021, 621,164 shares of common stock of the Company were issued upon exercise of stock options for cash of approximately $980. See Note 14, *Stock-Based Compensation*, for a discussion of the PAVmed Inc. 2014 Equity Plan.

- During the year ended, the PAVmed Inc. Employee Stock Purchase Plan purchased 234,592 shares of common stock of the Company. See Note 14, *Stock-Based Compensation*, for a discussion of the PAVmed Inc. Employee Stock Purchase Plan.

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 12, *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 14, *Stock-Based Compensation.*

Note 16 — Common Stock and Common Stock Purchase Warrants- continued

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				
	December 31, 2021	Weighted Average Exercise Price / Share	December 31, 2020	Weighted Average Exercise Price / Share	Expiration Date
Series Z Warrants	11,937,455	$ 1.60	16,814,939	$ 1.60	April 2024
UPO - Series Z Warrants	—	$ —	53,000	$ 1.60	January 2021
Series W Warrants	377,873	$ 5.00	381,818	$ 5.00	January 2022
Total	12,315,328	$ 1.70	17,249,757	$ 1.68	

During the year ended December 31, 2021, a total of4,877,484 Series Z Warrants were exercised for cash at $1.60 per share, resulting in the issue of the same number of shares of common stock of the Company.

During the year ended December 31, 2021, a total of3,945 Series W Warrants were exercised for cash at $5.00 per share, resulting in the issue of the same number of shares of common stock of the Company. Subsequent to December 31, 2021, the 377,873 Series W Warrants issued and outstanding as of December 31, 2021, expired unexercised as of January 29, 2022.

The Unit Purchase Options (UPO) expired unexercised as of January 29, 2021.

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.

Note 17 — Noncontrolling Interest

The noncontrolling interest ("NCI") included as a component of consolidated total stockholders' equity is summarized for the periods indicated as follows:

	Year Ended December 31,	
	2021	2020
NCI – equity (deficit) – beginning of period	$ (2,369)	$ (814)
Investment in Veris Health Inc.	6	—
Net loss attributable to NCI – Lucid Diagnostics Inc.	(5,280)	(1,503)
Net loss attributable to NCI – Solys Diagnostics Inc.	(34)	(109)
Net loss attributable to NCI – Veris Health Inc.	(465)	—
Impact of subsidiary equity transactions	16,760	—
Lucid Diagnostics Inc. 2018 Equity Plan stock option exercise	—	5
Stock-based compensation expense - Lucid Diagnostics Inc. 2018 Equity Plan	9,134	52
NCI – equity (deficit) – end of period	$ 17,752	$ (2,369)

The consolidated NCI presented above is with respect to the Company's consolidated majority-owned subsidiaries, inclusive of: Lucid Diagnostics Inc. and Solys Diagnostics Inc., as a component of consolidated total stockholders' equity as of December 31, 2021 and December 31, 2020, and the recognition of a net loss attributable to the NCI in the consolidated statement of operations for the years ended December 31, 2021 and 2020; and Veris Health Inc. as a component of consolidated total stockholders' equity as of December 31, 2021, and the recognition of a net loss attributable to the NCI in the consolidated statement of operations for the period May 28, 2021 (inception date) to December 31, 2021.

Lucid Diagnostics Inc.

As of December 31, 2021 there were34,917,907 shares of common stock of Lucid Diagnostics Inc. issued and outstanding, of which, PAVmed Inc. holds27,927,190 shares, representing a majority ownership equity interest and a controlling financial interest in Lucid Diagnostics Inc., and accordingly, Lucid Diagnostics Inc. is a consolidated majority-owned subsidiary of PAVmed Inc.

Effective October 6, 2021, the Lucid Diagnostics Inc. board of directors declared a 1.411-to-1.0 common stock-split. The number of shares of common stock of Lucid Diagnostics Inc. and the stock options and restricted stock awards granted under the Lucid Diagnostics Inc. 2018 Equity Plan, and the respective exercise and /or conversion price per share, for all periods presented, as applicable, have been adjusted for such common stock-split.

On October 13, 2021, Lucid Diagnostics Inc. issued15,803,200 shares of its common stock to PAVmed Inc. upon the election by PAVmed Inc. to convert the $22.4 million face value principal under the terms of a Senior Unsecured Promissory Note, dated June 1, 2021. The Senior Unsecured Promissory Note was issued by Lucid Diagnostics Inc. to PAVmed Inc. with a face value principal of $ 22,400,000, an annual interest rate of7.875%, and a maturity date of May 18, 2028. The Senior Unsecured Promissory Note replaced the $22.4 million aggregate outstanding and payable balance of the intercompany Due To: PAVmed Inc. as of June 1, 2021. The Senior Unsecured Promissory Note provided for the partial or full repayment of the face value principal and accrued but unpaid interest thereon by the issue of shares of Lucid Diagnostics Inc. common stock, at the election of PAVmed Inc., at a conversion price of $ 1.42 per share of Lucid Diagnostics Inc. common stock (with such number of such shares and the conversion price adjusted for the Lucid Diagnostics Inc. 1.411-to-1.0 common stock split effective October 6, 2021 as discussed above).

On October 14, 2021, Lucid Diagnostics Inc. completed an initial public offering ("IPO") of its common stock under an effective registration statement on Form S-1 (SEC File No. 333-259721), wherein a total of 5.0 million shares of common stock were issued, inclusive of571,428 issued to PAVmed Inc., at an IPO offering price of $14.00 per share, resulting gross proceeds to Lucid Diagnostics Inc. of $70.0 million, before underwriting fees of $4.9 million, and approximately $0.7 million of offering costs incurred by Lucid Diagnostics Inc.

Note 17 — Noncontrolling Interest - continued

Veris Health Inc.

As of December 31, 2021, there were8,000,000 shares of common stock of Veris Health Inc. issued and outstanding, of which PAVmed Inc. holds an 80.44% majority-interest ownership and has a controlling financial interest, with the remaining 19.56% minority-interest ownership held by an unrelated third-party. Accordingly, Veris Health 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, 2021 along with the recognition of a net loss attributable to the NCI in the consolidated statement of operations for the period of May 28, 2021 to December 31, 2021, upon its formation and contemporaneous acquisition of Oncodisc Inc., as such the acquisition is discussed in Note 6, *Acquisitions, subsection: Oncodisc Inc.*

Solys Diagnostics Inc.

As of each of December 31, 2021 and December 31, 2020, there were9,189,190 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 remaining9.6765% 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, 2021 and December 31, 2020, along with the recognition of a net loss attributable to the NCI in the consolidated statement of operations for the years ended December 31, 2021 and 2020.

Note 18 — Income Taxes

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

	Year Ended December 31,	
	2021	2020
Current		
Federal, State and Local	$ —	$ —
Deferred		
Federal	(9,528)	(4,571)
State and Local	(9,409)	(4,147)

	(18,937)	(8,718)
Less: Valuation allowance reserve	18,937	8,718
	$ —	$ —

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,	
	2021	2020
U.S. federal statutory rate	21.0%	21.0%
U.S. state and local income taxes, net of federal benefit	13.2%	9.9%
Permanent differences	(0.6)%	(5.8)%
Other	0.1%	(0.8)%
Valuation allowance	(33.7)%	(24.3)%
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,	
	2021	2020
Deferred Tax Assets		
Net operating loss	$ 35,989	$ 21,836
Non-deductible interest expense	—	517
Debt issue costs	—	205
Stock-based compensation expense	7,091	1,901
Patent licenses	—	14
Research and development tax credit carryforwards	428	396
Accrued expenses	897	552
Section 195 deferred start-up costs	16	24
Deferred tax assets	$ 44,421	$ 25,445
Deferred Tax Liabilities		
Depreciation	(22)	(19)
Patent licenses	(36)	—
Deferred Tax Liabilities	$ (58)	$ (19)
Deferred tax assets, net of deferred tax liabilities	44,363	25,426
Less: valuation allowance	(44,363)	(25,426)
Deferred tax assets, net after valuation allowance	$ —	$ —

Note 18 — Income Taxes - continued

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.

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, 2021 and 2020. As of December 31, 2021 and 2020, the deferred tax asset valuation allowance increased by $18,937 and $8,718, respectively.

The Company has total estimated federal net operating loss ("NOL") carryforward of approximately $104.1 million and $63.0 million as of December 31, 2021 and 2020, respectively, which is available to reduce future taxable income, of which approximately $13.8 million have statutory expiration dates commencing in 2036, and approximately $90.3 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 $103.9 million have statutory expiration dates commencing in 2036. The Company has total estimated research and development ("R&D") tax credit carryforward of approximately $0.4 million as of December 31, 2021 which are available to reduce future tax expense and have statutory expiration dates commencing in 2036.

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. The Company evaluated the impact of these CARES Act provisions and determined they did not 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 19 — Net Loss Per Share

The respective "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 periods indicated - is as follows:

	Year Ended December 31,	
	2021	2020
Numerator		
Net loss - before noncontrolling interest	$ (56,126)	$ (35,888)
Net loss attributable to noncontrolling interest	5,779	1,612
Net loss - as reported, attributable to PAVmed Inc.	$ (50,347)	$ (34,276)
Series B Convertible Preferred Stock dividends – earned[(1)]	$ (283)	$ (287)
Net loss attributable to PAVmed Inc. common stockholders	$ (50,630)	$ (34,563)
Denominator		
Weighted average common shares outstanding, basic and diluted[(2)]	77,515,767	47,432,115
Loss per share		
Basic and diluted		
Net loss - as reported, attributable to PAVmed Inc.	$ (0.65)	$ (0.72)
Net loss attributable to PAVmed Inc. common stockholders	$ (0.65)	$ (0.73)

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:

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. 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.

Basic weighted-average number of shares of common stock outstanding for the years ended December 31, 2021 and 2020 include the shares of the Company issued and outstanding during such periods, each on a weighted average basis. The basic weighted average number of shares common stock 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. The common stock equivalents excluded from the computation of diluted weighted average shares outstanding are as follows:

	Year Ended December 31,	
	2021	2020
PAVmed Inc. 2014 Equity Plan stock options and restricted stock awards	10,386,864	8,215,195
Unit purchase options - as to shares of common stock	—	53,000
Unit purchase options - as to shares underlying Series Z Warrants	—	53,000
Series Z Warrants	11,937,455	16,814,939
Series W Warrants	377,873	381,818
Series B Convertible Preferred Stock	1,113,919	1,228,075
Total	23,816,111	26,746,027

Note 20 - Subsequent Events

PAVmed Inc - Private Placement - Securities Purchase Agreement

Subsequent to December 31, 2021, on March 31, 2022, we entered into the March 2022 SPA with an accredited institutional investor , for the sale of up to $0,000,000 in initial principal amount of March 2022 Notes, in a registered direct offering (which we refer to as the Offering), for a purchase price equal to $1,000 for each $1,100 in principal amount of March 2022 Notes

Pursuant to the SPA we executed the agreements for an initial closing for the sale of $27.5 million in principal amount of March 2022 Notes, of which the Investor funded and the Company received cash proceeds of $24.9 million on April 5, 2022, after deduction of lender fees. Subject to certain conditions being met or waived, from time to time after such time that stockholder approval for an increase in our authorized shares from 150 million to 250 million is obtained, but before March 31, 2024, one or more additional closings for up to the remaining principal amount of March 2022 Notes may occur, upon five trading days' notice by us to the investor. The aggregate principal amount of March 2022 Notes that may be offered in the additional closings may not be more than $22.5 million. The investor's obligation to purchase the notes at each additional closing is subject to certain conditions set forth in the March 2022 SPA (including minimum price and volume thresholds, maximum ratio of debt to market capitalization, and minimum market capitalization), which may be waived by the Required Holders (as defined in the March 2022 SPA). Under the March 2022 SPA, the investor will be required to purchase March 2022 Notes in the additional closings if such conditions are met or waived. In addition, from and after March 31, 2023, the investor may by written notice to us elect to require us to issue up to $22.5 million in initial principal amount of March 2022 Notes, so long as in doing so it would not cause the ratio of (a) the outstanding principal amount of the March 2022 Notes (including the additional March 2022 Notes), accrued and unpaid interest thereon and accrued and unpaid late charges to (b) our average market capitalization over the prior ten trading days, to exceed 25%. If we fail to complete the sale of the additional Notes contemplated by any such written notice, or if the investor is unable to deliver any such notice prior to March 31, 2024 as a result of the limitation described in the preceding sentence, then we will be obligated to pay a break-up fee to the investor at such time in an aggregate amount equal to $1.35 million.

The March 2022 Notes have a voluntary fixed conversion price of $5.00 per share, a stated interest rate of 7.875% per annum, and a maturity of 24 months (subject to extension in certain circumstances). The March 2022 Notes will be secured by all our existing and future assets (including those of our significant subsidiaries, other than Lucid and its subsidiaries), but including only 9.99% of Lucid's outstanding common stock held by us, pursuant to a security agreement by and between the Company and the Investor.

We will be subject to certain customary affirmative and negative covenants regarding the rank of the March 2022 Notes, the incurrence of indebtedness, the existence of liens, the repayment of indebtedness and the making of investments, the payment of cash in respect of dividends, distributions or redemptions, the transfer of assets, the maturity of other indebtedness, and transactions with affiliates, among other customary matters. We also will be subject to financial covenants requiring that (i) the amount of our available cash equal or exceed $8.0 million at all times, (ii) the ratio of (a) the outstanding principal amount of the March 2022 Notes, accrued and unpaid interest thereon and accrued and unpaid late charges to (b) our average market capitalization over the prior ten trading days, not exceed 30%, and (iii) that our market capitalization shall at no time be less

than $75 million. The March 2022 Notes include certain customary events of default.

Note 20 - Subsequent Events - continued

Lucid Diagnostics Inc - Committed Equity Facility

Subsequent to December 31, 2021, on March 28, 2022, Lucid Diagnostics, Inc. entered into a committed equity facility with an affiliate of Cantor Fitzgerald ("Cantor"). Under the terms of the committed equity facility, Cantor has committed to purchase up to $50 million of Lucid Diagnostics Inc. common stock from time to time at the request of Lucid Diagnostics Inc. While there are distinct differences, the facility is structured similarly to a traditional at-the-market equity facility, insofar as it allows Lucid Diagnostics Inc. to raise primary equity capital on a periodic basis at prices based on the existing market price.

In connection with the execution of the agreement for the committed equity facility, Lucid Diagnostics Inc. agreed to pay Cantor $1.0 million as consideration for its irrevocable commitment to purchase the shares upon the terms and subject to the satisfaction of the conditions set forth in such agreement. In addition, pursuant to the agreement, e agreed to reimburse Cantor for certain of its expenses. Lucid Diagnostics Inc. also entered into a registration rights agreement with Cantor. Lucid Diagnostics Inc. has the right to terminate the agreement at any time after initial satisfaction of the conditions to Cantor's obligation to purchase shares under the facility, at no cost or penalty, upon three trading days' prior written notice.

Asset Purchase Agreement - ResearchDx Inc.

Subsequent to December 31, 2021, on February 25, 2022, Lucid Diagnostics, Inc., through its wholly-owned subsidiary LucidDx Labs, Inc., entered into an asset purchase agreement ("RDx APA") with ResearchDx, Inc. ("RDx"), an unrelated third-party. Under the RDx APA, LucidDx Labs Inc. acquired certain licenses and other related assets necessary to operate a CLIA-certified, CAP-accredited commercial clinical laboratory. The RDx APA acquired assets, along with other LucidDx Labs Inc. purchased and leased property and equipment, are being used to commence laboratory operations to perform the EsoGuard® Esophageal DNA assay, inclusive of DNA extraction, next generation sequencing ("NGS") and specimen storage. Prior to consummation of the RDx APA, RDx provided such laboratory services at its owned CLIA-certified, CAP-accredited laboratory. Under the RDx APA, LucidDx Labs Inc. will pay RDx an aggregate purchase price of up to $6.2 million for the acquired assets. Concurrent with the RDx APA, LucidDx Labs Inc. and RDx also entered into a management services agreement ("RDx MSA"), with a term of three years, and a total of approximately $1.8 million of quarterly payments.

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

As of December 31, 2021, PAVmed Inc. ("PAVmed," the "Company" or "we," "us" or "our") had two 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) Series Z warrants to purchase our common stock ("Series Z Warrants"); and (iii) Series W warrants to purchase our common stock ("Series W Warrants") (with the Series W Warrants expiring unexercised subsequent to December 31, 2021, as of January 29, 2022). Each of the Company's securities registered under Section 12 of the Exchange Act are listed on The Nasdaq Stock Market LLC (through their respective expiration date with respect to the common stock purchase warrants).

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 29, 2022, there were 1,136,210 shares of Series B Convertible Preferred Stock issued and outstanding.

Common Stock

As of December 31, 2021, there were 86,367,845 shares of our common stock issued and outstanding, and, as of such date, we also had issued and outstanding:

(i) Stock Options to purchase 8,720,198 shares of our common stock at a weighted average exercise price of $3.39 per share, with such total number inclusive of both stock options granted under the PAVmed Inc. 2014 Long-Term Incentive Equity Plan ("PAVmed Inc. 2014 Equity Plan") and stock options granted outside such plan; and 1,160,573 shares of our common stock reserved for issuance, but not subject to outstanding awards under the PAVmed Inc. 2014 Equity Plan; and 626,081 shares of our common stock reserved for issuance under the PAVmed Inc. Employee Stock Purchase Plan ("PAVmed Inc. ESPP");
(ii) Series Z Warrants to purchase 11,937,455 shares of our common stock at an exercise price of $1.60 per share; and Series W Warrants to purchase 377,873 shares of our common stock at an exercise price of $5.00 per share, with all such Series W Warrants expiring unexercised subsequent to December 31, 2021, as of January 29, 2022; and
(iii) Series B Convertible Preferred Stock of 1,113,919 shares, convertible into the same 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 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 11,937,455 Series Z Warrants outstanding, as of December 31, 2021. Each Series Z Warrant entitles the registered holder to purchase one share of our common stock at an exercise 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 Subsidiary of PAVmed Inc.*	Delaware (Incorporated May 8, 2018)
LucidDx Labs Inc. (87-41661458) - *Wholly-Owned Subsidiary of Lucid Diagnostics Inc.*	Delaware (Incorporated November 10, 2021)
Veris Health Inc. (87-0983820) - *Majority-Owned Subsidiary of PAVmed Inc.*	Delaware (Incorporated April 7, 2021)
Oncodisc Inc (82-4885133) *Wholly-Owned Subsidiary of Veris Health Inc.*	Delaware (Incorporated February 22, 2018)
PAVmed Subsidiary Corp Inc. (81-1637646) *Wholly-owned Subsidiary of PAVmed Inc.*	Delaware (Incorporated January 23, 2015)
CapNostics LLC (84-4876240) - *Wholly-owned Subsidiary of PAVmed Subsidiary Corp Inc.*	North Carolina (Established January 20, 2020)
Solys Diagnostics Inc. (84-3484870) - *Majority-Owned Subsidiary of PAVmed Inc.*	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 Forms S-1 [File No. 333-222581, File No. 333-222234, File No. 333-221406, File No. 333-216963, File No. 333-214288], Forms S-3 [File No. 333-261814, File No. 333-235335, File No. 333-229372, File No. 333-227718, File No. 333-221406] and Forms S-8 [File No. 333-258459, File No. 333-258458, File No. 333-256343, File No. 333-248529, File No. 333-231674] of our report dated April 5, 2022, with respect to our audits of the consolidated financial statements of PAVmed Inc. as of December 31, 2021 and 2020, and for each of the two years in the period ended December 31, 2021, which report is included in this Annual Report on Form 10-K of PAVmed Inc. for the year ended December 31, 2021.

/s/ Marcum llp

Marcum llp
New York, NY
April 5, 2022

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. and Subsidiaries -

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 that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 5, 2022

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. and Subsidiaries -

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 that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 5, 2022

By: */s/ Dennis M. McGrath*
Dennis M. McGrath
President and 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. and Subsidiaries (the "Company") for the year ended December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lishan Aklog, M.D., Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

Date: April 5, 2022

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. and Subsidiaries (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Dennis M. McGrath, President and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

Date: April 5, 2022

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