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, 2023

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	**47-1214177**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
360 Madison Avenue 25th Floor New York, NY	**10017**
(Address of Principal Executive Offices)	(Zip Code)

(917) 813-1828
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to 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 1/15th of 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 that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically 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 that 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023, 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 $38.6 million, based on 6,312,137 shares of common stock held by non-affiliates and a last reported sales price per share of the registrant's common stock of $6.12 on such date.

As of March 21, 2024, there were 9,172,331 shares of the registrant's Common Stock, par value $0.001 per share, issued and outstanding (with such number of shares inclusive of shares of common stock underlying unvested restricted stock awards granted under the PAVmed Inc. 2014 Long-Term Incentive Equity Plan as of such date).

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2024 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, 2023.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Form 10-K"), including the discussion and analysis of our consolidated financial condition and results of operations set forth under Item 7 of this Form 10-K, contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in 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 those expressed or implied 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 the Form 10-K under the heading "Risk Factors."

Important factors that may affect our actual results include:

- our limited operating history;
- our financial performance, including our ability to generate revenue;
- our ability to obtain regulatory approval for the commercialization of our products;
- the risk that the FDA will cease to exercise enforcement discretion with respect to LDTs, like EsoGuard;
- the 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;
- our regulatory and operational risks;
- cybersecurity risks;
- risks related to the COVID-19 pandemic and other health-related emergencies; and
- 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 results, plans, and/or objectives disclosed in our forward-looking statements, and the intended or expected developments and/or other events disclosed in our forward-looking statements may not actually occur, and accordingly 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 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 structured to be a multi-product life sciences company organized to advance a pipeline of innovative healthcare technologies. Led by a team of highly skilled personnel with a track record of bringing innovative products to market, PAVmed is focused on innovating, developing, acquiring, and commercializing novel products that target unmet needs with large addressable market opportunities. Leveraging our corporate structure—a parent company that will establish distinct subsidiaries for each financed asset—we have the flexibility to raise capital at the PAVmed level to fund product development, or to structure financing directly into each subsidiary in a manner tailored to the applicable product, the latter of which is our current strategy given prevailing market conditions.

Our current focus is multi-fold. We continue to pursue commercial expansion and execution of EsoGuard, which is the flagship product of our majority-owned subsidiary Lucid Diagnostics Inc. (Nasdaq: LUCD) ("Lucid" or "Lucid Diagnostics"). In addition, through a separate majority-owned subsidiary, Veris Health Inc. ("Veris" or "Veris Health"), we are focused on entering into strategic partnership opportunities with leading academic oncology systems to expand access to the Veris Platform. In terms of other existing products and technologies, we have created an incubator-type platform where we are looking to obtain financing on a product-by-product basis as necessary to advance each asset to a meaningful inflection point along its path to commercialization. Finally, as resources permit, we will continue to explore external innovations that fulfill our project selection criteria without limiting ourselves to any target sector, specialty or condition.

EsoGuard and EsoCheck

We believe that the flagship product of our majority-owned subsidiary Lucid, the EsoGuard Esophageal DNA Test, performed on samples collected with the EsoCheck Esophageal Cell Collection Device, constitutes the first and only commercially available diagnostic test capable of serving as a widespread testing tool with the goal of preventing esophageal adenocarcinoma ("EAC") deaths, through early detection of esophageal precancer in at-risk gastroesophageal reflux disease ("GERD," also commonly known as chronic heartburn, acid reflux or simply reflux) 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). EsoGuard is commercially available in the U.S. as a Laboratory Developed Test (LDT) performed at our CLIA-certified laboratory. Cell samples, including those collected with EsoCheck, as discussed below, are sent to our laboratory 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 procedure. 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.

EsoGuard and EsoCheck are based on patented technology licensed by Lucid from Case Western Reserve University ("CWRU"). EsoGuard and EsoCheck have been developed to provide accurate, non-invasive, patient-friendly testing for the early detection of EAC and Barrett's Esophagus ("BE"), including dysplastic BE and related pre-cursors to EAC in patients with chronic GERD.

Market Opportunity

In 2023, 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.

As discussed below under the heading "Clinical Guidelines for At-Risk Population", in July 2022, the American Gastroenterology Association ("AGA") significantly expanded the target population for esophageal precancer screening, recommending screening in at-risk patients without symptoms of GERD. Based on this revision, we believe the cohort recommended for screening consists of an estimated 30 million U.S. individuals with at least 3 established risk factors for BE. Accordingly, we believe EsoGuard's total addressable U.S. market opportunity approximates $60 billion based on an effective Medicare payment of $1,938 and the estimated 30 million U.S. patients recommended for screening by clinical practice guidelines. (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. As discussed below under the heading "Reimbursement and Market Access", in October 2020, CMS granted EsoGuard final Medicare payment determination of $1,938.01, effective January 1, 2021.)

Unfortunately, for a variety of reasons, less than 10% of at-risk 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 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). Until recently, the only missing element for such an early detection program is a widespread screening tool that can detect BE prior to EAC.

We believe EsoGuard, used with EsoCheck, constitutes that missing element—the first and only commercially available diagnostic test capable of serving as a widespread testing tool with the goal of preventing EAC deaths through early detection of esophageal precancer and cancer in patients with 3 or more risk factors.

Clinical Guidelines for At-Risk Population

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. In its Recommendation 5, the ACG suggests a single screening endoscopy in patients with chronic GERD symptoms and 3 or more additional risk factors for BE, including male sex, age greater than 50 years, White race, tobacco smoking, obesity, and family history of BE or EAC in a first-degree relative.

An ACG clinical guideline entitled "*Diagnosis and Management of Barrett's Esophagus: An Updated ACG Guideline*," the first such update since 2016, was published online in April 2022 in the American Journal of Gastroenterology. The clinical guideline reiterates the ACG's long-standing recommendation for esophageal precancer screening in at-risk patients with GERD. For the first time, however, the clinical guideline also endorses nonendoscopic biomarker screening as an acceptable alternative to costly and invasive endoscopy stating that "a swallowable nonendoscopic capsule device combined with a biomarker is an acceptable alternative to endoscopy for BE." The clinical guideline specifically mentions EsoCheck, along with Lucid's EsophaCap® device, as such swallowable, nonendoscopic esophageal cell collection devices, as well as methylated DNA biomarkers such as EsoGuard. The summary of evidence for this recommendation includes a reference to the seminal NIH-funded, multicenter, case-control study published in 2018 in *Science Translational Medicine*, which demonstrated that EsoGuard is highly accurate at detecting esophageal precancer and cancer, including on samples collected with EsoCheck.

In July 2022, the American Gastroenterology Association ("AGA") published in their "Clinical Practice Update on New Technology and Innovation for Surveillance and Screening in Barrett's Esophagus" updated clinical guidance that mirrors the same furnished by the ACG as described above, endorsing the use of non-endoscopic cell collection tools to screen for BE like our EsoCheck Cell Collection Device, which is cited in the update, as an acceptable alternative to endoscopy to directly address the need for noninvasive screening tools that are easy to administer, patient friendly, and cost-effective for the detection of BE. The clinical practice update by the AGA also significantly expands the target population for esophageal precancer screening, including for EsoGuard and EsoCheck, by recommending, for the first time, screening in at-risk patients without symptoms of GERD. The AGA does so by adding a history of chronic GERD as merely an additional, seventh risk factor to the six risk factors for BE and EAC that have traditionally identified at-risk symptomatic patients recommended for screening.

Commercialization

Our EsoGuard commercialization efforts span multiple channels including targeting primary care and 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.

To assure sufficient testing capacity and geographic coverage, we have undertaken multiple ways for patients have access to our test. Initially, we built a limited network of our own physical Lucid Test Centers, staffed by Lucid-employed clinical personnel, where patients can undergo the EsoCheck procedure and have the sample sent for EsoGuard testing at Lucid's CLIA-certified laboratory. Our current test center network currently includes locations in metropolitan areas in Arizona, California, Colorado, Florida, Idaho, Illinois, Nevada, Ohio, Oregon, Texas and Utah.

In addition to our own test center locations, we have broadened patient access to our test by establishing a satellite test center program, whereby we are making our personnel available to perform cell collection services inside physician offices or in certain geographies, closely nearby physician offices (in Florida, for the time being) by way of our Lucid Mobile Testing Unit.

Also, in January 2023, we completed our first #CheckYourFoodTube Precancer Testing Event, with the San Antonio Fire Department (the "SAFD") during Firefighter Cancer Awareness Month as designated by the International Association of Fire Fighters (IAFF). A total of 391 members who were deemed to be at-risk for esophageal precancer, underwent a brief, on-site, noninvasive cell collection procedure, performed by our clinical personnel using EsoCheck. Since then, additional testing events have been hosted with the SAFD, and many similar events have been held with fire departments throughout the country. These events are ongoing and are an extension of Lucid's satellite test center program, which brings our precancer testing directly to patients—at their physician's office and now at testing day events.

In March 2023, we launched a Direct Contracting Strategic Initiative ("DCSI") to engage directly with large Administrative Services Only ("ASO") self-insured employers, unions and other entities, seeking to replicate the successes of other cancer screening diagnostic companies that have deployed similar strategies. In August 2023, we contracted with the Ancira Automotive Group as a result of this initiative, providing access to esophageal precancer testing for its employees at all 12 San Antonio locations.

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.

Reimbursement and Market Access

As noted above, 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.

A final Local Coverage Determination ("LCD") L39256, entitled "*Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia*" became effective in May 2023 on the Center for Medicare and Medicaid Services ("CMS") website by MAC Palmetto GBA. (A substantially identical LCD was published by Noridian Healthcare Solutions, the MAC whose geographic jurisdiction covers our CLIA laboratory in Lake Forest, CA.) The LCD outlines criteria for future coverage that MolDX expects upper gastrointestinal precancer and cancer molecular diagnostic tests to meet. These criteria include active GERD with at least two risk factors, as well as evidence of analytic validity, clinical validity, and clinical utility. Although the LCD indicated that it found that no currently existing test has fulfilled all these criteria, it indicated that it will "monitor the evidence and may revise this determination based on the pertinent literature and society recommendations." We expect to submit EsoGuard for Technical Assessment under this foundational LCD later this year.

In parallel with preparing to submit EsoGuard for Technical Assessment with MolDX, Lucid is aggressively pursuing EsoGuard commercial insurer payment and coverage. Although the claim adjudication cycle can be prolonged during the early commercialization of a new test, Lucid has received and continues to receive out-of-network commercial insurance payments for the EsoGuard test, which accounts for the vast majority of our revenue to date.

Additionally, the legislatures in a number of states have passed laws mandating coverage of comprehensive biomarker testing over the past several years. We believe that EsoGuard falls within the definition of a biomarker test and thus we are reviewing how to leverage legislation in those states to expand access to EsoGuard.

Clinical Utility and Clinical Trials

Demonstrating EsoGuard's clinical utility, which requires providing evidence that the test has a meaningful impact on clinical practice, is very important for a variety of purposes, including, importantly, for Medicare and private payor payment and coverage. It has been established that one of the most important factors to private payors in deciding whether to grant payment and coverage will be demonstration that the EsoGuard test, when ordered by physicians, provides information that can be used to identify or exclude patients who would benefit from additional management and/or treatment. Clinical utility studies are also important for general EsoGuard commercialization by facilitating physician understanding of test indications and potential benefit to the patients.

Lucid continues to expand the EsoGuard and EsoCheck evidence portfolio with additional clinical utility, clinical validity, and analytical validity data from a range of ongoing studies and those that have recently completed or will be completed in the upcoming year. These efforts include planned publication of the results from the previously discussed "Multi-center, Single-arm EsoGuard clinical validation study" ("BE-1") which will also be presented at Digestive Disease Week (DDW) 2024; this third clinical validation study evaluated EsoGuard performance in the intended-use population. Publication of real-world experience of EsoCheck as a nonendoscopic cell collection device is also planned (previously presented as a poster at DDW 2023), in addition to results from EsoGuard analytical validation studies performed by LucidDx Labs, and a summary of real-world outcomes from several hundred patients who tested positive with EsoGuard and underwent confirmatory endoscopic evaluation. These four manuscripts will be submitted for peer review in the first half of 2024.

The Lucid-sponsored multi-center, prospective, observational **CL**inical **U**tility of **E**soGuard study (**CLUE**) with >500 subjects completed enrollment in late 2023, and full results are expected to be published in mid-2024; results from an additional data snapshot of the Lucid-sponsored **PREVENT** and **PREVENT-F**ire**f**ighter (**FF**) registries with a combined enrollment of >1,000 subjects are expected to be published in a similar timeframe. Both studies capture information on the diagnostic and/or therapeutic journey of subjects following EsoGuard testing, and in addition to provider decision impact, will contribute differing levels of clinical outcomes data to the Lucid evidence portfolio.

Similarly, results for the Lucid-sponsored virtual-patient study are expected to be ready for analysis in mid-2024.

Finally, the "EsoGuard case-control study" ("BE-2"), a Lucid-sponsored clinical validation study, resumed enrollment in 2023 and is expected to continue through 2024. This data will further supplement what has previously been produced by the two NCI-funded studies (Moinova, et al. Sci Transl Med. 2018; BETRNet).

Manufacturing

EsoCheck is currently manufactured for us by our partners Coastline International ("Coastline"), a high-volume device manufacturer, and Sage Product Development. Our current line at Coastline can produce up to 25,000 units per year. With Coastline's improvement and expansion, there is capacity to scale exponentially. Our EsoGuard Specimen Kits are currently manufactured for us by our partner Path-Tec. The warehousing, logistics, fulfillment and customer support of our products is managed for us by our partners HealthLink International (a leading third-party logistics company) and Path-Tec.

License Agreement

Under the terms of Lucid's license agreement with CWRU (as amended to date, the "Amended CWRU License Agreement"), Lucid acquired an exclusive worldwide right to use the intellectual property rights to the EsoGuard and EsoCheck technology for the detection of changes in the esophagus and on sample preservation. Lucid is required to pay CWRU royalties on net sales of licensed products as follows: 5% of net sales of less than $100 million per year; and 8% of net sales greater than $100 million per year. Lucid is also required to pay CWRU minimum annual royalty payments as follows: $50,000 per year, beginning January 1 following the first anniversary of a commercial sale of a licensed product; $150,000 per year, if net sales of a licensed product exceed $25 million in a year; $300,000 per year, if net sales of a licensed product exceed $50 million in a year; and $600,000 per year, if net sales of a licensed product exceed $100 million in a year. Minimum yearly royalty amounts are subject to increase based on the percentage change in the CPI-W Consumer Price Index and are credited against the royalties otherwise due. The license agreement was subject to four regulatory and commercialization milestones, of which one remains unachieved and unpaid. The remaining milestone is the FDA PMA submission of a licensed product, upon the achievement of which we will pay CWRU a milestone payment of $200,000. The license agreement terminates upon the expiration of the last-to-expire licensed patent, or on May 12, 2038, in countries where no such patents exist, or upon expiration of any exclusive marketing rights for a licensed product that have been granted by FDA or other U.S. government agency, whichever comes later.

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 followed by FDA 510(k) clearance in 2022, expanding the use of EsoCheck in adults and pediatric populations in the U.S. In December 2019, our CLIA-certified then-laboratory partner, completed documentation of EsoGuard analytical validity allowing us to commercialize it as a LDT.

In February 2020, we received FDA "Breakthrough Device Designation" for EsoGuard as an in-vitro diagnostic ("IVD") medical device. The FDA Breakthrough Device Program was created to offer patients more timely access to breakthrough technologies which provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions by expediting their development, assessment and review through enhanced communications and more efficient and flexible clinical study design, including more favorable pre/post market data collection balance. The Centers for Medicare and Medicaid Services and the United States Congress continue to work to provide an expedited coverage pathway for emerging technologies.

In May 2021, we received CE Mark certification for EsoCheck (under the Medical Devices Directive 93/42/EEC), and in June 2021, we completed CE Mark self-certification for EsoGuard (under the European In-Vitro Diagnostic Devices Directive (IVDD 98/79/EC)), indicating both may be marketed in CE Mark European countries.

In October 2023, FDA proposed a policy under which FDA intends to phase out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs. If finalized, FDA believes that this phaseout may also foster the manufacturing of innovative IVDs for which FDA has determined there is a reasonable assurance of safety and effectiveness. As such, FDA has structured the proposed phaseout policy to contain five key stages:

- Stage 1: End the general enforcement discretion approach with respect to Medical Device Regulation (MDR) requirements and correction and removal reporting requirements 1 year after FDA publishes a final phaseout policy, which FDA intends to issue in the preamble of the final rule.
- Stage 2: End the general enforcement discretion approach with respect to requirements other than MDR, correction and removal reporting, Quality System (QS), and premarket review requirements 2 years after FDA publishes a final phaseout policy.
- Stage 3: End the general enforcement discretion approach with respect to QS requirements 3 years after FDA publishes a final phaseout policy.
- Stage 4: End the general enforcement discretion approach with respect to premarket review requirements for high-risk IVDs 3.5 years after FDA publishes a final phaseout policy, but not before October 1, 2027.
- Stage 5: End the general enforcement discretion approach with respect to premarket review requirements for moderate risk and low risk IVDs (that require premarket submissions) 4 years after FDA publishes a final phaseout policy, but not before April 1, 2028.

It is currently anticipated that FDA will finalize the proposed policy by April 2024. Once the final policy is released, we will implement the QS requirements in the recommended staged approach and conduct pre-submission meetings with FDA to seek agreement on regulatory pathway for EsoGuard premarket submission. As required by the final policy, we will submit the regulatory premarket submission to the FDA as per the timeframe defined in the final policy. We are confident that the proposed policy will not have a commercial impact as the Company already has a robust QS management platform for medical devices and EsoGuard will be able to transition to the platform to fulfill the QS requirements, if and when required by the FDA.

Our longer-term strategy is to secure a specific indication, based on published guidelines, for BE testing in certain at-risk populations using EsoGuard on samples collected with EsoCheck. This use of EsoGuard together with EsoCheck as a testing system must be cleared or approved by the FDA as an IVD device.

Laboratory Operations

On February 25, 2022, our new, wholly owned subsidiary, LucidDx Labs Inc. ("LucidDx Labs"), acquired from ResearchDx Inc. ("RDx"), 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. Since March 2022, we have conducted EsoGuard testing at our own laboratory with, until February 10, 2023, the assistance of RDx, which had continued to provide certain testing and related services for the laboratory in accordance with the terms of a management services agreement ("MSA RDx"). LucidDx Labs and RDx agreed to terminate the MSA RDx effective as of February 10, 2023, such that LucidDx Labs now operates the laboratory itself, which the Company believes has improved the efficiency of the performance of the EsoGuard assay.

In November 2023, LucidDx Labs launched EsoGuard 2.0, which uses multiplexing thereby allowing both genes to be interrogated on a single DNA sample. The next-generation assay underwent rigorous analytical and clinical validation studies, including head-to-head comparisons of multiplexed triplicate consensus versus singleplex techniques, consistent with CLIA standards. Clinical validation analysis demonstrated improved sensitivity and specificity for the detection of esophageal precancer, having demonstrated enhanced assay performance and lower costs in extensive validation studies.

Competition

The U.S. market for esophageal cancer (i.e., EAC) and pre-cancer (i.e., BE, with or without dysplasia) testing is large, consisting of more than 30 million at-risk individuals over the age of 50. Given the large market for pre-cancer testing, 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 testing technologies such as multi-cancer early detection products. Our EsoCheck device faces competition from other manufactures with devices designed to collect cell samples from targeted regions of the esophagus. For example, EndoSign, commercialized by Cyted, and much like Cytosponge and our own EsophaCap before it, is a small mesh sponge within a soluble gelatin capsule that needs to reside 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 sample contamination as the brush later passes regions of the upper esophagus and mouth. Our competitors may also be developing additional methods of detecting esophageal cancer and pre-cancer that have not yet been announced.

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 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.

Veris Platform

Overview

In May 2021, we formed Veris Health, a 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's core technologies include designs and patents that would be the foundation for 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 experienced physician entrepreneurs, James Mitchell, M.D., who joined Veris Health as its full-time Chief Medical Officer, and Andrew Thoreson, M.D., who serves as a Veris Health consultant. They 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.

The Veris Platform is a digital cancer care platform with physiologic data collection, symptom reporting and telehealth functions, designed to improve personalized cancer care through remote patient monitoring. Cancer patients enrolled in the Veris Platform receive a VerisBox™ with Veris-branded Bluetooth enabled connected health care devices. The devices transmit clinical data to cancer care teams to detect early signs of common cancer-related complications, provide longitudinal trends of physiologic and clinical data, and offer data-driven risk management tools for precision oncology. The Veris Platform integrates directly with practices' and systems' Electronic Health Record ("EHR") systems, allowing care teams to easily view and interact with this data. We have also been developing a groundbreaking implantable physiologic monitor containing biologic sensors capable of generating continuous data on key physiologic parameters known to predict adverse outcomes in cancer patients undergoing treatment and as resources permit, we will resume further development activities for the implantable to bring it to market. The implantable will seamlessly interact with the Veris Platform. These technologies are the subject of multiple patent applications and one issued patent.

Market Opportunity

In 2023, approximately 1.9 million people in the U.S. were newly diagnosed with cancer, and cancer incidence in the U.S. is expected to continue to increase. Cancer patients face high rates of complications during the courses of their treatment which drive poor patient outcomes and healthcare costs. One driver of these issues is avoidable hospitalizations. We believe Veris Health's offerings can help drive costs down and improve outcomes through providing care teams with better, more continuous data.

Based on the aforementioned cancer prevalence in the U.S. and our current business model, we believe Veris Health's total addressable U.S. market opportunity exceeds $2 billion. In the future, we believe this opportunity will only expand through the implantable physiologic monitor, data commercialization, and the expansion into other markets aside from oncology.

Commercialization/Sales

We are currently pursuing strategic partnerships with leading academic oncology systems, whereby we would become the exclusive digital health solution for these institutions' oncology departments. More broadly, in terms of our commercialization strategy, we have a software-as-a-service recurring-revenue business model where we seek to generate recurring revenue through oncology practice and hospital-based subscriptions. These entities pay monthly fees for each patient on the platform, through which they are able to derive revenues from remote physiologic monitoring (and, in the future, device implantation) under existing CPT codes. Veris also plans to build a commercialization model around the oncology data it is collecting, as resources permit. We have identified multiple potential use cases across a number of verticals, including clinical trials, commercial use cases, and as a means to improve patient care.

Manufacturing

The components comprising the Veris Platform are currently supplied to us by our partners TransTek and their U.S.-based subsidiary, Mio Labs. Each has passed a SOC-2 audit by an outside auditor. The final packaging of the overall box and order fulfillment is managed by PAVmed at its Foxborough, MA location. Customer support is currently managed internally, while partnering with Zendesk for customer service management.

Regulatory

The Veris Platform software is considered a non-device Medical Device Data System ("MDDS") that is excluded from the statutory definition of a medical device under the FDC Act and as confirmed in the FDA's MDDS Guidance: Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices. Therefore, the Veris Platform is not subject to the FDA's regulatory requirements for devices.

Veris Health is also developing an implantable cardiac monitor and is currently interacting with the FDA via pre-submission process, seeking agreement on regulatory strategy and required testing to seek clearance of the monitor. We plan to make our 510(k) submission for the implantable monitor, which could happen as early as late 2024, if and to the extent resources permit us to do so.

Competition

The U.S. market for cancer patient care is large. There are many existing competitors in the remote physiological monitoring space, some of which possess significantly greater financial and other resources and development capabilities than us. Our Veris Platform faces competition from other digital care platforms providing many of the same features, including EHR integration and remote patient monitoring capabilities. While we are not aware of other implantable physiologic monitors containing biologic sensors, our competitors may also be developing similar devices that have not yet been announced.

Incubator Program

On March 21, 2024, the Company announced that it has launched a wholly owned incubator, PMX, to complete development and commercialization of existing portfolio technologies, including PortIO, EsoCure and CarpX. PMX and Hatch Medical, L.L.C. ("Hatch Medical"), a medical device incubator and technology brokerage firm, have executed a joint venture agreement to advance the technologies.

Pursuant to the joint venture agreement, PAVmed will assign PortIO, EsoCure and CarpX to its wholly owned incubator, PMX. Starting with PortIO, the Company will seek to independently finance a separate subsidiary of the incubator to develop and commercialize each technology. Hatch Medical will provide strategic advisory and brokerage services to the subsidiary to advance the technology through key milestones and, subsequently, seek to engage a strategic partner to acquire, license or distribute the commercial product.

Although the incubator, PMX, may seek to expand its portfolio with internal or externally sourced technologies in the future, its initial assets, as noted, will include the following products:

PortIO

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. 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. Currently available intraosseous devices pass through the skin into the bone and are therefore limited to short term use. PortIO is 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.

Esocure

In connection with our efforts to expand our presence in the EAC diagnostic market, we were developing the EsoCure 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. An acute and survival animal study of EsoCure Esophageal Ablation Device has also been completed, demonstrating successful direct thermal balloon catheter ablation of esophageal lining through the working channel of a standard endoscope. When resources permit, we plan to conduct additional development work and animal testing of EsoCure to support a future FDA 510(k) submission.

CarpX

CarpX is a patented, single-use, disposable, minimally invasive surgical device for use in the treatment of carpal tunnel syndrome. 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, and therefore will be significantly less invasive than existing treatments. 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.

CarpX received FDA 510(k) marketing clearance in April 2020, with the first commercial procedure successfully performed in December 2020. In May 2021 European CE Mark Certification was received for CarpX. Our limited-release commercialization efforts through 2022 were 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. As a result of this clinical input, we have initiated a product development project to incorporate intraluminal ultrasound into the device to include real time imaging of the ligament to be cut together with critical anatomic structures, and will continue to pursue that project, as resources permit.

Recent Developments

Business

Series Z Warrant Modification

On December 4, 2023, the Company announced the extension of the Company's Series Z Warrants, by 12 months, to April 30, 2025.

In addition, as a result of the reverse stock split, described below, the Series Z Warrants became exercisable to purchase one whole share of common stock of the Company at an exercise price of $24.00, which exercise price per whole share was further reduced to $23.48 as described below under the heading "*PAVmed Distribution of Lucid Diagnostics Common Stock to Shareholders*". The Company recognized the incremental value associated with the Series Z Warrants modification for the term extension as a deemed dividend charge of $1.8 million and as an increase of net loss available to common stockholders on the consolidated statements of operations in 2023.

Reverse Stock Split

On December 7, 2023, the Company implemented a 1-for-15 reverse stock split of its common stock and reduced its authorized shares from 250,000,000 to 50,000,000, each in accordance with shareholder approval granted at a March 31, 2023 special meeting of the Company's stockholders. The Company filed an amended Certificate of Incorporation reflecting the reduction in authorized shares.

The purpose of the reverse stock split was to regain compliance with the $1 minimum bid price requirement for continued listing on the Nasdaq Capital Market. Indeed, on January 7, 2024, the Company received a letter from the Listing Qualifications Department of Nasdaq, stating the Company had regained compliance with such requirement.

Management Services Agreement/Payroll Benefits and Expense Reimbursement Agreement with Lucid Diagnostics

On March 22, 2024, PAVmed and Lucid entered into an eighth amendment to the management services agreement between PAVmed and Lucid ("MSA") to increase the monthly fee thereunder from $0.75 million per month to $0.83 million per month, effective as of January 1, 2024. The amendment also reset the maximum number of shares issuable under the agreement to 19.99% of the shares outstanding as of the date of the amendment.

On January 26, 2024, in accordance with the MSA and the payroll, benefits and expense reimbursement agreement between PAVmed and Lucid ("PBERA"), PAVmed elected to receive payment of approximately $4.7 million of fees and reimbursements accrued under the MSA and the PBERA through the issuance of 3,331,771 shares of Lucid's common stock.

PAVmed Distribution of Lucid Diagnostics Common Stock to Shareholders

On February 15, 2024, the Company distributed by special dividend to the Company stockholders 3,331,747 shares of Lucid Diagnostics common stock held by the Company. On such date, each PAVmed shareholder as of the January 15, 2024 record date received a stock dividend of approximately 38 shares of Lucid common stock for every 100 shares of PAVmed common stock they held as of such date. The shares distributed were approximately equal to the number of shares of common stock that Lucid issued to PAVmed on or about January 26, 2024 in satisfaction of certain intercompany obligations due to Lucid from PAVmed, as discussed above.

This distribution constituted an "Extraordinary Dividend" as defined in the warrant agreement that governs the Company's Series Z Warrants. As a result, pursuant to the warrant agreement, the exercise price under the Series Z Warrants per full share of PAVmed common stock was automatically decreased by $0.52 (the fair market value of 0.37709668 of a share of Lucid Diagnostics' common stock) to $23.48 per share.

Nasdaq Notice

On March 7, 2024, the Company received a notice from the Nasdaq Listing Qualifications Department stating that, for the preceding 30 consecutive business days (through March 6, 2024), the market value of the Company's listed securities ("MVLS") had been below the minimum of $35 million required for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). The notification letter stated that the Company would be afforded 180 calendar days (until September 3, 2024) to regain compliance. In order to regain compliance, the Company's MVLS must close at $35 million or more for a minimum of ten consecutive business days. The notification letter also states that in the event the Company does not regain compliance prior to the expiration of the 180-day period, the Company will receive written notification that its securities are subject to delisting. The Nasdaq notification has no effect at this time on the listing of the Company's common stock or Series Z warrants, and the stock and warrants will continue to trade uninterrupted under the symbol "PAVM" and "PAVMZ", respectively.

Incubator Program

On March 21, 2024, the Company announced that it has launched a wholly owned incubator, PMX, to complete development and commercialization of existing portfolio technologies, including PortIO, EsoCure and CarpX. PMX and Hatch Medical, L.L.C. ("Hatch Medical"), a medical device incubator and technology brokerage firm, have executed a joint venture agreement to advance the technologies.

Pursuant to the joint venture agreement, PAVmed will assign PortIO, EsoCure and CarpX to its wholly owned incubator, PMX. Starting with PortIO, the Company will seek to independently finance a separate subsidiary of the incubator to develop and commercialize each technology. Hatch Medical will provide strategic advisory and brokerage services to the subsidiary to advance the technology through key milestones and, subsequently, seek to engage a strategic partner to acquire, license or distribute the commercial product.

Financing

Securities Purchase Agreement - March 31, 2022 - Senior Secured Convertible Note - April 4, 2022 and Senior Secured Convertible Note - September 8, 2022

Effective as of March 12, 2024, the Company entered into an amendment and waiver (the "Note Amendment and Waiver") with the holder of the April 2022 Senior Convertible Note and the September 2022 Senior Convertible Note (each such term as defined below). Pursuant to the Note Amendment and Waiver, the maturity date of the April 2022 Senior Convertible Note was extended to April 4, 2025 and the maturity date of the September 2022 Senior Convertible Note was extended to September 8, 2025, in each case subject to further extension in certain circumstances. The holder of the such note also waived, for the period commencing on December 1, 2023 and ending on August 31, 2024, the financial covenant contained in such notes requiring that the ratio of (a) the outstanding principal amount of the notes, accrued and unpaid interest thereon and accrued and unpaid late charges to (b) the Company's average market capitalization over the prior ten trading days, not exceed 30%, and that the Company's market capitalization not be less than $75 million. In consideration of the Note Amendment and Waiver, the Company agreed to pay the holder of the notes $2,000,000 in cash (or in such other form as may be mutually agreed in writing) by April 25, 2024.

See our accompanying consolidated financial statements Note 13, *Debt*, for further discussion of the SPA dated March 31, 2022 and the senior convertible notes.

Lucid Diagnostics - Preferred Stock Offerings

On March 13, 2024, Lucid entered into subscription agreements (each, a "Series B Subscription Agreement") and exchange agreements (each, an "Exchange Agreement") with certain accredited investors (collectively, the "Series B Investors"), which agreements provided for (i) the sale to the Series B Investors of 12,495 shares of Lucid's newly designated Series B Convertible Preferred Stock, par value $0.001 per share (the "Lucid Series B Preferred Stock"), at a purchase price of $1,000 per share, and (ii) the exchange by the Series B Investors of 13,625 shares of Lucid's Series A Convertible Preferred Stock, par value $0.001 per share (the "Lucid Series A Preferred Stock"), and 10,670 shares of Lucid's Series A-1 Convertible Preferred Stock, par value $0.001 per share (the "Lucid Series A-1 Preferred Stock"), held by them for 31,790 shares of Lucid Series B Preferred Stock (collectively, the "Lucid Series B Offering and Exchange"). Prior to the execution of the Series B Subscription Agreements and the Exchange Agreements, Lucid entered into subscription agreements with certain of the Series B Investors providing for the sale to such investors of 5,670 shares of Lucid Series A-1 Preferred Stock, at a purchase price of $1,000 per share, which shares the investors immediately agreed to exchange for shares of Lucid Series B Preferred Stock pursuant to the Exchange Agreements (and are included in the 10,670 shares of Lucid Series A-1 Preferred Stock set forth above). Each share of the Lucid Series B Preferred Stock has a stated value of $1,000 and a conversion price of $1.2444. The terms of the Lucid Series B Preferred Stock also include a one times preference on liquidation and a right to receive dividends equal to 20% of the number of shares of Lucid common stock into which such Lucid Series B Preferred Stock is convertible, payable on the one-year and two-year anniversary of the issuance date. The Lucid Series B Preferred Stock is a voting security. The aggregate gross proceeds to Lucid of these transactions was $18.16 million (inclusive of $5.67 million of aggregate gross proceeds from the sale of the Lucid Series A-1 Preferred Stock that was immediately exchanged for Lucid Series B Preferred Stock in the transactions).

As a result of 100% of the then-outstanding shares of Lucid Series A Preferred Stock and Lucid Series A-1 Preferred Stock being exchanged for shares of Lucid Series B Preferred Stock in the Lucid Series B Offering and Exchange, no shares of Lucid Series A Preferred Stock or Lucid Series A-1 Preferred Stock remain outstanding.

On October 17, 2023, Lucid sold 5,000 shares of Lucid Series A-1 Preferred Stock, solely to accredited investors (all of which were including in the 10,670 shares of Lucid Series A-1 Preferred exchanged for Lucid Series B Preferred Stock in the Lucid Series B Offering and Exchange). The aggregate gross proceeds to Lucid of this offering was $5.0 million.

PAVmed Inc. ATM Facility

In December 2021, we entered into 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. In March 2023, the "at-the-market offering" became subject to General Instruction I.B.6 of Form S-3, which limits sales of our securities under this instruction in any 12-month period to one-third of the aggregate market value of our public float (unless our public float rises to $75 million or more, in which case the instruction will cease to apply). As a result of this limitation and our then-current public float, in May 2023, we amended our "at-the-market offering" to cover up to an additional $18 million of our common stock. In the year ended December 31, 2023, the Company sold 321,288 shares through its at-the-market equity facility for net proceeds of approximately $1.8 million, after payment of 3% commissions.

Intellectual Property

Our business will depend proprietary medical device and diagnostic technologies to commercialize. We own or have the right to use intellectual property rights, such as patents, trademarks, copyrights, trade secrets and know-how, pertaining to our EsoCheck and EsoGuard technology, our Veris technology and our EsoCure, CarpX and PortIO products, among other technologies and products.

We intend to vigorously protect our proprietary technologies' intellectual property rights in patents, trademarks and copyrights, as available through registration in the United States and internationally. Patent protection and other proprietary rights are thus essential to our business. We currently have applied for, license or own 55 domestic and foreign patents across 11 families of products, including patents protecting our EsoCheck, EsoGuard and Veris technology. Each of the technologies noted below is protected by multiple families, and only the earliest expiration for the first of the families is listed. The date the patents protecting certain of our owned and licensed technology will first begin to expire is as set forth in the table below (although currently pending patent applications, both foreign and domestic, are positioned to provide protection beyond such date in each instance). For EsoGuard, families are pending that, when granted, will offer additional protections until at least 2037.

Technology	Year
EsoCheck	May 2034
EsoGuard	August 2024
Veris Health	November 2038
EsoCure	March 2036
CarpX	November 2037
PortIO	November 2035

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 other countries worldwide where there is a value in doing so. 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 (PTA), which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office ("USPTO") in granting a patent, or patent term extension, which restores time lost due to regulatory delays.

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 also rely upon trade secrets, know-how, continuing technological innovation, and upon licensing opportunities, 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.

PAVmed also has (directly or through its subsidiaries) proprietary rights to a range of trademarks, including, among others, PAVmed™, Lucid Diagnostics™, LUCID™, VERIS™, Oncodisc™, CarpX®, EsoCheck®, EsoGuard®, EsoCheck Cell Collection Device®, Collect + Protect®, EsoCure Esophageal Ablation Device™, and PortIO™. (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.)

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.

See "*EsoGuard and EsoCheck—Reimbursement and Market Access*" above for a fuller discussion of the reimbursement status for EsoCheck and EsoGuard.

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.

See "*EsoGuard and EsoCheck—Competition*" and "*Veris Cancer Care Platform—Competition*" above for a fuller discussion of the competitive environment for our key products, EsoCheck, EsoGuard and the Veris Cancer Care Platform.

Government Regulation

Key U.S. Regulation

FDA Regulation

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 de novo request or PMA application, likely with clinical data requirements.

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, 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 clearing a device as a 510(k) device or under a de novo classification pathway 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) clearance with a review of existing bench and animal data. A de novo classification pathway would have a similar cost to seeking 510(k) clearance, but with a slightly longer review timeline. The longest and most expensive path would be a PMA with extensive randomized human clinical trials. We cannot predict fully how FDA will classify our products, nor predict what requirements will be placed upon us to obtain market clearance or 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 FDCA, 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 FDCA 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.

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 and Diagnostic Tests

After a device is cleared or approved for marketing, numerous 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 FDA of certain adverse experience associated with use of the product.

We will continue to be subject to inspection by 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.

Laboratory Certification, Accreditation and Licensing

Lucid's CLIA-certified laboratory is subject to U.S. and state laws and regulations regarding the operation of clinical laboratories. CLIA requirements and laws of certain states, including those of California, New York, Maryland, Pennsylvania, Rhode Island and Florida, impose certification requirements for clinical laboratories, and establish standards for quality assurance and quality control, among other things. CLIA provides that a state may adopt different or more stringent regulations than federal law and permits states to apply for exemption from CLIA if the state's laboratory laws are equivalent to, or more stringent than, CLIA. For example, the State of New York's clinical laboratory regulations, which have received an exemption from CLIA, contain provisions that are in certain respects more stringent than federal law. Therefore, as long as New York maintains a licensure program that is CLIA-exempt, Lucid will need to comply with New York's clinical laboratory regulations in order to offer Lucid clinical laboratory products and services in New York.

Lucid has current certificates to perform clinical laboratory testing. Clinical laboratories are subject to inspection by regulators and to sanctions for failing to comply with applicable requirements. Sanctions available under CLIA and certain state laws include prohibiting a laboratory from running tests, requiring a laboratory to implement a corrective plan, and imposing civil monetary penalties. If Lucid's CLIA-certified laboratory fails to meet any applicable requirements of CLIA or state law, that failure could adversely affect any future CMS consideration of its technologies, prevent their approval entirely, and/or interrupt the commercial sale of any products and services and otherwise cause Lucid to incur significant expense.

Other U.S. Healthcare Regulation

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

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

In any event, we have established a substantial regulatory and compliance infrastructure that is designed to ensure compliance with these regulations.

Physician Payment Sunshine Act

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 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 produce 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, also mandate implementation of commercial compliance programs, and other states 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 that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated.

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

Federal False Claims Act

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

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

The Foreign Corrupt Practices Act

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

Healthcare Reform

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

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. Some of our activities, including at our Lucid Test Centers and within our clinical trials, involve interactions with patients and their health information which implicate HIPAA. Our activities also involve us entering into specific kinds of relationships with Covered Entities and business associates of Covered Entities, which also implicate HIPAA. 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. Since 2020 we have also had to comply with the California Consumer Privacy Act of 2018, which protects personal information other than health information covered by HIPAA. In the E.U., the General Data Protection Regulation ("GDPR") took effect in May 2018 and imposes increasingly stringent data protection and privacy rules. All of these laws may impact our business and may change periodically, which could have an effect on our business operations if compliance becomes substantially costlier than under current requirements. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain stool, blood and other patient samples and associated patient information could significantly impact our business and our future business plans.

Self-Referral Law

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

International Regulation

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

European Union

The European Union ("EU") will require a CE mark certification or approval in order to market our products in the various countries of the European Union or other countries outside the United States. To obtain CE mark certification of our products, we will be required to work with an accredited European notified body organization to determine the appropriate documents required to support certification in accordance with existing medical device directive. The predictability of the length of time and cost associated with such a CE mark may vary or may include lengthy clinical trials to support such a marking. Once the CE mark is obtained, we may market our product in the countries of the EU.

European Good Manufacturing Practices

In the European Union, the manufacture of medical devices is subject to good manufacturing practice ("GMP"), as set forth in the relevant laws and guidelines of the European Union and its member states. Compliance with GMP is generally assessed by the competent regulatory authorities. Typically, quality system evaluation is performed by a Notified Body, which also recommends to the relevant competent authority for the European Community CE Marking of a device. The Competent Authority may conduct inspections of relevant facilities, and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each device manufacturing facility must be audited on a periodic basis by the Notified Body. Further inspections may occur over the life of the product.

Other Laws

Occupational Safety and Health

In addition to its comprehensive regulation of health and safety in the workplace in general, the Occupational Safety and Health Administration has established extensive requirements aimed specifically at laboratories and other healthcare-related facilities. In addition, because Lucid's operations may require employees to use certain hazardous chemicals, Lucid also must comply with regulations on hazard communication and hazardous chemicals in laboratories. These regulations require Lucid, among other things, to develop written programs and plans, which must address methods for preventing and mitigating employee exposure, the use of personal protective equipment, and training.

Specimen Transportation

Our commercialization activities for EsoGuard subject Lucid 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 business. There were no material capital expenditures for environmental control facilities in the years ended December 31, 2023 and 2022.

Employees

As of March 21, 2024 we had 107 employees (all of whom were full-time employees), inclusive of our executive officers — our Chairman of the Board of Directors and Chief Executive Officer ("CEO"), our President and Chief Financial Officer ("CFO"), our Chief Operating Officer ("COO"), our Chief Medical Officer ("CMO") and our General Counsel and Secretary ("General Counsel"). 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 360 Madison Avenue, 25th Floor, New York, NY 10017, and our main telephone number is (917) 813-1828.

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.
- We have concluded there is substantial doubt of our ability to continue as a going concern and our independent registered public accounting firm's report on our financial statements contains an explanatory paragraph describing our ability to continue as a going concern.
- We have faced significant challenges raising capital under the current market conditions, and therefore are highly dependent on the ability of each of our subsidiaries to raise capital to fund its own and our operations.
- There can be no assurance that our common stock will continue to trade on the Nasdaq Capital Market or another national securities exchange.
- Our subsidiary Lucid may issue shares of its common and/or preferred stock in the future which could reduce the equity interest of PAVmed in Lucid and might cause us to cease to control a majority of the voting stock of Lucid.
- 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 Senior Convertible Notes, could have a material effect on our reported financial results.

Risks Associated with Our Business

- We will 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.
- 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.
- Our products may never achieve market acceptance.
- Recommendations, guidelines and quality metrics issued by various organizations may significantly affect payors' 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 currently 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 may make investments in products we have not yet developed, and those investments may not be realized.
- We may not obtain the expected benefits of the incubator financing structure and may incur additional costs.
- 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 may 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 and directors 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.
- 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 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 Associated with Healthcare Regulation, Billing and Reimbursement, and Product Safety and Effectiveness

- If private or governmental third-party payors do not maintain reimbursement for our products at adequate reimbursement rates, we may be unable to successfully commercialize our products which would limit or slow our revenue generation and likely have a material adverse effect on our business.
- FDA has proposed a policy under which it would phase out its general enforcement discretion approach for LDTs so that IVDs manufactured at a laboratory would generally fall under the same enforcement approach as other IVDs. While we are confident that the proposed policy will not have a material impact on our business, there can be no assurance that will be the case.
- Any future products or services we may develop may not be approved for sale in the U.S. or in any other country. In order to obtain approval, we may need to conduct 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.
- 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 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.
- 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.
- The Company's medical products may in the future be subject to product recalls that could harm its reputation, business and financial results.
- 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.
- 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.

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

- 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 cash dividends on our common stock at this time.
- We have made distributions of shares of Lucid common stock to our shareholders in the past, but there is no assurance we will do so in the future.
- 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 our and Lucid Diagnostics operating as a public company, and our management will be required to devote substantial time to compliance initiatives.
- If we experience material weaknesses in our internal control over financial reporting 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. While we have taken steps to reduce operating expenses, we expect to continue to incur operating expenses in excess of our revenues as we continue to maintain our commercial infrastructure, develop, enhance and commercialize products and incur additional operational and reporting costs associated with being a public company. As a result, we expect to continue to incur operating losses for the foreseeable future.

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

In our December 31, 2023 consolidated financial statements, we have concluded and stated that our recurring losses from operations, recurring cash flows used in operations and the requirement that we will need to raise additional capital in order to fund our ongoing operations beyond March 2025 raise substantial doubt regarding our ability to continue as a going concern. Additionally, our independent registered public accounting firm's report on our consolidated financial statements includes an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. Our plans to address this going concern risk include pursuing further financings at Lucid in addition to the recently completed offering of Lucid Series B Preferred Stock (Lucid has recently raised over $18 million in such offering), seeking to restructure our and Lucid Diagnostics' outstanding indebtedness and pursuing additional offerings of debt and/or equity securities. The consolidated financial statements do not include any adjustments that might result from our inability to consummate such offerings or our ability to continue as a going concern. Moreover, there is no assurance if we consummate additional offerings, we will raise sufficient proceeds in such offerings to pay our financial obligations as they become due. These factors raise substantial doubt about our ability to continue as a going concern.

We have faced significant challenges raising capital under the current market conditions, and therefore are highly dependent on the ability of each of our subsidiaries to raise capital to fund its own and our operations.

Due to challenging market conditions, we have found it difficult to raise capital directly into PAVmed. As a result, we have become highly dependent on the ability of each of our subsidiaries to raise capital to fund their own operations. There is no assurance that our subsidiaries will be able to raise capital as needed to fund its operations, or that any of them will be able to do so on commercially reasonable terms. Accordingly, the failure of any of our subsidiaries to raise the capital it needs to fund its operations, could have a material adverse effect on the portion of our business related to such subsidiary.

In addition, because of the challenges PAVmed has faced in terms of raising capital, we are highly dependent on our subsidiaries, including Lucid Diagnostics, as resources for funding our operations (notably, PAVmed may elect that Lucid Diagnostics satisfy its obligations under our management services agreement through cash payment). If Lucid Diagnostics is unable to continue to make any such cash payments we elect to receive, or determines to terminate the management services agreement (i.e., because it retains its own management team to oversee its operations), and PAVmed is unable to raise sufficient capital itself, it may not have sufficient capital to fund its operations, which in turn could have a material adverse effect on our business. All intercompany obligations between PAVmed, on the one hand, and any of its subsidiaries (including Lucid Diagnostics), on the other hand, are subject to approval by the PAVmed board and the board of the applicable subsidiary (including, in the case of Lucid Diagnostics, their independent directors).

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.

On March 7, 2024, the Company received a notice from the Nasdaq Listing Qualifications Department stating that, for the preceding 30 consecutive business days (through March 6, 2024), the market value of the Company's listed securities ("MVLS") had been below the minimum of $35 million required for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). The notification letter stated that the Company would be afforded 180 calendar days (until September 3, 2024) to regain compliance. In order to regain compliance, the Company's MVLS must close at $35 million or more for a minimum of ten consecutive business days. The notification letter also states that in the event the Company does not regain compliance prior to the expiration of the 180-day period, the Company will receive written notification that its securities are subject to delisting. There can be no assurance that the Company will be able to regain compliance by such deadline, in which case, unless the Company is able to obtain an extension for regaining compliance, the Company's stock would be delisted. If we were so delisted, that could have a material adverse effect on your investment in the Company, including without limitation by substantially reducing the liquidity of our common stock, and by further limiting our access to capital markets for fundraising.

Our subsidiary Lucid may issue shares of its common and/or preferred stock in the future which could reduce the equity interest of PAVmed in Lucid and might cause us to cease to control a majority of the voting stock of Lucid.

As of the date hereof, our subsidiary Lucid has issued 44,285 shares of Lucid Series B Preferred Stock. If the maximum amount of common stock underlying such securities were issued (including shares of Lucid common stock issued as a dividend thereon), the percentage of shares of Lucid common stock held by PAVmed would be reduced from approximately [●]% to approximately [●]%. This reduced percentage would be further diluted in the event of future convertible debt or stock issuances by Lucid or by issuances under Lucid's long-term incentive plan and employee stock purchase plan. While PAVmed would still retain a large ownership interest in Lucid in such event, it may cease to control the vote on matters requiring shareholder approval, including the election of Lucid's board of directors.

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 and our subsidiaries may be required to repay or redeem, or to pay interest on, the April 2022 Senior Convertible Note, the September 2022 Senior Convertible Note and the March 2023 Lucid Senior Convertible Note (collectively, the "Senior Convertible 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 Senior Convertible 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 Senior Convertible 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. For example, while the Company is currently in compliance with the financial covenants under the Senior Convertible Notes it has issued, from time to time since the date of issuance of such notes (including, in the case of the indebtedness to market capitalization ratio test under such notes, as of December 31, 2023), the Company was not in compliance with certain financial covenants thereunder. The holders of such notes agreed to waive any such non-compliance through August 31, 2024 in consideration of our agreement to pay a $2,000,000 consent fee in cash (or in such other form as may be mutually agreed in writing) by April 25, 2024. However, there can be no assurance that we will have the cash to make such payment or that the holders will be willing to accept payment in another form of consideration, or if they are willing to do so, that it will be on terms and conditions agreeable to us. There is also no assurance that the holders will be willing to waive any future non-compliance with this or any other provision under the Senior Convertible Notes, or if they are willing to do so, if the terms on which they are so willing will be acceptable to us.

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 Senior Convertible Notes, 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 Senior Convertible 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 Senior Convertible 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 Senior Convertible 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 Senior Convertible Notes to their face amount over the term of the Senior Convertible 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 Senior Convertible 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 Senior Convertible Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Senior Convertible 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 Senior Convertible Notes, then our diluted earnings per share would be adversely affected.

Risks Associated with Our Business

We will 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 try to raise capital through each of our subsidiaries to support our business growth. Because we have not generated substantial revenue or cash flow to date, unless we are able to generate substantial revenue in the near-term (which we do not anticipate being able to do), 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.

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.

The only two products, EsoGuard and the Veris Cancer Care Platform, that we are actively seeking to commercialize have not generated substantial revenue from product sales to date. Accordingly, we will need to find other sources of capital to fund their activities, and there can be no assurance that we will be able to do so. We may also encounter difficulties retaining and managing the specialized workforce our activities require. We may seek to partner with others to assist us with any or all of these functions, although we may be unable to find appropriate third parties with whom to enter into these arrangements.

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 the Veris Cancer Care Platform, 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 test and the Veris Cancer Care Platform or any future tests or other products. Establishing and maintaining these capabilities may require our raising additional capital, which we may be unable to do.

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 relatively recently began to market our two products and services for sale, we have no basis to predict whether our current products and services (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 payors' 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 payor engagement strategies. These guidelines, recommendations and quality metrics may shape payors' coverage decisions and healthcare providers' cancer screening procedures. There can be no assurance that we will be able to secure such recommendations or inclusion in healthcare guidelines and inclusion in quality measures. Any such failures could have a material impact on our ability to commercialize 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.

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.

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 sales 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.

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 currently 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.

We may make investments in products we have not yet developed, and those investments may not be realized.

We may expend considerable funds and other resources on the development of new and existing 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.

We may not obtain the expected benefits of the incubator financing structure and may incur additional costs.

We believe that the incubator financing structure will provide us with future benefits. These expected benefits are not guaranteed and may not be obtained if market conditions or other circumstances prevent us from taking advantage of the investment, financing and structuring flexibility we expect to gain as a result of the incubator financing structure. If we fail to achieve some or all of the expected benefits of our incubator financing structure, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. The implementation of our incubator financing structure also may result in substantial direct costs, which are expected to consist primarily of attorneys' fees and accountants' fees, as well as loss of certain efficiencies. Moreover, the incubator financing structure may be not fully insulate the liabilities of our subsidiaries from each other or from PAVmed, especially if we do not observe the requisite corporate formalities or adequately capitalize PAVmed or its subsidiaries.

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"), or the applicable authorized in other countries in which we may seek to protect our intellectual property rights, 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, or foreign patent offices. Patents that may be issued to or licensed by us in the future may expire or may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related technologies. Upon expiration of our issued or licensed patents, we may lose some of our rights to exclude others from making, using, selling or importing products using the technology based on the expired patents. There is no assurance that competitors will not be able to design around our patents.

We also rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology. 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.

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. Any unanticipated rapid growth of our business may place a strain on our management, operations and financial systems. We need to ensure our existing systems and controls are adequate to support our business and its anticipated growth.

Our officers may 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. Certain of our officers are engaged in other business endeavors. 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. We are limited in shares available for issuance under our long-term incentive plan, which could limit our ability to attract and retain key personnel, until such amount is increased. An inability to attract and retain key personnel may impact our ability to continue and grow our operations.

Our officers and directors 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 and directors have fiduciary obligations to other companies engaged in medical device business activities. 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 board or 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 COVID-19 pandemic, 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.

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

Risks Associated with Healthcare Regulation, Billing and Reimbursement, and Product Safety and Effectiveness If private or governmental third-party payors do not maintain reimbursement for our products at adequate reimbursement rates, we may be unable to successfully commercialize our products which would limit or slow our revenue generation and likely have a material adverse effect on our business.

Successful commercialization of Lucid's EsoGuard test and EsoCheck device, and of any other product or service we develop, license or acquire depends, in large part, on the availability of adequate reimbursement from private or governmental third-party payors.

EsoGuard's PLA code 0114U has been granted "gapfill" determination through the CMS CLFS process, allowing us to engage directly with Medicare Administrative Contractor ("MAC") Palmetto GBA, whose Molecular Diagnostics Program ("MolDx") performs technical assessment of molecular diagnostic tests on behalf of itself and other MACs. Although CMS granted EsoGuard final Medicare payment determination of $1,938.01, effective January 1, 2021, we have not received a final Medicare local coverage determination from MolDx. Most recently, in May 2023, a final Local Coverage Determination ("LCD") L39256, entitled "*Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia*" became effective on the CMS website by MAC Palmetto GBA. (A substantially identical LCD was published by Noridian Healthcare Solutions, the MAC whose geographic jurisdiction covers our CLIA laboratory in Lake Forest, CA.) The LCD outlines criteria for future coverage that MolDX expects upper gastrointestinal precancer and cancer molecular diagnostic tests to meet. These criteria include active GERD with at least two risk factors, as well as evidence of analytic validity, clinical validity, and clinical utility. Although the LCD indicated that it found that no currently existing test has fulfilled all these criteria, it indicated that it will "monitor the evidence and may revise this determination based on the pertinent literature and society recommendations." Lucid expects to submit EsoGuard for Technical Assessment under this foundational LCD later this year. However, even if Lucid does submit EsoGuard for Technical Assessment as currently planned, there can be no assurance that MolDx will determine that EsoGuard meets the criteria for coverage as specified in the LCD. If Lucid is not granted coverage, or if a determination is substantially delayed, that could have a material adverse effect on Lucid's ability to commercialize EsoGuard.

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

Coverage determinations and reimbursement rates are also subject to the effects of federal and state coverage mandates and other healthcare regulations and reform initiatives as described below. As noted below, federal and state coverage mandates may be deemed not to apply to EsoGuard and EsoCheck (or any other product or service we develop), may be interpreted in a manner unfavorable to us, may be difficult to enforce and are subject to repeal or modification.

In addition to the risk of adverse reimbursement decisions, we also may experience material delays in obtaining such reimbursement decisions and payment that are beyond our control. Further, there can be no assurance that CMS and other third-party payors who initially decide to cover our products will continue to do so. Coverage determinations and reimbursement rates are subject to change, including as a result of reimbursement rate adjustments under the Protecting Access to Medicare Act of 2014, ("PAMA") as described below, and we cannot guarantee that even if we initially achieve coverage and adequate reimbursement rates, they will continue to be applicable to our products in the future. Furthermore, it is possible that Medicare or other federal payors that provide reimbursement for our tests may suspend, revoke or discontinue coverage at any time, may require co-payments from patients, or may reduce the reimbursement rates payable to us.

If we are unable to obtain favorable decisions from third-party payors, including CMS and managed care organizations, approving reimbursement at adequate levels for our EsoGuard test and EsoCheck device, and any other product or service we may develop, or if coverage is later revoked or reimbursement levels are reduced, our commercial success will be compromised, our ability to raise capital may be restricted and our revenues would be significantly limited. Healthcare providers may be reluctant to prescribe our products if they believe that reimbursement for the test will not be available for a significant number of their patients.

Even where a third-party payor agrees to cover EsoGuard and EsoCheck or any other product or service we develop at an adequate reimbursement rate, other factors may have a significant impact on the actual reimbursement we receive from that payor. For example, if we do not have a contract with a given payor, we may be deemed an "out-of-network" provider by that payor, which could result in the payor allocating a portion of the cost of the product or service to the patient, notwithstanding any applicable coverage mandate. We may be unsuccessful in our efforts to enter into, or maintain, a network contract with a given payor, and we expect that our network status with a given payor may change from time to time for a variety of reasons, many of which may be outside our control. To the extent a product or service is out of network for a given payor, physicians may be less likely to prescribe such product or service for their patients and their patients may be less likely to comply with those prescriptions that are written. Also, some payors may require that they give prior authorization for a product or service before they are willing to pay for it or review claims post-service to ensure the service was medically appropriate for specific patients. Prior authorization and other medical management practices may require that we, patients or physicians provide the payor with extensive medical records and other information. Prior authorization and other medical management practices impose a significant additional cost on us, may be difficult to comply with given our position as a laboratory that generally does not have direct access to patient medical records, may make physicians less likely to prescribe our product or service for their patients, and may make patients less likely to comply with physician orders for the same, all or any of which may have an adverse effect on our revenues. Payment rates also 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.

FDA has proposed a policy under which it would phase out its general enforcement discretion approach for LDTs so that IVDs manufactured at a laboratory would generally fall under the same enforcement approach as other IVDs. While we are confident that the proposed policy will not have a material impact on our business, there can be no assurance that will be the case.

In October 2023, FDA proposed a policy under which FDA intends to phase out its general enforcement discretion approach for LDTs so that IVDs (like EsoGuard) manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs. If finalized, FDA believes that this phaseout may also foster the manufacturing of innovative IVDs for which FDA has determined there is a reasonable assurance of safety and effectiveness. As such, FDA has structured the proposed phaseout policy to contain five key stages:

- Stage 1: End the general enforcement discretion approach with respect to Medical Device Regulation (MDR) requirements and correction and removal reporting requirements 1 year after FDA publishes a final phaseout policy, which FDA intends to issue in the preamble of the final rule.
- Stage 2: End the general enforcement discretion approach with respect to requirements other than MDR, correction and removal reporting, Quality System (QS), and premarket review requirements 2 years after FDA publishes a final phaseout policy.
- Stage 3: End the general enforcement discretion approach with respect to QS requirements 3 years after FDA publishes a final phaseout policy.
- Stage 4: End the general enforcement discretion approach with respect to premarket review requirements for high-risk IVDs 3.5 years after FDA publishes a final phaseout policy, but not before October 1, 2027.
- Stage 5: End the general enforcement discretion approach with respect to premarket review requirements for moderate risk and low risk IVDs (that require premarket submissions) 4 years after FDA publishes a final phaseout policy, but not before April 1, 2028.

It is currently anticipated that FDA will finalize the proposed policy by April 2024. Once the final policy is released, we will implement the QS requirements in the recommended staged approach and conduct pre-submission meetings with FDA to seek agreement on regulatory pathway for EsoGuard premarket submission. As required by the final policy, Lucid will submit the regulatory premarket submission to the FDA as per the timeframe defined in the final policy. We are confident that the proposed policy will not have a commercial impact as Lucid already has a robust QS management platform for medical devices and EsoGuard will be able to transition to the platform to fulfill the QS requirements, if and when required by FDA. However, there can be no assurance that Lucid will be able to successfully transition the platform to fulfill the QS requirements, if and when required by FDA, and its failure to do so could have a material impact on Lucid's ability to commercialize EsoGuard and on our business as a whole.

Any future products or services we may develop may not be approved for sale in the U.S. or in any other country. In order to obtain approval, we may need to conduct 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.

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

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.

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. 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. 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.

As 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 or otherwise influence medical decisions in the manner we need to show to evidence the clinical utility of our product candidates, which could cause us to abandon a product candidate and may delay development of others. In addition, if clinical data does not support our product candidate claims, 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. Any delay or termination of our clinical trials will delay the filing of any related product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues (in particular where evidence of clinical utility is a critical factor to payor's decisions around reimbursement). 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.

Our principal ongoing clinical trials are those that relate to EsoGuard. For a summary of the status and certain information concerning the results of those trials, please see above under "*Background and Overview—EsoGuard and EsoCheck—Clinical Utility and Clinical Trials*".

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.

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

There likely will 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.

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.

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

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

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

Risks Associated with 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 50,000,000 shares of common stock, par value $.001 per share, and 20,000,000 shares of preferred stock, par value $.001 per share. We may issue a substantial number of additional shares of our common stock or preferred stock, or a combination of common and preferred stock, to raise additional funds or in connection with any strategic acquisition. The issuance of additional shares of our common stock or any number of shares of our preferred stock:

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

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, 2023, our management and their affiliates collectively owned approximately 11% of our issued and outstanding shares of common stock. Accordingly, these individuals would have considerable influence regarding the outcome of any transaction that requires stockholder approval. Furthermore, our Board of Directors is and will be divided into three classes, each of which will generally serve for a term of three years with only one class of directors being elected in each year. As a consequence of our "staggered" Board of Directors, only a minority of the Board of Directors will be considered for election in any given year and our initial stockholders, because of their ownership position, will have considerable influence regarding the outcome.

A robust public market for our common stock may not 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, 2023, there were 8,578,505 shares of our common stock issued and outstanding, and, as of such date, we also had issued and outstanding:

(i) stock options to purchase 1,192,458 shares of our common stock at a weighted average exercise price of $26.18 per share, with such total number inclusive of both stock options granted under the PAVmed Inc. 2014 Long-Term Incentive Equity Plan ("PAVmed 2014 Equity Plan"); 77,518 shares of our common stock reserved for issuance, but not subject to outstanding stock-based equity awards under the PAVmed 2014 Equity Plan; and 7,528 shares of our common stock reserved for issuance under the PAVmed Inc. Employee Stock Purchase Plan ("PAVmed ESPP")

(ii) 11,937,450 Series Z Warrants, representing the right to purchase 795,830 shares of the Company's common stock at an exercise price of $23.48 per whole share; and

(iii) 1,305,213 shares of Series B Convertible Preferred Stock, convertible into 87,015 shares of our common stock.

In addition, the Senior Convertible Notes have a current outstanding principal amount of $26.7 million, which are convertible into 355,520 shares of our common stock (assuming the Senior Convertible Notes were converted in full on such date at the initial fixed conversion price of $75.00 per share). The number of shares of common stock to be issued under the Senior Convertible 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 cash 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 have made distributions of shares of Lucid common stock to our shareholders in the past, but there is no assurance we will do so in the future.

On February 15, 2024, the Company distributed by special dividend to the Company stockholders 3,331,747 shares of Lucid Diagnostics common stock held by the Company. On such date, each PAVmed shareholder as of the January 15, 2024 record date received a stock dividend of approximately 38 shares of Lucid common stock for every 100 shares of PAVmed common stock they held as of such date. However, our Board of Directors has no intention to make any further distributions of shares of Lucid common stock or other assets 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 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 our and Lucid Diagnostics operating as a public company, and our management will be required to devote substantial time to compliance initiatives.

As a public company, with a majority-owned subsidiary that is also 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.

Under our management services agreement with Lucid Diagnostics, many of our personnel and other resources are devoted to ensuring Lucid Diagnostics complies with the above requirements applicable to public companies. This further exhausts management and other personnel resources that could be used for other revenue-generating activities.

If we experience material weaknesses in 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, 2023, 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 1C. Cybersecurity

Governance

Our board administers its cybersecurity risk oversight function directly through our audit committee. Our audit committee has primary responsibility for overseeing our risk assessment and risk management policies (including with respect to cybersecurity matters). Our audit committee regularly discusses with management, counsel, and auditors the Company's major risk exposures. This includes potential financial impact on the Company and the steps taken to monitor and control those risks. Additionally, our board is informed regarding the risks facing the Company and coordinates with management and our cybersecurity team to ensure our board receives regular risk assessment updates from management.

We retain Techneto, Inc. d/b/a CyberTeam ("CyberTeam"), a third party vendor that reports directly to our Chief Operating Officer, to be responsible for identifying, assessing and managing the Company's risks from cybersecurity threats. CyberTeam has been with the Company since its inception and has over 25 years of experience in cybersecurity.

CyberTeam provides our board and executive leadership team with periodic updates about our cybersecurity program and material risks. This includes updates on cybersecurity practices, programs, and the status of projects designed to strengthen internal cybersecurity and data protection.

Risk Management and Strategy

Processes for identifying and assessing cybersecurity risks

Senior management, with the support of CyberTeam, monitors current events and trends related to cybersecurity and assesses any potential impact on current systems and operations. Third-party partners who are in possession of our confidential information are generally required to notify us in the event of a cybersecurity incident within their systems that have, or are reasonably likely to, compromise the security of such information. When appropriate, we enlist CyberTeam to perform a risk and security assessment of the cybersecurity protocols and procedures of critical third-party partners.

Processes for managing cybersecurity risks

CyberTeam tracks risks and incidents related to cybersecurity until the risk is mitigated to an acceptable level or fully remediated. When risks are identified, CyberTeam oversees mitigation plans with the risk owner which are communicated to necessary teams and remediation steps are taken.

Processes for incorporating cybersecurity risks into the overall risk management process

Our process for identifying, assessing, and managing risks related to cybersecurity generally involves CyberTeam regularly meeting with our executive leadership team, and when appropriate, our board and/or audit committee to discuss cybersecurity related risks identified and the potential likelihood and severity of each risk.

Currently, we are not aware of any risks from cybersecurity threats, or from previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect the Company.

Item 2. Property

Our corporate offices are located at 360 Madison Avenue, 25th Floor, New York, NY 10017. The lease for this space is for seven years and eight months, starting on February 1, 2023, and may not be terminated prior to expiration of its stated term, except in limited circumstances due to misconduct by our landlord. The Company or its subsidiaries also have entered into leases for a research and development facility in Massachusetts with 7,375 square feet, which has a remaining term expiring April 30, 2027, a CLIA laboratory in California with 21,019 square feet, which has a remaining term expiring December 31, 2024, and an office space in Pennsylvania with 4,300 square feet, which has a remaining term expiring October 31, 2027. We also have lease agreements for our Lucid Test Centers in various locations in Arizona, California, Colorado, Florida, Idaho, Illinois, Nevada, Ohio, Oregon, Texas and Utah that in the aggregate approximate 15,048 square feet. At this time, we consider our facility space to be commensurate with our current operations. Notwithstanding, we may obtain additional space in the future, as warranted by our business operations.

Item 3. Legal Proceedings

In the ordinary course of PAVmed business, particularly as it begins commercialization of its products, the Company may be subject to legal actions and claims, including product liability, consumer, commercial, tax and governmental matters, which may arise from time to time. The Company is not aware of any such pending legal or other proceedings that are reasonably likely to have a material impact on the Company. 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 stock is traded on the Nasdaq Capital Market under the symbol "PAVM" and our Series Z Warrants are traded on the Nasdaq Capital Market under the symbol "PAVMZ." On March 7, 2024, the Company received a notice from the Nasdaq Listing Qualifications Department stating that, for the preceding 30 consecutive business days (through March 6, 2024), the market value of the Company's listed securities had been below the minimum of $35 million required for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). The notification letter stated that the Company would be afforded 180 calendar days (until September 3, 2024) to regain compliance. See "*Recent Developments—Business—Nasdaq Notice*" in Item 7 below for more information.

Holders

As of March 21, 2024, there were 9,172,331 shares of our common stock outstanding. Our shares of common stock are held by an estimated 225 holders of record and we believe our shares of common stock are held by significantly more beneficial owners.

Dividends

Common Stock

We have not paid any cash dividends on our common stock to date.

Any future decisions regarding cash dividends will be made by our board of directors. We do not anticipate paying cash dividends in the foreseeable future but expect to retain earnings to finance the growth of our business. Subject to the restrictions described below and applicable law, our board of directors has complete discretion on whether to pay cash dividends. Even if our board of directors decides to pay cash 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.

As long as the Senior Convertible Notes (see "*Liquidity and Capital Resources*" in Item 7 below) are outstanding, we may not, directly or indirectly, redeem, or declare or pay any cash dividend or cash distribution on, any of our securities without the prior express written consent of the purchasers of the Senior Convertible Notes (other than as required by the Series B Convertible Preferred Stock). Furthermore, our common stock is junior to the Series B Convertible Preferred Stock with respect to dividends.

We have paid one in-kind dividend on our common stock to date. On February 15, 2024, we distributed by special dividend to our stockholders 3,331,747 shares of Lucid common stock held by us. On such date, each of our stockholders as of the January 15, 2024 record date received a stock dividend of approximately 38 shares of Lucid common stock for every 100 shares of PAVmed common stock they held as of such date. Our board of directors has no present intention to pay any further in-kind dividends.

Series B Convertible Preferred Stock

The Series B Convertible Preferred Stock has a par value of $0.001 per share, no voting rights, a stated value of $3.00 per share, and at the holders' election, every fifteen shares of Series B Convertible Preferred Stock is convertible into one whole share of our common stock .

The Series B Convertible Preferred Stock accrues dividends at a rate of 8% per annum based on the $3.00 per share stated value. Dividends are payable in arrears on January 1, April 1, July 1, and October 1, 2023. 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 are payable at our election in any combination of shares of Series B Convertible Preferred Stock, cash or shares of our common stock.

During the period ended December 31, 2022 at each of the respective holders' election, a total of 45 shares of Series B Convertible Preferred Stock were converted into 3 shares of common stock of PAVmed Inc, adjusted for the 1-for-15 reverse stock split effective December 7, 2023, as disclosed in Note 3, *Summary of Significant Accounting Policies*. There were no Series B Convertible Preferred Stock converted during the year ended December 31, 2023.

During the year ended December 31, 2023, the Company's board of directors declared an aggregate of approximately $298 of Series B Convertible Preferred Stock dividends, earned as of December 31, 2022; March 31, 2023; June 30, 2023; and September 30, 2023, which have been settled by the issue of an additional aggregate 99,454 shares of Series B Convertible Preferred Stock.

During the year ended December 31, 2022, the Company's board of directors declared an aggregate of approximately $276 of Series B Convertible Preferred Stock dividends, earned as of December 31, 2021; March 31, 2022; June 30, 2022; and September 30, 2022, which have been settled by the issue of an additional aggregate 91,885 shares of Series B Convertible Preferred Stock.

Subsequent to December 31, 2023, the Company's board of directors declared a Series B Convertible Preferred Stock dividend, earned as of December 31, 2023, of $78, to be settled by the issue of 26,123 additional shares of Series B Convertible Preferred Stock.

Recent Sales of Unregistered Securities

Except as previously disclosed in our current reports on Form 8-K and quarterly reports on Form 10-Q or as described under the heading "*Recent Developments—Financing*" in Item 7 below, we did not sell any unregistered securities or repurchase any of our securities during the fiscal year ended December 31, 2023.

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 (the "Financial Statements"). 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, (i) "we", "us", and "our", and the "Company" and "PAVmed" refer to PAVmed Inc. and its subsidiaries, including its majority-owned subsidiary Lucid Diagnostics Inc. ("Lucid Diagnostics" or "Lucid") and its majority-owned subsidiary Veris Health Inc. ("Veris Health" or "Veris"), (ii) "FDA" refers to the Food and Drug Administration, (iii) "510(k)" refers to a premarket notification, submitted to the FDA by a manufacturer pursuant to § 510(k) of the Food, Drug and Cosmetic Act and 21 CFR § 807 subpart E, (iv) "CLIA" refers to the Clinical Laboratory Improvement Amendments of 1988 and associated regulations set forth in 42 CFR § 493, and (v) "LDT" refers to a diagnostic test, defined by the FDA as "an IVD that is intended for clinical use and designed, manufactured and used within a single laboratory," which is generally subject only to self-certification of analytical validity under the CMS CLIA program.

Overview

PAVmed is structured to be a multi-product life sciences company organized to advance a pipeline of innovative healthcare technologies. Led by a team of highly skilled personnel with a track record of bringing innovative products to market, PAVmed is focused on innovating, developing, acquiring, and commercializing novel products that target unmet needs with large addressable market opportunities. Leveraging our corporate structure—a parent company that will establish distinct subsidiaries for each financed asset—we have the flexibility to raise capital at the PAVmed level to fund product development, or to structure financing directly into each subsidiary in a manner tailored to the applicable product, the latter of which is our current strategy given prevailing market conditions.

Our current focus is multi-fold. We continue to pursue commercial expansion and execution of EsoGuard, which is the flagship product of our majority-owned subsidiary Lucid Diagnostics Inc. (Nasdaq: LUCD) ("Lucid" or "Lucid Diagnostics"). In addition, through a separate majority-owned subsidiary, Veris Health Inc. ("Veris" or "Veris Health"), we are focused on entering into strategic partnership opportunities with leading academic oncology systems to expand access to the Veris Platform. In terms of other existing products and technologies, we have created an incubator-type platform where we are looking to obtain financing on a product-by-product basis as necessary to advance each asset to a meaningful inflection point along its path to commercialization. Finally, as resources permit, we will continue to explore external innovations that fulfill our project selection criteria without limiting ourselves to any target sector, specialty or condition.

See *Part I, Item 1, Business* above for a more detailed summary of the medical device, diagnostics, and digital health sectors and our key products, including in particular EsoGuard and the Veris Platform, which are currently our two leading products.

Recent Developments

Business

Series Z Warrant Modification

On December 4, 2023, the Company announced the extension of the Company's Series Z Warrants, by 12 months, to April 30, 2025.

In addition, as a result of the reverse stock split, described below, the Series Z Warrants became exercisable to purchase one whole share of common stock of the Company at an exercise price of $24.00, which exercise price per whole share was further reduced to $23.48 as described below under the heading "*PAVmed Distribution of Lucid Diagnostics Common Stock to Shareholders*". The Company recognized the incremental value associated with the Series Z Warrants modification for the term extension as a deemed dividend charge of $1.8 million and as an increase of net loss available to common stockholders on the consolidated statements of operations in 2023.

Reverse Stock Split

On December 7, 2023, the Company implemented a 1-for-15 reverse stock split of its common stock and reduced its authorized shares from 250,000,000 to 50,000,000, each in accordance with shareholder approval granted at a March 31, 2023 special meeting of the Company's stockholders. The Company filed an amended Certificate of Incorporation reflecting the reduction in authorized shares.

The purpose of the reverse stock split was to regain compliance with the $1 minimum bid price requirement for continued listing on the Nasdaq Capital Market. Indeed, on January 7, 2024, the Company received a letter from the Listing Qualifications Department of Nasdaq, stating the Company had regained compliance with such requirement.

Management Services Agreement/Payroll Benefits and Expense Reimbursement Agreement with Lucid Diagnostics

On March 22, 2024, PAVmed and Lucid entered into an eighth amendment to the the management services agreement between PAVmed and Lucid ("MSA") to increase the monthly fee thereunder from $0.75 million per month to $0.83 million per month, effective as of January 1, 2024. The amendment also reset the maximum number of shares issuable under the agreement to 19.99% of the shares outstanding as of the date of the amendment.

On January 26, 2024, in accordance with the MSA and the payroll, benefits and expense reimbursement agreement between PAVmed and Lucid ("PBERA"), PAVmed elected to receive payment of approximately $4.7 million of fees and reimbursements accrued under the MSA and the PBERA through the issuance of 3,331,771 shares of Lucid's common stock.

PAVmed Distribution of Lucid Diagnostics Common Stock to Shareholders

On February 15, 2024, the Company distributed by special dividend to the Company stockholders 3,331,747 shares of Lucid Diagnostics common stock held by the Company. On such date, each PAVmed shareholder as of the January 15, 2024 record date received a stock dividend of approximately 38 shares of Lucid common stock for every 100 shares of PAVmed common stock they held as of such date. The shares distributed were approximately equal to the number of shares of common stock that Lucid issued to PAVmed on or about January 26, 2024 in satisfaction of certain intercompany obligations due to Lucid from PAVmed, as discussed above.

This distribution constituted an "Extraordinary Dividend" as defined in the warrant agreement that governs the Company's Series Z Warrants. As a result, pursuant to the warrant agreement, the exercise price under the Series Z Warrants per full share of PAVmed common stock was automatically decreased by $0.52 (the fair market value of 0.37709668 of a share of Lucid Diagnostics' common stock) to $23.48 per share.

Nasdaq Notice

On March 7, 2024, the Company received a notice from the Nasdaq Listing Qualifications Department stating that, for the preceding 30 consecutive business days (through March 6, 2024), the market value of the Company's listed securities ("MVLS") had been below the minimum of $35 million required for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). The notification letter stated that the Company would be afforded 180 calendar days (until September 3, 2024) to regain compliance. In order to regain compliance, the Company's MVLS must close at $35 million or more for a minimum of ten consecutive business days. The notification letter also states that in the event the Company does not regain compliance prior to the expiration of the 180-day period, the Company will receive written notification that its securities are subject to delisting. The Nasdaq notification has no effect at this time on the listing of the Company's common stock or Series Z warrants, and the stock and warrants will continue to trade uninterrupted under the symbol "PAVM" and "PAVMZ", respectively.

Incubator Program

On March 21, 2024, the Company announced that it has launched a wholly owned incubator, PMX, to complete development and commercialization of existing portfolio technologies, including PortIO, EsoCure and CarpX. PMX and Hatch Medical, L.L.C. ("Hatch Medical"), a medical device incubator and technology brokerage firm, have executed a joint venture agreement to advance the technologies.

Pursuant to the joint venture agreement, PAVmed will assign PortIO, EsoCure and CarpX to its wholly owned incubator, PMX. Starting with PortIO, the Company will seek to independently finance a separate subsidiary of the incubator to develop and commercialize each technology. Hatch Medical will provide strategic advisory and brokerage services to the subsidiary to advance the technology through key milestones and, subsequently, seek to engage a strategic partner to acquire, license or distribute the commercial product.

Financing

Securities Purchase Agreement - March 31, 2022 - Senior Secured Convertible Note - April 4, 2022 and Senior Secured Convertible Note - September 8, 2022

Effective as of March 12, 2024, the Company entered into an amendment and waiver (the "Note Amendment and Waiver") with the holder of the April 2022 Senior Convertible Note and the September 2022 Senior Convertible Note (each such term as defined below). Pursuant to the Note Amendment and Waiver, the maturity date of the April 2022 Senior Convertible Note was extended to April 4, 2025 and the maturity date of the September 2022 Senior Convertible Note was extended to September 8, 2025, in each case subject to further extension in certain circumstances. The holder of the such note also waived, for the period commencing on December 1, 2023 and ending on August 31, 2024, the financial covenant contained in such notes requiring that the ratio of (a) the outstanding principal amount of the notes, accrued and unpaid interest thereon and accrued and unpaid late charges to (b) the Company's average market capitalization over the prior ten trading days, not exceed 30%, and that the Company's market capitalization not be less than $75 million. In consideration of the Note Amendment and Waiver, the Company agreed to pay the holder of the notes $2,000,000 in cash (or in such other form as may be mutually agreed in writing) by April 25, 2024.

See our accompanying consolidated financial statements Note 13, *Debt*, for further discussion of the SPA dated March 31, 2022 and the senior convertible notes.

Financing *- continued*

Lucid Diagnostics - Preferred Stock Offerings

On March 13, 2024, Lucid entered into subscription agreements (each, a "Series B Subscription Agreement") and exchange agreements (each, an "Exchange Agreement") with certain accredited investors (collectively, the "Series B Investors"), which agreements provided for (i) the sale to the Series B Investors of 12,495 shares of Lucid's newly designated Series B Convertible Preferred Stock, par value $0.001 per share (the "Lucid Series B Preferred Stock"), at a purchase price of $1,000 per share, and (ii) the exchange by the Series B Investors of 13,625 shares of Lucid's Series A Convertible Preferred Stock, par value $0.001 per share (the "Lucid Series A Preferred Stock"), and 10,670 shares of Lucid's Series A-1 Convertible Preferred Stock, par value $0.001 per share (the "Lucid Series A-1 Preferred Stock"), held by them for 31,790 shares of Lucid Series B Preferred Stock (collectively, the "Lucid Series B Offering and Exchange"). Prior to the execution of the Series B Subscription Agreements and the Exchange Agreements, Lucid entered into subscription agreements with certain of the Series B Investors providing for the sale to such investors of 5,670 shares of Lucid Series A-1 Preferred Stock, at a purchase price of $1,000 per share, which shares the investors immediately agreed to exchange for shares of Lucid Series B Preferred Stock pursuant to the Exchange Agreements (and are included in the 10,670 shares of Lucid Series A-1 Preferred Stock set forth above). Each share of the Lucid Series B Preferred Stock has a stated value of $1,000 and a conversion price of $1.2444. The terms of the Lucid Series B Preferred Stock also include a one times preference on liquidation and a right to receive dividends equal to 20% of the number of shares of Lucid common stock into which such Lucid Series B Preferred Stock is convertible, payable on the one-year and two-year anniversary of the issuance date. The Lucid Series B Preferred Stock is a voting security. The aggregate gross proceeds to Lucid of these transactions was $18.16 million (inclusive of $5.67 million of aggregate gross proceeds from the sale of the Lucid Series A-1 Preferred Stock that was immediately exchanged for Lucid Series B Preferred Stock in the transactions).

As a result of 100% of the then-outstanding shares of Lucid Series A Preferred Stock and Lucid Series A-1 Preferred Stock being exchanged for shares of Lucid Series B Preferred Stock in the Lucid Series B Offering and Exchange, no shares of Lucid Series A Preferred Stock or Lucid Series A-1 Preferred Stock remain outstanding.

On October 17, 2023, Lucid sold 5,000 shares of Lucid Series A-1 Preferred Stock, solely to accredited investors (all of which were including in the 10,670 shares of Lucid Series A-1 Preferred exchanged for Lucid Series B Preferred Stock in the Lucid Series B Offering and Exchange). The aggregate gross proceeds to Lucid of this offering was $5.0 million.

PAVmed Inc. ATM Facility

In December 2021, we entered into 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. In March 2023, the "at-the-market offering" became subject to General Instruction I.B.6 of Form S-3, which limits sales of our securities under this instruction in any 12-month period to one-third of the aggregate market value of our public float (unless our public float rises to $75 million or more, in which case the instruction will cease to apply). As a result of this limitation and our then-current public float, in May 2023, we amended our "at-the-market offering" to cover up to an additional $18 million of our common stock. In the year ended December 31, 2023, the Company sold 321,288 shares through its at-the-market equity facility for net proceeds of approximately $1.8 million, after payment of 3% commissions.

Lucid Diagnostics Inc. - Committed Equity Facility and ATM Facility

In March 2022, Lucid Diagnostics entered into a committed equity facility with a Cantor affiliate. Under the terms of the committed equity facility, the Cantor affiliate has committed to purchase up to $50 million of Lucid Diagnostics' common stock from time to time at Lucid Diagnostics' request. While there are distinct differences, the committed equity facility is structured similarly to a traditional at-the-market equity facility, insofar as it allows Lucid Diagnostics to raise primary equity capital on a periodic basis at prices based on the existing market price. Cumulatively a total of 680,263 shares of Lucid Diagnostics' common stock were issued for net proceeds of approximately $1.8 million, after a 4% discount, as of December 31, 2023.

In November 2022, Lucid Diagnostics also entered into an "at-the-market offering" for up to $6.5 million of its common stock that may be offered and sold under a Controlled Equity Offering Agreement between Lucid Diagnostics and Cantor. In the year ended December 31, 2023, Lucid Diagnostics sold 230,068 shares through its at-the-market equity facility for net proceeds of approximately $0.3 million, after payment of 3% commissions.

Results of Operations

Overview

Revenue

The Company recognized revenue resulting from the delivery of patient EsoGuard test results when the Company considered the collection of such consideration to be probable to the extent that it is unconstrained. Additionally, in the three months ended March 31, 2022, revenue was recognized with respect to the EsoGuard Commercialization Agreement, dated August 1, 2021, between the Lucid Diagnostics and ResearchDx Inc. ("RDx"), a CLIA certified commercial laboratory service provider. On February 25, 2022, the EsoGuard Commercialization Agreement was terminated upon Lucid's acquisition, pursuant to the APA-RDx, of certain assets necessary to operate its own CLIA certified laboratory. For a fuller description of the APA-RDx, see Note 5, *Asset Purchase Agreement and Management Services Agreement*, to our accompanying consolidated financial statements.

Cost of revenue

Cost of revenues recognized from the delivery of patient EsoGuard test results includes costs related to EsoCheck device usage, shipment of test collection kits, royalties and the cost of services to process tests and provide results to physicians. We incur expenses for tests in the period in which the activities occur, therefore, gross margin as a percentage of revenue may vary from quarter to quarter due to costs being incurred in one period that relate to revenues recognized in a later period.

We expect that gross margin for our services will continue to fluctuate and be affected by EsoGuard test volume, our operating efficiencies, patient compliance rates, payer mix, the levels of reimbursement, and payment patterns of payers and patients.

For the previously terminated EsoGuard Commercialization Agreement in February 2022, the cost of revenue recognized is inclusive of: a royalty fee incurred under our license agreement with CWRU; the cost of EsoCheck devices and EsoGuard mailers (cell sample shipping costs); 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, sales support and marketing activities, as well as advertising and promotion expenses. We anticipate our sales and marketing expenses will increase in the future, to the extent we expand our commercial sales and marketing operations as resources permit and insurance reimbursement coverage for our EsoGuard test expands.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, travel expenses, facility-related costs, professional fees for accounting, tax, audit and legal services, salaries and related costs for employees involved in third-party payor reimbursement contract negotiations and consulting fees and other expenses associated with obtaining and maintaining patents within our intellectual property portfolio.

We anticipate our general and administrative expenses will increase in the future to the extent our business operations grow. Furthermore, we anticipate continued expenses related to being a public company, including fees and expenses for audit, legal, regulatory, tax-related services, insurance premiums and investor relations costs associated with maintaining compliance as a public company.

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 development of our products, including:

- consulting costs for engineering design and development;
- salary and benefit costs associated with our medical research personnel 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
- expenses for facilities maintained solely for research and development purposes.

Our current research and development activities, including our clinical trials, are focused principally on the acceleration of EsoGuard and Veris Cancer Care Platform commercialization. We will resume research and development activities with respect to other products in our pipeline as well as applicable new technologies, as resources permit.

Other Income and Expense, net

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

Results of Operations - continued

Presentation of Dollar Amounts

All dollar amounts in this Management's Discussion and Analysis of Financial Condition and Results of Operations are presented as dollars in millions, except for share and per share amounts.

The year ended December 31, 2023 as compared to year ended December 31, 2022

Revenue

In the year ended December 31, 2023, revenue was $2.5 million as compared to $0.4 million in the prior year. The $2.1 million increase principally relates to the revenue for our EsoGuard Esophageal DNA Test performed in our own CLIA laboratory. During the year ended December 31, 2022, there was revenue from the EsoGuard Commercialization Agreement with RDx recognized in first two months of the year. The EsoGuard Commercialization Agreement was terminated on February 25, 2022 when Lucid Diagnostics transitioned to its own laboratory operations.

Cost of revenue

In the year ended December 31, 2023, cost of revenue was approximately $6.4 million as compared to $3.6 million in the prior year. The $2.8 million increase was principally related to:

- approximately $1.6 million increase in EsoCheck and EsoGuard supplies costs; and
- approximately $1.2 million increase in compensation related costs, including stock-based compensation at Lucid and Veris.

Sales and marketing expenses

In the year ended December 31, 2023, sales and marketing costs were approximately $17.6 million as compared to $19.3 million in the prior year. The net decrease of $1.7 million was principally related to:

- approximately $1.9 million decrease in third party marketing expenses; and
- approximately $0.2 million increase in facility-related costs.

General and administrative expenses

In the year ended December 31, 2023, general and administrative costs were approximately $30.9 million as compared to $41.4 million in the prior year. The net decrease of $10.5 million was principally related to:

- approximately $8.1 million decrease in stock-based compensation, primarily related to decreases at Lucid, partially offset by increases at PAVmed;
- approximately $3.5 million decrease in third-party professional fees and expenses related to legal services, consulting fees and professional recruiting services;
- approximately $1.3 million increase in compensation related costs; and

- approximately $0.2 million decrease related to facility related costs at Lucid, partially offset by an increase in facility related costs at PAVmed.

Research and development expenses

In the year ended December 31, 2023, research and development costs were approximately $14.3 million as compared to $25.3 million in the prior year. The net decrease of $11.0 million was principally related to:

- approximately $10.1 million decrease in development costs, particularly in clinical trial activities and outside professional and consulting fees; and
- approximately $0.9 million decrease in third party professional fees and expenses related to consulting.

Amortization of Acquired Intangible Assets

The amortization of acquired intangible assets increased to $2.0 million in the year ended December 31, 2023, as compared to $1.8 million in the prior year. The increase of $0.2 million in the current period was due to the timing of the acquired intangible assets in 2022.

Results of Operations - continued

The year ended December 31, 2023 as compared to year ended December 31, 2022 - *continued*

Other Income and Expense

Change in fair value of convertible debt

In the year ended December 31, 2023, the change in the fair value of our convertible notes was approximately $6.0 million of expense, related to the April 2022 Senior Convertible Note, the September 2022 Senior Convertible Note, and the Lucid March 2023 Senior Convertible Note. The April 2022 Senior Convertible Note, the September 2022 Senior Convertible Note, and the Lucid March 2023 Senior Convertible Note were initially measured at their issue-date estimated fair value and subsequently remeasured at estimated fair value as of each reporting period date. The Company initially recognized an aggregate of $4.3 million of fair value non-cash expense on the issue dates.

Loss on Issue and Offering Costs - Senior Secured Convertible Note

In the year ended December 31, 2023, in connection with the issue of the Lucid March 2023 Senior Convertible Note, we recognized a total of approximately $1.2 million of lender fees and offering costs paid by us. In the year ended December 31, 2022, in connection with the issue of the April 2022 Senior Convertible Note and the September 2022 Senior Convertible Note, we recognized a total of approximately $4.3 million of lender fees and offering costs.

Loss on Debt Extinguishment

In the year ended December 31, 2023, a debt extinguishment loss in the aggregate of approximately $3.8 million was recognized in connection with our April 2022 Senior Convertible Note and September 2022 Senior Convertible Note as discussed below.

- In the year ended December 31, 2023, approximately $6.1 million of principal repayments along with $0.4 million of interest expense thereon, were settled through the issuance of 1,745,824 shares of common stock of the Company, with such shares having a fair value of approximately $10.0 million (with such fair value measured as the respective conversion date quoted closing price of the common stock of the Company). In addition, the Company paid $0.2 million in cash related to acceleration floor payments on these notes related to the conversion price being below $2.70, recorded as debt extinguishment loss. The conversions resulted in a debt extinguishment loss of $3.8 million in the year ended December 31, 2023.

In comparison, in the year ended December 31, 2022, a debt extinguishment loss in the aggregate of approximately $5.4 million was recognized in connection with our April 2022 Senior Convertible Note as discussed below.

- In August 2022, approximately $6.0 million of principal repayments along with $0.4 million of interest expense thereon, were settled through the issuance of 479,291 shares of common stock of the Company, with such shares having a fair value of approximately $11.8 million (with such fair value measured as the respective conversion date quoted closing price of the common stock of the Company). The conversions resulted in a debt extinguishment loss of $5.4 million in the year ended December 31, 2022.

See Note 13*, Debt*, to the Financial Statements, for additional information with respect to the April 2022 Senior Convertible Note, the September 2022 Senior Convertible Note, and the Lucid March 2023 Senior Convertible Note.

Liquidity and Capital Resources

Our current financing strategy is to obtain capital directly into Lucid, Veris and other subsidiaries to fund any product development or other related activities. There are no assurances, however, we will be able to obtain an adequate level of financial resources required for the short-term or long-term commercialization and development of our products and services.

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 experienced a net loss before noncontrolling interests of approximately $79.3 million and used approximately $52.0 million of cash in operations for the year ended December 31, 2023. Financing activities provided $31.2 million of cash during the year ended December 31, 2023. We ended the year with cash on-hand of $19.6 million as of December 31, 2023. We expect to continue to experience recurring losses and negative cash flows from operations, and will continue to fund our operations with debt and/or equity financing transactions, including current obligations on the Company's existing convertible debt which in accordance with management's plans may include conversions to equity and refinancing our existing debt obligations to extend the maturity date. The Company's ability to continue operations beyond March 2025 will depend upon generating substantial revenue that is conditioned on obtaining positive third-party reimbursement coverage for its EsoGuard Esophageal DNA Test from both government and private health insurance providers, increasing revenue through contracting directly with self-insured employers, and on its ability to raise additional capital through various potential sources including equity and/or debt financings or refinancing existing debt obligations. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the accompanying consolidated financial statements are issued.

Liquidity and Capital Resources - continued

Issue of Shares of Our Common Stock

During the year ended December 31, 2023

- We issued 58,483 shares of our common stock for proceeds of approximately $0.3 million under the PAVmed Employee Stock Purchase Plan ("ESPP"), as such plan is discussed in Note 14, *Stock-Based Compensation,* to the Financial Statements.
- We issued 321,288 shares of our common stock for net proceeds of approximately $1.8 million, after payment of 3% commissions, from the sale of shares through PAVmed's at-the-market equity facility through Cantor. See below for more information.
- We issued 100,000 shares of our common stock to a service provider as the consideration for services rendered. The issued shares of common stock had a fair value of approximately $0.6 million. See Note 16, *Common Stock and Common Stock Purchase Warrants* for additional discussion.
- We issued 1,745,824 shares of our common stock in satisfaction of approximately $6.1 million of principal repayments along with approximately $0.4 million of interest expense thereon under the April 2022 Senior Convertible Note and September 2022 Senior Convertible Note.

Securities Purchase Agreement - March 31, 2022 - Senior Secured Convertible Notes - April 4, 2022 and September 8, 2022

Effective as of March 31, 2022, we entered into the SPA with an accredited investor, pursuant to which we agreed to sell, and the investor agreed to purchase an aggregate of $50.0 million face value principal of Senior Secured Convertible Notes. The SPA provided for the sale of the initial Senior Secured Convertible Note with a face value principal of $27.5 million, which closed on April 4, 2022 (referred to as the "April 2022 Senior Convertible Note"). The SPA also provided for sales of additional Senior Secured Convertible Notes in one or more additional closings (upon the satisfaction of certain conditions), with an aggregate face value principal of up to an additional $22.5 million. The April 2022 Senior Secured Convertible Note has a 7.875% annual stated interest rate, a contractual conversion price (adjusted for the December 2023 1-for-15 reverse stock split) of $75.00 per share of the Company's common stock (subject to standard adjustments in the event of any stock split, stock dividend, stock combination, recapitalization or other similar transaction), and an initial contractual maturity date of April 4, 2024, which maturity date the investor agreed to extend by one year, to April 4, 2025. The April 2022 Senior Convertible Note may be converted into or otherwise paid in shares of our common stock as described in Note 13, *Debt*. The April 2022 Senior Convertible Note proceeds were $24.4 million after deducting a $2.5 million lender fee and the Company's offering costs of approximately $0.6 million, inclusive primarily of $0.5 million placement agent fees.

On September 8, 2022, we completed an additional closing under the SPA, in which we sold to the investor an additional Senior Secured Convertible Note with a face value principal of $11.25 million (referred to as the "September 2022 Senior Convertible Note"). The September 2022 Senior Secured Convertible Note has a 7.875% annual stated interest rate, a contractual conversion price (adjusted for the December 2023 1-for-15 reverse stock split) of $75.00 per share of the Company's common stock (subject to standard adjustments in the event of any stock split, stock dividend, stock combination, recapitalization or other similar transaction), and a contractual maturity date of September 8, 2024 which maturity date the investor agreed to extend by one year, to September 8, 2025. The September 2022 Senior Convertible Note may be converted into or otherwise paid in shares of our common stock as described in Note 13, *Debt*. The September 2022 Senior Convertible Note proceeds were $10.0 million after deducting a $1.0 million lender fee and the Company's total offering costs of approximately $0.2 million, inclusive primarily of placement agent fees.

Under the April 2022 Senior Convertible Note, the September 2022 Senior Convertible Note and the SPA, we are subject to certain customary affirmative and negative covenants regarding 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 are 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 notes issued under the SPA, 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% (the "Debt to Market Cap Ratio Test"), and (iii) that our market capitalization shall at no time be less than $75 million (the "Market Cap Test" and, together with the Debt to Market Cap Ratio Test, the "Financial Tests"). From time to time from and after December 1, 2023 through March 12, 2024, the Company was not in compliance with the Financial Tests. As of March 12, 2024, the investor agreed to waive any such non-compliance during such time period and thereafter through August 31, 2024. Based on the waiver, as of December 31, 2023, the Company was in compliance with the Financial Tests. In addition, based on the waiver, the Company presently is in compliance with the Financial Tests.

In consideration of the covenant waiver and maturity extensions discussed above, the Company agreed to pay the holder of the notes $2,000,000 in cash (or in such other form as may be mutually agreed in writing) by April 25, 2024.

See Note 13*, Debt*, to the Financial Statements for additional information about the SPA, the April 2022 Senior Convertible Note, and the September 2022 Senior Convertible Note.

Liquidity and Capital Resources - continued

Lucid Diagnostics - Preferred Stock Offerings

On March 13, 2024, Lucid entered into subscription agreements (each, a "Series B Subscription Agreement") and exchange agreements (each, an "Exchange Agreement") with certain accredited investors (collectively, the "Series B Investors"), which agreements provided for (i) the sale to the Series B Investors of 12,495 shares of Lucid's newly designated Series B Convertible Preferred Stock, par value $0.001 per share (the "Lucid Series B Preferred Stock"), at a purchase price of $1,000 per share, and (ii) the exchange by the Series B Investors of 13,625 shares of Lucid's Series A Convertible Preferred Stock, par value $0.001 per share (the "Lucid Series A Preferred Stock"), and 10,670 shares of Lucid's Series A-1 Convertible Preferred Stock, par value $0.001 per share (the "Lucid Series A-1 Preferred Stock"), held by them for 31,790 shares of Lucid Series B Preferred Stock (collectively, the "Lucid Series B Offering and Exchange"). Prior to the execution of the Series B Subscription Agreements and the Exchange Agreements, Lucid entered into subscription agreements with certain of the Series B Investors providing for the sale to such investors of 5,670 shares of Lucid Series A-1 Preferred Stock, at a purchase price of $1,000 per share, which shares the investors immediately agreed to exchange for shares of Lucid Series B Preferred Stock pursuant to the Exchange Agreements (and are included in the 10,670 shares of Lucid Series A-1 Preferred Stock set forth above). Each share of the Lucid Series B Preferred Stock has a stated value of $1,000 and a conversion price of $1.2444. The terms of the Lucid Series B Preferred Stock also include a one times preference on liquidation and a right to receive dividends equal to 20% of the number of shares of Lucid common stock into which such Lucid Series B Preferred Stock is convertible, payable on the one-year and two-year anniversary of the issuance date. The Lucid Series B Preferred Stock is a voting security. The aggregate gross proceeds to Lucid of these transactions was $18.16 million (inclusive of $5.67 million of aggregate gross proceeds from the sale of the Lucid Series A-1 Preferred Stock that was immediately exchanged for Lucid Series B Preferred Stock in the transactions).

As a result of 100% of the then-outstanding shares of Lucid Series A Preferred Stock and Lucid Series A-1 Preferred Stock being exchanged for shares of Lucid Series B Preferred Stock in the Lucid Series B Offering and Exchange, no shares of Lucid Series A Preferred Stock or Lucid Series A-1 Preferred Stock remain outstanding.

On October 17, 2023, Lucid sold 5,000 shares of Lucid Series A-1 Preferred Stock, solely to accredited investors (all of which were including in the 10,670 shares of Lucid Series A-1 Preferred exchanged for Lucid Series B Preferred Stock in the Lucid Series B Offering and Exchange). The aggregate gross proceeds to Lucid of this offering was $5.0 million.

Lucid Diagnostics - Securities Purchase Agreement - March 13, 2023 - Senior Secured Convertible Note - March 21, 2023

Effective as of March 13, 2023, Lucid Diagnostics entered into the Lucid SPA with an accredited institutional investor, pursuant to which Lucid Diagnostics agreed to sell, and the investor agreed to purchase the Lucid March 2023 Senior Convertible Note with a face value principal of $11.1 million. Lucid Diagnostics issued the Lucid March 2023 Senior Convertible Note on March 21, 2023 pursuant to the Lucid SPA. The Lucid March 2023 Senior Convertible Note proceeds were $9.925 million after deducting a $1.186 million lender fee and offering costs as described under the heading "*Recent Developments—Financing*" in Item 7 above,

Under the Lucid March 2023 Senior Convertible Note, Lucid Diagnostics is subject to certain customary affirmative and negative covenants regarding 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. Under the Lucid March 2023 Senior Convertible Note, Lucid Diagnostics is also subject to financial covenants requiring that (i) the amount of its available cash equal or exceed $5.0 million at all times, (ii) the ratio of (a) the outstanding principal amount of the notes issued under the Lucid SPA, accrued and unpaid interest thereon and accrued and unpaid late charges, as of the last day of any fiscal quarter commencing with September 30, 2023, to (b) Lucid Diagnostics' average market capitalization over the prior ten trading days, not exceed 30%, and (iii) that Lucid Diagnostics' market capitalization shall at no time be less than $30 million (the "Lucid Financial Tests"). As of December 31, 2023, Lucid Diagnostics was in compliance with the Lucid Financial Tests. In addition, Lucid Diagnostics presently is in compliance with the Lucid Financial Tests.

PAVmed Inc. ATM Facility

In December 2021, we entered into 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 as described under the heading "*Recent Developments—Financing*" in Item 7 above. In the year ended December 31, 2023, the Company sold 321,288 shares through its at-the-market equity facility for net proceeds of approximately $1.8 million, after payment of 3% commissions.

Lucid Diagnostics Inc. - Committed Equity Facility and ATM Facility

In March 2022, Lucid Diagnostics entered into a committed equity facility with a Cantor affiliate. Cumulatively a total of 680,263 shares of Lucid Diagnostics' common stock were issued for net proceeds of approximately $1.8 million, after a 4% discount, as of December 31, 2023.

In November 2022, Lucid Diagnostics also entered into an "at-the-market offering" for up to $6.5 million of its common stock that may be offered and sold under a Controlled Equity Offering Agreement between Lucid Diagnostics and Cantor. In the year ended December 31, 2023, Lucid Diagnostics sold 230,068 shares through its at-the-market equity facility for net proceeds of approximately $0.3 million, after payment of 3% commissions.

Critical Accounting Policies 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

Revenues are recognized when the satisfaction of the performance obligation occurs, in an amount that reflects the consideration we expect to collect in exchange for those services. Our revenue is primarily generated by its laboratory testing services utilizing its EsoGuard Esophageal DNA tests. The services are completed upon release of a patient's test result to the ordering healthcare provider. Revenue recognized is inclusive of both variable consideration in connection with an individual patient's third-party insurance coverage policy and fixed consideration in connection with a contracted services arrangement with an unrelated third party legal entity. To determine revenue recognition for the arrangements that we determine are within the scope of ASC 606, Revenue from Contracts with Customers, we perform the following five steps: (1) identify the contract(s) with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

The key aspects we consider include the following:

Contracts—Our customer is primarily the patient, but we do not enter into a formal reimbursement contract with a patient. We establish a contract with a patient in accordance with other customary business practices, which is the point in time an order is received from a provider and a patient specimen has been returned to the laboratory for testing. Payment terms are a function of a patient's existing insurance benefits, including the impact of coverage decisions with Center for Medicare & Medicaid Services ("CMS") and applicable reimbursement contracts established between us and payers. However, when a patient is considered self-pay, we require payment from the patient prior to the commencement of our performance obligations. Our consideration can be deemed variable or fixed depending on the structure of specific payer contracts, and we consider collection of such consideration to be probable to the extent that it is unconstrained.

Performance obligations—A performance obligation is a promise in a contract to transfer a distinct good or service (or a bundle of goods or services) to the customer. Our contracts have a single performance obligation, which is satisfied upon rendering of services, which culminates in the release of a patient's test result to the ordering healthcare provider. We elected the practical expedient related to the disclosure of unsatisfied performance obligations, as the duration of time between providing testing supplies, the receipt of a sample, and the release of a test result to the ordering healthcare provider is far less than one year.

Transaction price—The transaction price is the amount of consideration that we expects to collect in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration expected to be collected from a contract with a customer may include fixed amounts, variable amounts, or both.

If the consideration derived from the contracts is deemed to be variable, we estimate the amount of consideration to which it will be entitled in exchange for the promised goods or services. We limit the amount of variable consideration included in the transaction price to the unconstrained portion of such consideration. In other words, we recognize revenue up to the amount of variable consideration that is not subject to a significant reversal until additional information is obtained or the uncertainty associated with the additional payments or refunds is subsequently resolved.

When we do not have significant historical experience or that experience has limited predictive value, the constraint over estimates of variable consideration may result in no revenue being recognized upon delivery of patient EsoGuard test results to the ordering healthcare provider. As such, we recognize revenue up to the amount of variable consideration not subject to a significant reversal until additional information is obtained or the uncertainty associated with additional payments or refunds, if any, is subsequently resolved. Differences between original estimates and subsequent revisions, including final settlements, represent changes in estimated expected variable consideration, with the change in estimate recognized in the period of such revised estimate. With respect to a contracted service arrangement, the fixed consideration revenue is recognized on an as-billed basis upon delivery of the laboratory test report with realization of such fixed consideration deemed probable based upon actual historical experience.

Allocate transaction price—The transaction price is allocated entirely to the performance obligation contained within the contract with a customer on the basis of the relative standalone selling prices of each distinct good or service.

Practical Expedients—We do not adjust the transaction price for the effects of a significant financing component, as at contract inception, we expect the collection cycle to be one year or less.

Fair Value Option ("FVO") Election

Under a Securities Purchase Agreement dated March 31, 2022, the Company issued a Senior Secured Convertible Note dated April 4, 2022, referred to herein as the "April 2022 Senior Convertible Note", and a Senior Secured Convertible Note dated September 8, 2022, referred to herein as the "September 2022 Senior Convertible Note", which are accounted under the "fair value option election" as discussed below.

Under a Securities Purchase Agreement dated March 13, 2023, Lucid Diagnostics issued a Senior Secured Convertible Note dated March 21, 2023, referred to herein as the "Lucid March 2023 Senior Convertible Note", which is accounted under the "fair value option election" as discussed below.

Under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 815, *Derivative and Hedging*, ("ASC 815"), a financial instrument containing embedded features and /or options may be required to be bifurcated from the financial instrument host and recognized as separate derivative asset or liability, with the bifurcated derivative asset or liability initially measured at estimated fair value as of the transaction issue date and then subsequently remeasured at estimated fair value as of each reporting period balance sheet date.

Alternatively, 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 estimated fair value as of the transaction issue date and then subsequently remeasured at estimated fair value as of each reporting period balance sheet date, with changes in the estimated fair value recognized as other income (expense) in the statement of operations. The estimated fair value adjustment of the April 2022 Senior Convertible Note, the September 2022 Senior Convertible Note and the Lucid March 2023 Senior Convertible Note are presented in a single line item within other income (expense) in the accompanying consolidated statement of operations (as provided for by ASC 825-10-50-30(b)). 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") (for which there was no such adjustment with respect to the April 2022 Senior Convertible Note, the September 2022 Senior Convertible Note or the Lucid March 2023 Senior Convertible Note).

The estimated fair values recognized utilized PAVmed and Lucid's common stock prices, along with certain Level 3 inputs, 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 and analyses, including the respective common stock prices, the dividend yields, 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 respective common stock prices. Changes in these assumptions can materially affect the recognized estimated fair values.

See Note 12, *Financial Instruments Fair Value Measurements*, with respect to the FVO election; and Note 13, *Debt*, for a discussion of the April 2022 Senior Convertible Note, the September 2022 Senior Convertible Note and the Lucid March 2023 Senior Convertible Note.

Stock-Based Compensation

Stock-based awards are made to members of the board of directors of the Company, the Company's employees and nonemployees, under each of the PAVmed 2014 Equity Plan and the Lucid Diagnostics 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 2014 Equity Plan and the Lucid Diagnostics 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 2014 Equity Plan, the expected stock price volatility is based on the historical stock price volatility of PAVmed Inc. common stock 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, 2023 and 2022;
- With respect to stock options granted under the Lucid Diagnostics 2018 Equity Plan, the expected stock price volatility is based on the historical stock price volatility of Lucid Diagnostics 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 employees in the years ended December 31, 2023 and 2022;
- 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 2014 Equity Plan is its quoted closing price per share.

The price per share of Lucid Diagnostics common stock used in the computation of estimated fair value of stock options and restricted stock awards granted under the Lucid Diagnostics 2018 Equity Plan is its quoted closing price per share.

Recent Accounting Standards Updates Adopted

In June 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The updated guidance requires companies to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets, including trade receivables. The guidance was adopted by the Company on January 1, 2023. The adoption of the ASU did not have an impact on the Company's consolidated financial statements.

Recent Accounting Standards Updates Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740)—Improvements to Income Tax Disclosures ("ASU 2023-09"), which is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 provide for enhanced income tax information primarily through changes to the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for the Company prospectively to all annual periods beginning after December 15, 2024. Early adoption is permitted. We are currently evaluating the impact this update will have on our consolidated financial statements and disclosures.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures ("ASU 2023-07"), which require public companies disclose significant segment expenses and other segment items on an annual and interim basis and to provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. The guidance is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The guidance is applied retrospectively to all periods presented in the financial statements, unless it is impracticable. We are currently evaluating the impact this update will have on our consolidated financial statements and disclosures.

In October 2023, the FASB issued ASU No. 2023-06, Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative. This update modifies the disclosure or presentation requirements of a variety of topics in the Accounting Standards Codification to conform with certain SEC amendments in Release No. 33-10532, Disclosure Update and Simplification. The amendments in this update should be applied prospectively, and the effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or S-K becomes effective. However, if the SEC has not removed the related disclosure from its regulations by June 30, 2027, the amendments will be removed from the Codification and not become effective. Early adoption is prohibited. We are currently evaluating the potential impact of this guidance on its 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, 2023. 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, 2023.

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 has been no change in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Item 9B. Other Information

Material Modification to Rights of Security Holders

On December 4, 2023, the Company announced the extension of the Company's Series Z Warrants, by 12 months, to April 30, 2025. Such extension became effective as of December 31, 2023.

Rule 10b5-1 Trading Plans

During the fiscal quarter ended December 31, 2023, none of our directors or officers (as defined in Rule 16a-1 under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" (as those terms are defined in Item 408 of Regulation S-K).

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 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023.

Item 11. Executive Compensation

The information required by this Item 11 is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023.

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 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023.

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 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023.

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 Stockholders' 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	Incorporation by Reference		
		Form	Exhibit No.	Date
2.1	Asset Purchase Agreement, dated as of February 25, 2022, by and among LucidDx Labs Inc., Lucid Diagnostics Inc. and ResearchDx, Inc.	8-K (LUCD)	2.1	3/3/22
3.1.1	Certificate of Incorporation	S-1	3.1	4/22/15
3.1.2	Certificate of Amendment to Certificate of Incorporation	S-1	3.2	4/22/15
3.1.3	Certificate of Amendment to Certificate of Incorporation, dated October 1, 2018	8-K	3.1	10/2/18
3.1.4	Certificate of Amendment to Certificate of Incorporation, dated June 26, 2019	8-K	3.1	6/27/19
3.1.5	Certificate of Amendment to Certificate of Incorporation, dated July 24, 2020	8-K	3.1	7/27/20
3.1.6	Certificate of Amendment to Certificate of Incorporation, dated June 21, 2022	8-K	3.1	6/22/22
3.1.7	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock	8-K/A	3.1	4/20/18
3.2	Amended and Restated Bylaws	8-K	3.1	1/15/21
4.1	Description of Registrant's Securities	†		
4.2	Specimen Common Stock Certificate	S-1/A	4.2	9/29/15
4.6	Specimen Series Z Warrant Certificate	8-K	4.1	4/5/18
4.7	Amended and Restated Series Z Warrant Agreement, dated as of June 8, 2018, by and between PAVmed Inc. and Continental Stock Transfer & Trust Company, as Warrant Agent	8-K	10.1	6/8/18
4.8	Form of PAVmed Inc. Senior Secured Convertible Note	8-K	4.1	4/4/22
4.9	Form of Lucid Diagnostics Senior Secured Convertible Note	8-K (LUCD)	4.1	3/14/23
10.1	Patent Option Agreement	S-1	10.1	4/22/15
10.2.1	Form of Letter Agreement with HCFP Capital Partners III LLC	S-1	10.4.1	4/22/15
10.2.2	Form of Letter Agreement with Pavilion Venture Partners LLC	S-1	10.4.2	4/22/15
10.3.1	Letter agreement regarding corporate opportunities executed by Lishan Aklog, M.D.	S-1	10.5.1	4/22/15
10.3.2	Letter agreement regarding corporate opportunities executed by Michael Glennon	S-1	10.5.2	4/22/15
10.3.3	Letter agreement regarding corporate opportunities executed by Brian deGuzman, M.D.	S-1	10.5.3	4/22/15
10.4*	Amended and Restated Employment Agreement between PAVmed Inc. and Lishan Aklog, M.D.	8-K	10.1	3/20/19
10.5*	Amended and Restated Employment Agreement between PAVmed Inc. and Dennis M. McGrath	8-K	10.2	3/20/19
10.6*	Employment Agreement between PAVmed Inc. and Brian J. deGuzman, M.D.	8-K	10.1	7/19/16
10.7	PAVmed Inc. Fifth Amended and Restated 2014 Long-Term Incentive Equity Plan	DEF 14A	Annex A	4/30/21
10.8	PAVmed Inc. Employee Stock Purchase Plan	DEF 14A	Annex B	4/30/21
10.9*	Employment Agreement between PAVmed Inc. and Michael A. Gordon	10-K	10.9	3/14/23
10.10*	Employment Agreement between PAVmed Inc. and Shaun M. O'Neil	8-K	10.1	2/24/22
10.11	Amended and Restated License Agreement, dated as of August 23, 2021, by and between Case Western Reserve University and Lucid Diagnostics Inc.	S-1/A (LUCD)	10.2	10/1/21
10.12	Form of Stock Option Agreement	10-K	10.12	3/14/23
10.13	Form of Indemnification Agreement	10-K	10.13	3/14/23
10.14	Controlled Equity Offering[SM], dated as of December 21, 2021, by and between Cantor Fitzgerald & Co. and PAVmed Inc.	S-3	1.2	12/21/21
10.15.1	Form of Securities Purchase Agreement	8-K	10.1	4/4/22
10.15.2	Form of Security Agreement	8-K	10.2	4/4/22
10.15.3	Form of Voting Agreement	8-K	10.3	4/4/22

10.16.1	Common Stock Purchase Agreement, dated as of March 28, 2022, by and between CF Principal Investments LLC and Lucid Diagnostics Inc.	8-K (LUCD)	10.1	4/1/22
10.16.2	Registration Rights Agreement, dated as of March 28, 2022, by and between CF Principal Investments LLC and Lucid Diagnostics Inc.	8-K (LUCD)	10.2	4/1/22
10.17	Controlled Equity Offering[SM], dated as of November 23, 2022, by and between Cantor Fitzgerald & Co. and Lucid Diagnostics Inc.	8-K (LUCD)	1.2	11/25/22
10.18.1	Form of Securities Purchase Agreement (LUCD)	8-K (LUCD)	10.1	3/14/23
10.18.2	Form of Guaranty (LUCD)	8-K (LUCD)	10.3	3/14/23
10.18.3	Form of Registration Rights Agreement (LUCD)	8-K (LUCD)	10.1	3/24/23
10.19.1	Management Services Agreement, dated as of May 12, 2018, by and between PAVmed Inc. and Lucid Diagnostics Inc.	S-1/A (LUCD)	10.4.1	10/7/21
10.9.2	Eighth Amendment to Management Services Agreement, dated as of March 22, 2024, by and between PAVmed Inc. and Lucid Diagnostics Inc.	10-K (LUCD)	10.4.9	3/25/24
14.1	Form of Code of Ethics	10-K	14.1	3/14/23
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. †	†		
97.1	Form of Compensation Clawback Policy	†		
101.INS	XBRL Instance Document	†		
101.SCH	XBRL Taxonomy Extension Schema	†		
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	†		
101.DEF	XBRL Taxonomy Extension Definition Linkbase	†		
101.LAB	XBRL Taxonomy Extension Label Linkbase	†		
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	†		

*	Management contract or compensatory plan or arrangement.
†	Filed herewith
LUCD	Lucid Diagnostics Inc.

Item 16. Form 10-K Summary

None

SIGNATURES

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

PAVmed Inc.

March 25, 2024

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

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

Signature	Title	Date
/s/ Lishan Aklog, M.D. Lishan Aklog, M.D.	Chairman of the Board of Directors Chief Executive Officer *(Principal Executive Officer)*	March 25, 2024
/s/ Dennis M. McGrath Dennis M. McGrath	President Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 25, 2024
/s/ Michael J. Glennon Michael J. Glennon	Vice Chairman Director	March 25, 2024
/s/ Debra J. White Debra J. White	Director	March 25, 2024
/s/ James L. Cox, M.D. James L. Cox, M.D.	Director	March 25, 2024
/s/ Ronald M. Sparks Ronald M. Sparks	Director	March 25, 2024
/s/ Timothy Baxter Timothy Baxter	Director	March 25, 2024
/s/ Joan Harvey Joan Harvey	Director	March 25, 2024

PAVMED INC.
and SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders 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, 2023 and 2022, the related consolidated statements of operations, changes in stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

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

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our 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 Matter

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 matter 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.

Valuation of Convertible Notes

Critical Audit Matter Description

As described in Notes 12 and 13 to the consolidated financial statements, the Company's aggregate principal balance of the Senior Secured Convertible Notes amounted to $37.68 million as of December 31, 2023. The Senior Secured Convertible Notes contain conversion and redemption features. The Company elected to account for the Senior Secured Convertible Notes under the fair value option in accordance with ASC 825. The fair value of the Senior Secured Convertible Notes was $44.2 million as of December 31, 2023.

We identified the valuation of convertible notes as a critical audit matter as auditing the Company's fair value of the Senior Secured Convertible Notes was complex and involved a high degree of subjectivity because the Company used a complex valuation methodology that incorporated significant management assumptions including discount rate and expected volatility. Also, this matter caused us to use increased effort including involvement of professionals with specialized skill and knowledge.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the valuation of convertible notes included the following, among others:

- We obtained an understanding of the design of the Company's controls over the valuation of the convertible notes, including controls over management's review of the valuation model and the significant assumptions used in determining the fair value of the convertible notes.
- With assistance of our valuation specialists, we audited the fair value of the Senior Secured Convertible Notes, valuation methodology and key assumptions used in determining the fair value of the Senior Secured Convertible Notes by:

    a. Evaluating the appropriateness of the valuation model and techniques used in determining the fair value;

    b. Assessing whether significant valuation assumption inputs, including discount rate and expected volatility are consistent with those that would be used by market participants through the testing of source information, checking the mathematical accuracy of the calculation, and developing independent estimates and comparing to those selected by management, where applicable; and

    c. Recalculating the fair value that management arrived to verify it was reasonable.

- We tested the completeness and accuracy of the underlying data supporting the significant assumptions and estimates.

/s/ Marcum LLP

Marcum LLP

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

New York, NY
March 25, 2024

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

	December 31, 2023	December 31, 2022
Assets:		
Current assets:		
Cash	$ 19,639	$ 39,744
Accounts receivable	61	17
Inventory	278	111
Prepaid expenses, deposits, and other current assets	4,520	4,054
Total current assets	24,498	43,926
Fixed assets, net	1,783	2,451
Operating lease right-of-use assets	4,267	3,037
Intangible assets, net	1,424	3,445
Other assets	1,147	1,121
Total assets	$ 33,119	$ 53,980
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,786	$ 2,704
Accrued expenses and other current liabilities	6,626	3,705
Operating lease liabilities, current portion	1,565	1,141
Senior Secured Convertible Notes - at fair value	44,200	33,650
Total current liabilities	54,177	41,200
Operating lease liabilities, less current portion	2,960	1,846
Total liabilities	57,137	43,046
Commitments and contingencies (Note 11)		
Stockholders' Equity:		
Preferred stock, $0.001 par value. Authorized, 20,000,000 shares; Series B Convertible Preferred Stock, par value $0.001, issued and outstanding 1,305,213 at December 31, 2023 and 1,205,759 shares at December 31, 2022	2,993	2,695
Common stock, $0.001 par value. Authorized, 50,000,000 shares; 8,578,505 and 6,300,703 shares outstanding as of December 31, 2023 and December 31, 2022, respectively	9	6
Additional paid-in capital	237,600	216,195
Accumulated deficit	(294,433)	(228,169)
Treasury stock	—	(408)
Total PAVmed Inc. Stockholders' Equity (Deficit)	(53,831)	(9,681)
Noncontrolling interests	29,813	20,615
Total Stockholders' Equity (Deficit)	(24,018)	10,934
Total Liabilities and Stockholders' Equity (Deficit)	$ 33,119	$ 53,980

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 data)

	Years Ended December 31,	
	2023	**2022**
Revenue	$ 2,452	$ 377
Operating expenses:		
Cost of revenue	6,420	3,614
Sales and marketing	17,583	19,318
General and administrative	30,947	41,410
Amortization of acquired intangible assets	2,021	1,784
Research and development	14,276	25,338
Total operating expenses	71,247	91,464
Operating loss	(68,795)	(91,087)
Other income (expense):		
Interest income	505	169
Interest expense	(589)	(1,281)
Change in fair value - Senior Secured Convertible Notes	(6,026)	(1,273)
Loss on issue and offering costs - Senior Secured Convertible Note	(1,186)	(4,332)
Debt extinguishments loss - Senior Secured Convertible Notes	(3,782)	(5,434)
Change in fair value - derivative liability	(390)	—
Gain on sale of intellectual property	1,000	—
Other income (expense), net	(10,468)	(12,151)
Loss before provision for income tax	(79,263)	(103,238)
Provision for income taxes	—	—
Net loss before noncontrolling interests	(79,263)	(103,238)
Net loss attributable to the noncontrolling interests	15,088	14,255
Net loss attributable to PAVmed Inc.	(64,175)	(88,983)
Less: Deemed dividend on Series Z warrant modification	(1,791)	—
Less: Series B Convertible Preferred Stock dividends earned	(304)	(281)
Net loss attributable to PAVmed Inc. common stockholders	$ (66,270)	$ (89,264)
Per share information[(1)]:		
Net loss per share attributable to PAVmed Inc. common stockholders – basic and diluted	$ (9.16)	$ (15.03)
Weighted average common shares outstanding, basic and diluted	7,231,546	5,938,406

(1) Reflects the Company's 1-for-15 reverse stock split that became effective December 7, 2023. Refer to Note 3 - Summary of Significant Accounting Policies for further information.

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARIES
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
for the YEAR ENDED December 31, 2023
(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	Treasury	Non controlling	
	Shares	Amount	Shares	Amount	Capital	Deficit	Stock	Interest	Total
Balance - December 31, 2022	1,205,759	$ 2,695	6,300,703	$ 6	$ 216,195	$ (228,169)	$ (408)	$ 20,615	$ 10,934
Dividends declared - Series B Convertible Preferred Stock	99,454	298	—	—	—	(298)	—	—	—
Issue common stock - PAVM ATM Facility	—	—	321,288	1	1,823	—	—	—	1,824
Vest - restricted stock awards	—	—	6,666	—	—	—	—	—	—
Conversions - Senior Secured Convertible Note	—	—	1,745,824	2	10,000	—	—	—	10,002
Conversions - majority-owned subsidiary common stock - Senior Secured Convertible Note	—	—	—	—	—	—	—	167	167
Purchase - Employee Stock Purchase Plan	—	—	45,893	—	198	—	60	—	258
Purchase - majority-owned subsidiary common stock - Employee Stock Purchase Plan	—	—	—	—	—	—	—	551	551
Issuance - majority-owned subsidiary common stock - At-The-Market Facility, net of financing charges	—	—	—	—	—	—	—	284	284
Impact of subsidiary equity transactions	—	—	—	—	1,983	—	—	(1,983)	—
Issuance - majority-owned subsidiary common stock - Settlement APA-RDx - Termination Payment	—	—	—	—	—	—	—	713	713
Issuance - vendor service agreement	—	—	100,000	—	601	—	—	147	748
Issuance - majority-owned subsidiary preferred stock	—	—	—	—	—	—	—	18,625	18,625
Issuance of shares related to reverse stock split	—	—	45,541	—	—	—	—	—	—
Incremental value from Z Warrant modification	—	—	—	—	1,791	(1,791)	—	—	—
Stock-based compensation - PAVmed Inc.	—	—	—	—	4,255	—	—	—	4,255
Stock-based compensation - majority-owned subsidiaries	—	—	—	—	1,102	—	—	5,782	6,884
Treasury stock	—	—	12,590	—	(348)	—	348	—	—
Net loss	—	—	—	—	—	(64,175)	—	(15,088)	(79,263)
Balance - December 31, 2023	1,305,213	$ 2,993	8,578,505	$ 9	$ 237,600	$ (294,433)	$ —	$ 29,813	$(24,018)

See accompanying notes to the consolidated financial statements.

PAVMED INC.
and SUBSIDIARIES
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
for the YEAR ENDED December 31, 2022
(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	Treasury	Non controlling	
	Shares	Amount	Shares	Amount	Capital	Deficit	Stock	Interest	Total
Balance - December 31, 2021	1,113,919	$ 2,419	5,757,856	$ 5	$ 198,152	$ (138,910)	$ —	$ 17,752	$ 79,418
Dividends declared - Series B Convertible Preferred Stock	91,885	276	—	—	—	(276)	—	—	—
Conversions - Series B Convertible Preferred Stock	(45)	—	3	—	—	—	—	—	—
Issue common stock - PAVM ATM Facility	—	—	7,082	—	79	—	—	—	79
Vest - restricted stock awards	—	—	36,112	1	(1)	—	—	—	—
Exercise - Series Z warrants	—	—	1	—	—	—	—	—	—
Conversions - Senior Secured Convertible Note	—	—	479,291	—	11,807	—	—	—	11,807
Exercise - stock options	—	—	20,000	—	302	—	—	—	302
Exercise - stock options of majority-owned subsidiary	—	—	—	—	—	—	—	695	695
Purchase - Employee Stock Purchase Plan	—	—	12,950	—	218	—	140	—	358
Purchase - majority-owned subsidiary common stock - Employee Stock Purchase Plan	—	—	—	—	—	—	—	109	109
Issuance - majority-owned subsidiary common stock - Committed Equity Facility, net of financing charges	—	—	—	—	—	—	—	1,767	1,767
Impact of subsidiary equity transactions	—	—	—	—	(28)	—	—	28	—
Issuance - majority-owned subsidiary common stock - Settlement APA-RDx - Installment Payment	—	—	—	—	—	—	—	653	653
Stock-based compensation - PAVmed Inc.	—	—	—	—	5,666	—	—	—	5,666
Stock-based compensation - majority-owned subsidiaries	—	—	—	—	—	—	—	13,866	13,866
Treasury stock	—	—	(12,592)	—	—	—	(548)	—	(548)
Net Loss	—	—	—	—	—	(88,983)	—	(14,255)	(103,238)
Balance - December 31, 2022	1,205,759	$ 2,695	6,300,703	$ 6	$ 216,195	$ (228,169)	$ (408)	$ 20,615	$ 10,934

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)

	Years Ended December 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss - before noncontrolling interest ("NCI")	$ (79,263)	$ (103,238)
Adjustments to reconcile net loss - before NCI to net cash used in operating activities		
Depreciation and amortization expense	2,932	2,457
Stock-based compensation	11,139	19,532
Gain on sale of intellectual property	(1,000)	—
APA-RDx: Issue common stock of majority-owned subsidiary - termination payment	713	653
Issue common stock - vendor service agreement	625	—
Change in fair value - Senior Secured Convertible Notes	6,026	1,273
Loss on issue - Senior Secured Convertible Note	1,111	3,523
Debt extinguishment loss - Senior Secured Convertible Note	3,782	5,434
Non-cash lease expense	308	97
Changes in operating assets and liabilities:		
Accounts receivable	(44)	183
Prepaid expenses, deposits and current and other assets	(246)	397
Accounts payable	(918)	(742)
Accrued expenses and other current liabilities	2,799	(554)
Net cash flows used in operating activities	(52,036)	(70,985)
Cash flows from investing activities		
Purchase of equipment	(242)	(1,540)
Proceeds from sale of intellectual property	1,000	—
Asset acquisitions	—	(3,200)
Net cash flows provided by (used in) investing activities	758	(4,740)
Cash flows from financing activities		
Proceeds – issue of preferred stock - majority-owned subsidiary	18,625	—
Proceeds – issue of Senior Secured Convertible Note	10,000	35,227
Payment – Senior Secured Convertible Note – acceleration floor payments.	(79)	—
Proceeds – issue of common stock - At-The-Market Facility	1,533	79
Proceeds – majority-owned subsidiary common stock - Committed Equity Facility and At-The-Market Facility	284	1,807
Proceeds – exercise of stock options	—	302
Proceeds – issue common stock – Employee Stock Purchase Plan	259	358
Proceeds – majority-owned subsidiary common stock – Employee Stock Purchase Plan	551	109
Proceeds – exercise of stock options issued under equity plan of majority owned subsidiary	—	695
Purchase Treasury Stock – payment of employee payroll tax obligation in connection with stock-based compensation	—	(366)
Net cash flows provided by financing activities	31,173	38,211
Net increase (decrease) in cash	(20,105)	(37,514)
Cash, beginning of period	39,744	77,258
Cash, end of period	$ 19,639	$ 39,744

See accompanying notes to the consolidated financial statements.

Note 1 — The Company

Description of the Business

PAVmed is structured to be a multi-product life sciences company organized to advance a pipeline of innovative healthcare technologies. Led by a team of highly skilled personnel with a track record of bringing innovative products to market, PAVmed is focused on innovating, developing, acquiring, and commercializing novel products that target unmet needs with large addressable market opportunities. Leveraging our corporate structure—a parent company that will establish distinct subsidiaries for each financed asset—we have the flexibility to raise capital at the PAVmed level to fund product development, or to structure financing directly into each subsidiary in a manner tailored to the applicable product, the latter of which is our current strategy given prevailing market conditions.

Our current focus is multi-fold. We continue to pursue commercial expansion and execution of EsoGuard, which is the flagship product of our majority-owned subsidiary Lucid Diagnostics Inc. (Nasdaq: LUCD) ("Lucid"). In addition, through a separate majority-owned subsidiary, Veris Health ("Veris"), we are focused on entering into strategic partnership opportunities with leading academic oncology systems to expand access to the Veris Platform. In terms of other existing products and technologies, we have adopted an incubator-type platform where we are looking to obtain financing on a product-by-product basis as necessary to advance each asset to a meaningful inflection point along its path to commercialization. Finally, as resources permit, we will continue to explore external innovations that fulfill our project selection criteria without limiting ourselves to any target sector, specialty or condition.

Note 2 — Liquidity and Going Concern

The Company's management is required to assess the Company's ability to continue as a going concern for the one year period following the date of the financial statements being 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 generated $2.5 million of revenues for the year ended December 31, 2023, however the Company does not expect to generate positive cash flows from operating activities in the near future.

The Company incurred a net loss attributable to PAVmed Inc. common stockholders of approximately $66.3 million and had net cash flows used in operating activities of approximately $52.0 million for the year ended December 31, 2023. As of December 31, 2023, the Company had negative working capital of approximately $29.7 million, with such working capital inclusive of the Senior Secured Convertible Notes classified as a current liability of an aggregate of approximately $44.2 million and approximately $19.6 million of cash.

The Company's ability to continue operations beyond March 2025, will depend upon generating substantial revenue that is conditioned upon obtaining positive third-party reimbursement coverage for its EsoGuard Esophageal DNA Test from both government and private health insurance providers, increasing revenue through contracting directly with self-insured employers, and on its ability to raise additional capital through various potential sources including equity and/or debt financings or refinancing existing debt obligations. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the accompanying consolidated financial statements are issued.

Note 3 — Summary of Significant Accounting Policies

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. and Veris Health 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.

Reverse Stock Split

In February 2023, the Company distributed a proxy statement for a special meeting of shareholders that was held on March 31, 2023 (the "Special Meeting"), at which the Company sought approval of an amendment to the Company's Certificate of Incorporation, to effect, (i) a reverse split of the Company's outstanding shares of common stock at a specific ratio, ranging from 1-for-5 to 1-for-15, to be determined by the board of directors of the Company in its sole discretion, and (ii) an associated reduction in the number of shares of common stock the Company is authorized to issue, from 250,000,000 shares to 50,000,000 shares. On March 31, 2023, the shareholders approved the above proposal to amend the Company's Certificate of Incorporation, to effect, at any time prior to the one-year anniversary date of the Special Meeting. On November 28, 2023 the Company's board of directors, unanimously authorized management to effect the reverse split at the ratio of 1-for-15. The reverse stock split became effective on December 7, 2023. At the effective date, every 15 shares of the Company's common stock that were issued and outstanding were automatically combined into one issued and outstanding share, without any change in par value of such shares. No fractional shares were issued in connection with the reverse stock split. Instead, each fractional share remaining after completion of the reverse stock split that was less than a whole share was rounded up to one whole share. The reverse stock split also correspondingly affected all outstanding PAVmed equity awards and outstanding convertible securities.

All authorized, issued and outstanding stock and per share amounts contained in the accompanying consolidated financial statements have been adjusted to reflect this reverse stock split for all prior periods presented.

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, intangible assets, estimated fair value of debt obligations, and common stock purchase warrants. Other significant estimates include the estimated incremental borrowing rate, 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.

Note 3 — Summary of 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 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

Revenues are recognized when the satisfaction of the performance obligation occurs, in an amount that reflects the consideration the Company expects to collect in exchange for those services. The Company's revenue is primarily generated by its laboratory testing services utilizing its EsoGuard Esophageal DNA tests. The services are completed upon release of a patient's test result to the ordering healthcare provider. Revenue recognized is inclusive of both variable consideration in connection with an individual patient's third-party insurance coverage policy and fixed consideration in connection with a contracted services arrangement with an unrelated third party legal entity. To determine revenue recognition for the arrangements that the Company determines are within the scope of ASC 606, Revenue from Contracts with Customers, the Company performs the following five steps: (1) identify the contract(s) with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

The key aspects considered by the Company include the following:

Contracts—The Company's customer is primarily the patient, but the Company does not enter into a formal reimbursement contract with a patient. The Company establishes a contract with a patient in accordance with other customary business practices, which is the point in time an order is received from a provider and a patient specimen has been returned to the laboratory for testing. Payment terms are a function of a patient's existing insurance benefits, including the impact of coverage decisions with Center for Medicare & Medicaid Services ("CMS") and applicable reimbursement contracts established between the Company and payers. However, when a patient is considered self-pay, the Company requires payment from the patient prior to the commencement of the Company's performance obligations. The Company's consideration can be deemed variable or fixed depending on the structure of specific payer contracts, and the Company considers collection of such consideration to be probable to the extent that it is unconstrained.

Performance obligations—A performance obligation is a promise in a contract to transfer a distinct good or service (or a bundle of goods or services) to the customer. The Company's contracts have a single performance obligation, which is satisfied upon rendering of services, which culminates in the release of a patient's test result to the ordering healthcare provider. The Company elects the practical expedient related to the disclosure of unsatisfied performance obligations, as the duration of time between providing testing supplies, the receipt of a sample, and the release of a test result to the ordering healthcare provider is far less than one year.

Transaction price—The transaction price is the amount of consideration that the Company expects to collect in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration expected to be collected from a contract with a customer may include fixed amounts, variable amounts, or both.

Note 3 — Summary of Significant Accounting Policies - continued

If the consideration derived from the contracts is deemed to be variable, the Company estimates the amount of consideration to which it will be entitled in exchange for the promised goods or services. The Company limits the amount of variable consideration included in the transaction price to the unconstrained portion of such consideration. In other words, the Company recognizes revenue up to the amount of variable consideration that is not subject to a significant reversal until additional information is obtained or the uncertainty associated with the additional payments or refunds is subsequently resolved.

When the Company does not have significant historical experience or that experience has limited predictive value, the constraint over estimates of variable consideration may result in no revenue being recognized upon delivery of patient EsoGuard test results to the ordering healthcare provider. As such, the Company recognizes revenue up to the amount of variable consideration not subject to a significant reversal until additional information is obtained or the uncertainty associated with additional payments or refunds, if any, is subsequently resolved. Differences between original estimates and subsequent revisions, including final settlements, represent changes in estimated expected variable consideration, with the change in estimate recognized in the period of such revised estimate. With respect to a contracted service arrangement, the fixed consideration revenue is recognized on an as-billed basis upon delivery of the laboratory test report with realization of such fixed consideration deemed probable based upon actual historical experience.

Allocate transaction price—The transaction price is allocated entirely to the performance obligation contained within the contract with a customer on the basis of the relative standalone selling prices of each distinct good or service.

Practical Expedients—The Company does not adjust the transaction price for the effects of a significant financing component, as at contract inception, the Company expects the collection cycle to be one year or less.

Inventory

The Company carries test supply inventories to support our laboratory activities. The inventories are carried at the lower of weighted average cost and net realizable value and expensed through cost of sales as the supplies are used.

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. 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 or an operating lease. 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 operating ROU asset also includes any lease incentives received for improvements to leased property, when the improvements are lessee-owned. For improvements to leased property that are lessor-owned, the Company includes amounts the Company incurred for the improvements as ROU assets which are amortized on a straight-line basis over the life of the lease.

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.

Intangible Assets

Purchased intangible assets are recorded at cost and depreciated using the straight-line method over the assets' estimated useful life. See Note 9, *Intangible Assets, net*, 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.

Stock-Based Compensation

Stock-based awards are made to members of the board of directors of the Company, the Company's employees and nonemployees, under each of the PAVmed 2014 Equity Plan and the Lucid Diagnostics 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 2014 Equity Plan and the Lucid Diagnostics 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 2014 Equity Plan, the expected stock price volatility is based on the historical stock price volatility of PAVmed Inc. common stock 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, 2023 and 2022;

- With respect to stock options granted under the Lucid Diagnostics 2018 Equity Plan, the expected stock price volatility is based on the historical stock price volatility of Lucid Diagnostics 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 employees in the years ended December 31, 2023 and 2022;

- 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,

Note 3 — Summary of Significant Accounting Policies - continued

- 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 2014 Equity Plan is its quoted closing price per share.

The price per share of Lucid Diagnostics common stock used in the computation of estimated fair value of stock options and restricted stock awards granted under the Lucid Diagnostics 2018 Equity Plan is its quoted closing price per share.

Financial Instruments Fair Value Measurements

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

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

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

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

As of December 31, 2023 and 2022, 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

Under a Securities Purchase Agreement dated March 31, 2022, the Company issued a Senior Secured Convertible Note dated April 4, 2022, referred to herein as the "April 2022 Senior Convertible Note", and a Senior Secured Convertible Note dated September 8, 2022, referred to herein as the "September 2022 Senior Convertible Note", which are accounted under the "fair value option election" as discussed below.

Note 3 — Summary of Significant Accounting Policies - continued

Under a Securities Purchase Agreement dated March 13, 2023, Lucid Diagnostics issued a Senior Secured Convertible Note dated March 21, 2023, referred to herein as the "Lucid March 2023 Senior Convertible Note", which is accounted under the "fair value option election" as discussed below.

Under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 815, *Derivative and Hedging*, ("ASC 815"), a financial instrument containing embedded features and /or options may be required to be bifurcated from the financial instrument host and recognized as separate derivative asset or liability, with the bifurcated derivative asset or liability initially measured at estimated fair value as of the transaction issue date and then subsequently remeasured at estimated fair value as of each reporting period balance sheet date.

Alternatively, 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 estimated fair value as of the transaction issue date and then subsequently remeasured at estimated fair value as of each reporting period balance sheet date, with changes in the estimated fair value recognized as other income (expense) in the statement of operations. The estimated fair value adjustment of the April 2022 Senior Convertible Note, the September 2022 Senior Convertible Note and the Lucid March 2023 Senior Convertible Note are presented in a single line item within other income (expense) in the accompanying consolidated statement of operations (as provided for by ASC 825-10-50-30(b)). 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") (for which there was no such adjustment with respect to the April 2022 Senior Convertible Note, the September 2022 Senior Convertible Note or the Lucid March 2023 Senior Convertible Note).

See Note 12, *Financial Instruments Fair Value Measurements*, with respect to the FVO election; and Note 13, *Debt*, for a discussion of the April 2022 Senior Convertible Note, the September 2022 Senior Convertible Note and the Lucid March 2023 Senior Convertible Note.

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.

Note 3 — Summary of Significant Accounting Policies - continued

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.

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, 2023 and 2022.

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, 2023, 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, 2023 and December 31, 2022 or recognized during the years ended December 31, 2023 and 2022. 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, 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.

Note 3 — Summary of Significant Accounting Policies - continued

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.

Reclassifications

Certain prior-year amounts have been reclassified to conform to the current year presentation, which includes presenting interest income and classification of certain general and administrative expenses and research and development expenses within operating expenses on the statements of operations, in the consolidated financial statements and accompanying notes to the consolidated financial statements. The impact of the reclassifications made to prior year amounts is not material and did not affect net loss.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued Accounting Standards Update No. 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The updated guidance requires companies to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets, including trade receivables. The guidance was adopted by the Company on January 1, 2023. The adoption of the ASU did not have an impact on the Company's consolidated financial statements.

Recent Accounting Standards Updates Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740)—Improvements to Income Tax Disclosures ("ASU 2023-09"), which is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 provide for enhanced income tax information primarily through changes to the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for the Company prospectively to all annual periods beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact this update will have on our consolidated financial statements and disclosures.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures ("ASU 2023-07"), which require public companies disclose significant segment expenses and other segment items on an annual and interim basis and to provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. The guidance is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The guidance is applied retrospectively to all periods presented in the financial statements, unless it is impracticable. The Company is currently evaluating the impact this update will have on our consolidated financial statements and disclosures.

In October 2023, the FASB issued ASU No. 2023-06, Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative. This update modifies the disclosure or presentation requirements of a variety of topics in the Accounting Standards Codification to conform with certain SEC amendments in Release No. 33-10532, Disclosure Update and Simplification. The amendments in this update should be applied prospectively, and the effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or S-K becomes effective. However, if the SEC has not removed the related disclosure from its regulations by June 30, 2027, the amendments will be removed from the Codification and not become effective. Early adoption is prohibited. The Company is currently evaluating the impact this update will have on its consolidated financial statements and disclosures.

Note 4 — Revenue from Contracts with Customers

EsoGuard Commercialization Agreement

The Company, through its majority-owned subsidiary, Lucid Diagnostics, entered into the EsoGuard Commercialization Agreement, dated August 1, 2021, with its former commercial laboratory service provider, ResearchDx Inc. ("RDx"), an unrelated third-party. The EsoGuard Commercialization Agreement was on a month-to-month basis, and was terminated on February 25, 2022 upon the execution of an asset purchase agreement ("APA") dated February 25, 2022, between LucidDx Labs Inc. (a wholly-owned subsidiary of Lucid Diagnostics) and RDx, with such agreement further discussed in Note 5*, Asset Purchase Agreement and Management Services Agreement.*

Revenue Recognized

In the year ended December 31, 2023, the Company recognized total revenue of $2,452, primarily resulting from the delivery of patient EsoGuard test results. Revenue recognized from customer contracts deemed to include a variable consideration transaction price is limited to the unconstrained portion of the variable consideration. The Company's revenue for the year ended December 31, 2022 was $377, primarily resulting from the delivery of patient EsoGuard test results, along with the revenue recognized under the EsoGuard Commercialization Agreement, which represented the minimum fixed monthly fee of $100 for the period January 1, 2022 to the February 25, 2022 termination date as discussed above. 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 revenues principally includes the costs related to the Company's laboratory operations (excluding estimated costs associated with research activities), the costs related to the EsoCheck cell collection device, cell sample mailing kits and license royalties.

In the year ended December 31, 2023, the cost of revenue was $6,420, primarily related to costs for our laboratory operations and EsoCheck device supplies. The Company's cost of revenue for the year ended December 31, 2022 was $3,614, primarily related to costs for our laboratory operations and EsoCheck device supplies, along with the costs attributable to delivering the services under the EsoGuard Commercialization Agreement for the period January 1, 2022 thru its termination on February 25, 2022.

Note 5 — Asset Purchase Agreement and Management Services Agreement

Asset Purchase Agreement and Management Services Agreement - ResearchDx Inc.

LucidDx Labs, a wholly-owned subsidiary of Lucid Diagnostics, entered into an asset purchase agreement ("APA") dated February 25, 2022, with ResearchDx, Inc. ("RDx"), an unrelated third-party ("APA-RDx"). Under the APA-RDx, LucidDx Labs acquired certain assets from RDx which were combined with LucidDx Labs purchased and leased property and equipment to establish a Company-owned Commercial Lab Improvements Act ("CLIA") certified, College of American Pathologists ("CAP") accredited commercial clinical laboratory capable of performing the EsoGuard® Esophageal DNA assay, inclusive of DNA extraction, next generation sequencing ("NGS") and specimen storage. Prior to February 25, 2022, RDx provided such laboratory services at its owned CLIA-certified, CAP-accredited clinical laboratory. In connection with the execution and delivery of the APA-RDx, LucidDx Labs and RDx entered into a separate management services agreement ("MSA-RDx"), dated and effective February 25, 2022, pursuant to which RDx provided certain testing and related services for the Laboratory.

The total purchase price consideration payable under the APA-RDx is a face value of $3,200 comprised of three contractually specified periodic payments. The APA-RDx is being accounted for as an asset acquisition, with the recognition of an intangible asset of approximately $3,200, which is included in "Intangible assets, net" on the accompanying consolidated balance sheet, as further discussed in Note 9, *Intangible Assets, net.*

Termination of Management Services Agreement and Modification of Other Payment Obligations - ResearchDx Inc

On February 14, 2023, Lucid Diagnostics and LucidDx Labs entered into an agreement (the "MSA Termination Agreement") with RDx, pursuant to which the parties mutually agreed to terminate the MSA-RDx without cause. The termination was effective as February 10, 2023. Until the termination of the management service agreement with RDx, RDx had continued to provide certain testing and related services for the Laboratory in accordance with the terms of the MSA-RDx.

Note 5 — Asset Purchase Agreement and Management Services Agreement - continued

The MSA Termination Agreement reduces the remaining amounts of the earnout payments and management fees due under the APA-RDx and the MSA-RDx to $713. The payment was satisfied through the issuance of 553,436 shares of Lucid Diagnostics' common stock in February 2023. Lucid Diagnostics was not required to make any cash payments in connection with the termination.

Note 6 — Prepaid Expenses, Deposits, and Other Current Assets

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

	December 31, 2023	December 31, 2022
Advanced payments to service providers and suppliers	$ 739	$ 599
Prepaid insurance	848	300
Deposits	2,672	3,005
Veris Box supplies	261	150
Total prepaid expenses, deposits and other current assets	$ 4,520	$ 4,054

Note 7 — Fixed Assets

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

	Estimated Useful Life	December 31, 2023	December 31, 2022
Computer and office equipment	2-5 years	$ 835	$ 784
Laboratory equipment	3-7 years	2,255	2,064
Furniture and fixtures	3-5 years	394	379
Leasehold improvements	(1)	2	2
Assets under construction	n/a	16	30
Total Fixed Assets		3,502	3,259
Less Accumulated Depreciation		(1,719)	(808)
Total Fixed Assets, net		$ 1,783	$ 2,451

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

Depreciation expense of $911 and $673 for the years ended December 31, 2023 and 2022, respectively, is included in general and administrative expenses in the accompanying consolidated statements of operations.

Note 8 — Leases

During the year ended December 31, 2023, the Company entered into additional lease agreements that have commenced and are classified as operating leases and short-term leases, including for each of: principal corporate offices and additional Lucid Test Centers.

The components of lease expense were as follows:

	Years Ended December 31,	
	2023	2022
Operating lease cost	$ 1,871	$ 1,174
Short-term lease cost	89	191
Variable lease cost	113	52
Total lease cost	$ 2,073	$ 1,417

Note 8 — Leases - continued

The Company's future lease payments as of December 31, 2023, which are presented as operating lease liabilities, current portion and operating lease liabilities, less current portion on the Company's consolidated balance sheets are as follows:

2024	$	1,854
2025		835
2026		787
2027		617
2028		471
Thereafter		848
Total lease payments	$	5,412
Less: imputed interest		(887)
Present value of lease liabilities	$	4,525

Supplemental disclosure of cash flow information related to the Company's cash and non-cash activities with its leases are as follows:

	Years Ended December 31,			
	2023		2022	
Cash paid for amounts included in the measurement of lease liabilities				
Operating cash flows from operating leases	$	1,563	$	1,078
Non-cash investing and financing activities				
Right-of-use assets obtained in exchange for new operating lease liabilities	$	2,728	$	3,949
Weighted-average remaining lease term - operating leases (in years)		4.62		2.84
Weighted-average discount rate - operating leases		7.875%		7.875%

As of December 31, 2023 and 2022, the Company's right-of-use assets from operating leases were $4,267 and $3,037, respectively, which are reported in operating lease right-of-use assets in the consolidated balance sheets. As of December 31, 2023 and December 31, 2022, the Company had outstanding operating lease obligations of $4,525 and $2,987, respectively, of which $1,565 and $1,141, respectively, are reported in operating lease liabilities, current portion and $2,960 and $1,846, respectively, are reported in operating lease liabilities less current portion in the Company's consolidated balance sheets. The Company calculates its incremental borrowing rates for specific lease terms, used to discount future lease payments, as a function of the financing terms the Company would likely receive on the open market.

In September 2022, the Company entered into a lease agreement for its principal corporate offices, in New York, New York. The lease agreement term is from the September 15, 2022 execution date to the date which is seven years and eight months from the lease commencement date, with the rent abated for the first eight months of the lease term. The lease commenced on February 1, 2023. The aggregate (undiscounted) rent payments are approximately $3.2 million over the lease term.

Note 9 — Intangible Assets, net

Intangible assets, less accumulated amortization, consisted of the following as of:

	Estimated Useful Life	December 31, 2023	December 31, 2022
Defensive asset	60 months	$ 2,105	$ 2,105
Laboratory licenses and certifications and laboratory information management software	24 months	3,200	3,200
Other	1 year	70	70
Total Intangible assets		5,375	5,375
Less Accumulated Amortization		(3,951)	(1,930)
Intangible Assets, net		$ 1,424	$ 3,445

Note 9 — Intangible Assets, net - continued

The defensive technology intangible asset was recognized upon its acquisition of CapNostics, an unrelated third-party, for total purchase consideration paid on the October 5, 2021 acquisition date of approximately $2.1 million in cash. The CapNostics transaction was accounted for as an asset acquisition, resulting in the recognition of the defensive technology intangible asset. The defensive technology intangible asset is being amortized on a straight-line basis over an expected useful life 60 months commencing on the acquisition date.

The intangible assets recognized under the APA-RDx are the laboratory licenses and certifications, inclusive of a CLIA certification, CAP accreditation, and clinical laboratory licenses for five (5) U.S. States transfer to the Company from RDx, and a laboratory information management software perpetual-use royalty-free license granted under the APA-RDx, with such intangible asset having a useful life of twenty-four months commencing on the APA-RDx February 25, 2022 transaction date.

Amortization expense of the intangible assets discussed above was $2,021 and $1,784 for the years ended December 31, 2023 and 2022, respectively, and is included in amortization of acquired intangible assets in the accompanying consolidated statements of operations. As of December 31, 2023, the estimated future amortization expense associated with the Company's finite-lived intangible assets for each of the five succeeding fiscal years is as follows:

2024	$	688
2025		421
2026		315
Total	$	1,424

Note 10 — Accrued Expenses and Other Current Liabilities

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

	December 31, 2023	December 31, 2022
Compensation and Employee Benefits	$ 2,507	$ 1,940
CWRU Amended License Agreement - Royalty fee	96	10
Operating expenses	3,246	1,755
Other current liabilities	777	—
Total accrued expenses and other current liabilities	$ 6,626	$ 3,705

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.

Note 11 — Commitment and Contingencies

Other Matters

In the ordinary course of PAVmed 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. The Company is not aware of any such pending legal or other proceedings that are reasonably likely to have a material impact on the Company. 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 periods indicated is as follows:

	Fair Value Measurement on a Recurring Basis at Reporting Date Using[1]			
	Level-1 Inputs	Level-2 Inputs	Level-3 Inputs	Total
December 31, 2023				
Senior Secured Convertible Note - April 2022	$ —	$ —	$ 19,000	$ 19,000
Senior Secured Convertible Note - September 2022	—	—	11,250	11,250
Lucid Senior Secured Convertible Note - March 2023	—	—	13,950	13,950
Totals	$ —	$ —	$ 44,200	$ 44,200

	Level-1 Inputs	Level-2 Inputs	Level-3 Inputs	Total
December 31, 2022				
Senior Secured Convertible Note - April 2022	$ —	$ —	$ 22,000	$ 22,000
Senior Secured Convertible Note - September 2022	—	—	11,650	11,650
Totals	$ —	$ —	$ 33,650	$ 33,650

[1] There were no transfers between the respective Levels during the year ended December 31, 2023.

As discussed in Note 13, *Debt*, the Company issued Senior Secured Convertible Notes dated April 4, 2022 and September 8, 2022, with an initial $27.5 million face value principal ("April 2022 Senior Convertible Note") and an initial $11.25 million face value principal ("September 2022 Senior Convertible Note"), respectively. Both convertible notes are 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.

As discussed in Note 13, *Debt,* Lucid Diagnostics issued a Senior Secured Convertible Note dated March 21, 2023, with an initial $11.1 million face value principal ("Lucid March 2023 Senior Convertible Note"). This convertible note is also 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.

The estimated fair value of the financial instruments classified within the Level 3 category was determined using both observable inputs and unobservable inputs. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long- dated volatilities) inputs.

Note 12 — Financial Instruments Fair Value Measurements - continued

The estimated fair value of the Lucid March 2023 Senior Convertible Note as of each of March 21, 2023 and December 31, 2023, and the estimated fair value of the April 2022 Senior Convertible Note and the September 2022 Senior Convertible Note as of December 31, 2023, 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:

	April 2022 Senior Convertible Note: December 31, 2023	September 2022 Senior Convertible Note: December 31, 2023	Lucid March 2023 Senior Convertible Note: March 21, 2023	Lucid March 2023 Senior Convertible Note: December 31, 2023
Fair Value	$ 19,000	$ 11,250	$ 11,900	$ 13,950
Face value principal payable	$ 17,602	$ 9,062	$ 11,111	$ 11,019
Required rate of return	10.00% - 10.50%	10.00% - 10.20%	11.00%	10.00%
Conversion Price	$ 75.00	$ 75.00	$ 5.00	$ 5.00
Value of common stock	$ 4.12	$ 4.12	$ 1.54	$ 1.41
Expected term (years)	0.26 - 1.26	0.69 - 1.69	2.00	1.22
Volatility	85.00%	85.00%	75.00%	60.00%
Risk free rate	4.54% - 5.25%	4.31% - 4.96%	4.09%	4.56%
Dividend yield	—%	—%	—%	—%

The estimated fair values recognized utilized PAVmed and Lucid's common stock prices, along with certain Level 3 inputs (as presented in the respective tables 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 and analyses, including the respective common stock prices, the dividend yields, 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 respective common stock prices. Changes in these assumptions can materially affect the recognized estimated fair values.

Note 13 — Debt

The fair value and face value principal outstanding of the Senior Convertible Notes as of the dates indicated are as follows:

	Contractual Maturity Date	Stated Interest Rate	Conversion Price per Share	Face Value Principal Outstanding	Fair Value
April 2022 Senior Convertible Note	April 4, 2025	7.875%	$ 75.00	$ 17,602	$ 19,000
September 2022 Senior Convertible Note	September 8, 2025	7.875%	$ 75.00	$ 9,062	$ 11,250
Lucid March 2023 Senior Convertible Note	March 21, 2025	7.875%	$ 5.00	$ 11,019	$ 13,950
Balance as of December 31, 2023				$ 37,683	$ 44,200

	Contractual Maturity Date	Stated Interest Rate	Conversion Price per Share	Face Value Principal Outstanding	Fair Value
April 2022 Senior Convertible Note	April 4, 2025	7.875%	$ 75.00	$ 21,497	$ 22,000
September 2022 Senior Convertible Note	September 6, 2025	7.875%	$ 75.00	$ 11,250	$ 11,650
Balance as of December 31, 2022				$ 32,747	$ 33,650

Note 13 — Debt - continued

The changes in the fair value of debt during the year ended December 31, 2023 is as follows:

	April 2022 Senior Convertible Note	September 2022 Senior Convertible Note	Lucid March 2023 Senior Convertible Note	Sum of Balance Sheet Fair Value Components	Other Income (expense)
Fair Value - December 31, 2022	$ 22,000	$ 11,650	$ —	$ 33,650	$ —
Face value principal – issue date	—	—	11,111	11,111	—
Fair value adjustment – issue date	—	—	789	789	(789)
Installment repayments – common stock	(3,895)	(2,188)	(92)	(6,175)	—
Non-installment payments – common stock	(249)	(114)	(49)	(412)	—
Change in fair value	1,144	1,902	2,191	5,237	(5,237)
Fair Value at December 31, 2023	$ 19,000	$ 11,250	$ 13,950	$ 44,200	
Other Income (Expense) - Change in fair value – year ended December 31, 2023					$ (6,026)

The changes in the fair value of debt during the year ended December 31, 2022 is as follows:

	April 2022 Senior Convertible Note	September 2022 Senior Convertible Note	Sum of Balance Sheet Fair Value Components	Other Income (expense)
Fair Value - December 31, 2021	$ —	$ —	$ —	$ —
Face value principal – issue date	27,500	11,250	38,750	—
Fair value adjustment – issue date	2,600	950	3,550	(3,550)
Installment repayments – common stock	(6,003)	—	(6,003)	—
Non-installment payments – common stock	(370)	—	(370)	—
Change in fair value	(1,727)	(550)	(2,277)	2,277
Fair Value at December 31, 2022	$ 22,000	$ 11,650	$ 33,650	
Other Income (Expense) - Change in fair value – year ended December 31, 2022				$ (1,273)

PAVmed - Senior Secured Convertible Notes

The Company entered into a Securities Purchase Agreement ("SPA") dated March 31, 2022, with an accredited institutional investor ("Investor", "Lender", and /or "Holder"), wherein, the Company agreed to sell, and the Investor agreed to purchase an aggregate of $50.0 million face value principal of debt - comprised of: an initial issuance of $27.5 million face value principal; and up to an additional $22.5 million of face value principal (upon the satisfaction of certain conditions). The debt was issued in a registered direct offering under the Company's effective shelf registration statement.

Under the SPA, the Company issued a Senior Secured Convertible Note dated April 4, 2022, referred to herein as the "April 2022 Senior Convertible Note", with such note having a $27.5 million face value principal, a 7.875% annual stated interest rate, a contractual conversion price of $75.00 per share of the Company's common stock (subject to standard adjustments in the event of any stock split, stock dividend, stock combination, recapitalization or other similar transaction), and a contractual maturity date of April 4, 2024, which maturity date the investor agreed to extend by one year, to April 4, 2025. The April 2022 Senior Convertible Note may be converted into shares of common stock of the Company at the Holder's election.

Under the same SPA, the Company issued an additional Senior Secured Convertible Note dated September 8, 2022, referred to herein as the "September 2022 Senior Convertible Note", with such note having a $11.25 million face value principal, a 7.875% annual stated interest rate, a contractual conversion price of $75.00 per share of the Company's common stock (subject to standard adjustments in the event of any stock split, stock dividend, stock combination, recapitalization or other similar transaction), and a contractual maturity date of September 6, 2024, which maturity date the investor agreed to extend by one year, to September 8, 2025. The September 2022 Senior Convertible Note may be converted into shares of common stock of the Company at the Holder's election.

Note 13 — Debt - continued

The Company is subject to financial covenants requiring: (i) a minimum of $8.0 million of available cash at all times; (ii) the ratio of (a) the outstanding principal amount of the total senior convertible notes outstanding, accrued and unpaid interest thereon and accrued and unpaid late charges to (b) the Company's average market capitalization over the prior ten trading days, to not exceed 30% (the "Debt to Market Cap Ratio Test"); and (iii) the Company's market capitalization to at no time be less than $75 million (the "Market Cap Test" and, together with the Debt to Market Cap Ratio Test, the "Financial Tests"). From time to time from and after December 1, 2023 through March 12, 2024, the Company was not in compliance with the Financial Tests. As of March 12, 2024, the Investor agreed to waive any such non-compliance during such time period and thereafter through August 31, 2024.

In consideration of the covenant waiver and maturity extensions discussed above, the Company agreed to pay the holder of the notes $2,000,000 in cash (or in such other form as may be mutually agreed in writing) by April 25, 2024.

The April 2022 Senior Convertible Note and September 2022 Senior Convertible Note installment payments may be made in shares of PAVmed common stock at a conversion price that is the lower of the contractual conversion price and 82.5% of the two lowest VWAPs during the last 10 trading days preceding the date of conversion, subject to a conversion price floor of $2.70. The notes are also subject to certain provisions that may require redemption upon the occurrence of certain events, including an event of default, a change of control, or certain equity issuances.

In the year ended December 31, 2023, approximately $6,083 of principal repayments along with approximately $364 of interest expense thereon, were settled through the issuance of 1,745,824 shares of common stock of the Company, with such shares having a fair value of approximately $10,001 (with such fair value measured as the respective conversion date quoted closing price of the common stock of the Company). In addition the Company paid $202 in cash related to acceleration floor payments on these notes related to the conversion price being below $2.70, which is included in debt extinguishment loss on the Company's consolidated statements of operations. The conversions and cash paid resulted in a debt extinguishment loss of $3,756 in the year ended December 31, 2023.

Lucid Diagnostics - Senior Secured Convertible Note

Lucid Diagnostics entered into a Securities Purchase Agreement ("Lucid SPA") dated March 13, 2023, with an accredited institutional investor ("Investor", "Lender", and /or "Holder"), wherein, Lucid agreed to sell, and the Investor agreed to purchase an aggregate of $11.1 million face value principal of debt. The debt was issued in a registered direct offering under Lucid's effective shelf registration statement.

Under the SPA dated March 13, 2023, Lucid issued a Senior Secured Convertible Note dated March 21, 2023, referred to herein as the "Lucid March 2023 Senior Convertible Note", with such note having a $11.1 million face value principal, a 7.875% annual stated interest rate, a contractual conversion price of $5.00 per share of Lucid's common stock (subject to standard adjustments in the event of any stock split, stock dividend, stock combination, recapitalization or other similar transaction), and a contractual maturity date of March 21, 2025. The Lucid March 2023 Senior Convertible Note may be converted into shares of common stock of Lucid at the Holder's election.

The Lucid March 2023 Senior Convertible Note proceeds were $9.925 million after deducting a $1.186 million lender fee and offering costs. The lender fee and offering costs were recognized as of the March 21, 2023 issue date as a current period expense in other income (expense) in the Company's consolidated statement of operations.

During the period from March 21, 2023 to September 20, 2023, Lucid was required to pay interest expense only (on the $11.1 million face value principal), at 7.875% per annum, computed on a 360 day year. Lucid paid in cash interest expense of $391 for the year ended December 31, 2023.

Commencing September 21, 2023, and then on each of the successive first and tenth trading day of each month thereafter through to and including March 14, 2025 (each referred to as an "Installment Date"); and on the March 21, 2025 maturity date, Lucid will be required to make a principal repayment of $292 together with accrued interest thereon, with such 38 payments referred to herein as the "Installment Amount", settled in shares of common stock of Lucid, subject to customary equity conditions, including minimum share price and volume thresholds, or at the election of Lucid, in cash, in whole or in part.

Note 13 — Debt - continued

In addition to the Installment Amount repayments, the Holder may elect to accelerate the conversion of future Installment Amount repayments, and interest thereon, subject to certain restrictions, as defined, utilizing the then current conversion price of the most recent Installment Date conversion price.

The payment of all amounts due and payable under this senior convertible note is guaranteed by Lucid's subsidiaries; and the obligations under this senior convertible note are secured by all of the assets of Lucid and its subsidiaries.

Lucid is subject to certain customary affirmative and negative covenants regarding the rank of the note, along with the incurrence of further 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.

Lucid is subject to financial covenants requiring: (i) a minimum of $5.0 million of available cash at all times; (ii) the ratio of (a) the outstanding principal amount of the total senior convertible notes outstanding, accrued and unpaid interest thereon and accrued and unpaid late charges to (b) Lucid's average market capitalization over the prior ten trading days, as of the last day of any fiscal quarter commencing with September 30, 2023, to not exceed 30%; and (iii) Lucid's market capitalization to at no time be less than $30 million. As of December 31, 2023, the Company was in compliance, and as of the date hereof, the Company is in compliance, with these financial covenants.

The Lucid March 2023 Senior Convertible Note installment payments may be made in shares of Lucid Diagnostics common stock at a conversion price that is the lower of the contractual conversion price and 82.5% of the two lowest VWAPs during the last 10 trading days preceding the date of conversion, subject to a conversion price floor of $0.30. The notes are also subject to certain provisions that may require redemption upon the occurrence of an event of default, a change of control, or certain equity issuances.

In the year ended December 31, 2023, approximately $92 of principal repayments along with approximately $48 of interest expense thereon, were settled through the issuance of 115,388 shares of common stock of Lucid, with such shares having a fair value of approximately $166 (with such fair value measured as the respective conversion date quoted closing price of the common stock of Lucid). The conversions resulted in a debt extinguishment loss of $26 in the year ended December 31, 2023. Subsequent to December 31, 2023, as of March 21, 2024, approximately $260 of interest expense thereon, was settled through the issuance of 242,390 shares of common stock of the Lucid, with such shares having a fair value of approximately $359 (with such fair value measured as the respective conversion date quoted closing price of the common stock of Lucid).

During the years ended December 31, 2023 and 2022, the Company recognized debt extinguishment losses in total of approximately $3,782 and $5,434, respectively, in connection with issuing common stock for principal repayments on convertible debt mentioned above.

See Note 12, *Financial Instruments Fair Value Measurements*, for a further discussion of fair value assumptions.

Note 14 — Stock-Based Compensation

PAVmed Inc. 2014 Long-Term Incentive Equity Plan

The PAVmed Inc. 2014 Long-Term Incentive Equity Plan (the "PAVmed 2014 Equity Plan") is designed to enable PAVmed to offer employees, officers, directors, and consultants, as defined, an opportunity to acquire shares of common stock of PAVmed. The types of awards that may be granted under the PAVmed 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 compensation committee.

A total of 1,403,518 shares of common stock of PAVmed are reserved for issuance under the PAVmed 2014 Equity Plan, with 77,518 shares available for grant as of December 31, 2023. The share reservation is not diminished by a total of 66,723 PAVmed Inc. stock options and restricted stock awards granted outside the PAVmed 2014 Equity Plan as of December 31, 2023. In January 2024, the number of shares available for grant was increased by 432,452 in accordance with the evergreen provisions of the plan.

Note 14 — Stock-Based Compensation - continued

PAVmed Stock Options

PAVmed stock options granted under the PAVmed 2014 Equity Plan and stock options granted outside such plan are summarized as follows:

	Number of Stock Options	Weighted Average Exercise Price	Remaining Contractual Term (Years)	Intrinsic Value[2]
Outstanding stock options at December 31, 2021[4]	581,833	$ 50.86	6.8	$ 3,516
Granted[1]	320,252	$ 22.87		
Exercised	(19,998)	$ 15.11		
Forfeited	(110,934)	$ 47.15		
Outstanding stock options at December 31, 2022[4]	771,153	$ 40.70	7.4	$ —
Granted[1]	576,975	$ 6.87		
Exercised	—	$ —		
Forfeited	(155,670)	$ 26.51		
Outstanding stock options at December 31, 2023[3]	1,192,458	$ 26.18	7.3	$ —
Vested and exercisable stock options at December 31, 2023	722,039	$ 35.82	6.4	$ —

(1) Stock options granted under the PAVmed 2014 Equity Plan and those granted outside such plan generally vest one-third in one year then ratably over the next eight quarters, 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 common stock on each of December 31, 2023 and December 31, 2022 and the exercise price of the underlying PAVmed stock options, to the extent such quoted price is greater than the exercise price.

(3) The outstanding stock options presented in the table above, are inclusive of 60,057 and 33,391, stock options granted outside the PAVmed 2014 Equity Plan, as of December 31, 2023 and December 31, 2022, respectively.

(4) Share activity and weighted average grant date fair values include immaterial rounding due to the Company's 1-for-15 reverse stock split.

Subsequent to December 31, 2023, on February 22, 2024, the Company granted 59,500 stock options under the PAVmed Inc 2014 Equity Plan with a weighted average exercise price of $1.85 for which will generally vest one-third after one year then ratably over the next eight quarters. In addition, on February 22, 2024, a total of 390,000 restricted stock awards were granted to the Board of Directors under the PAVmed 2014 Equity Plan, with such restricted stock awards having an aggregate fair value of approximately $0.7 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 restricted stock awards vest ratably on an annual basis over a three year period with the initial annual vesting date of November 30, 2024. The restricted stock awards are subject to forfeiture if the requisite service period is not completed.

Note 14 — Stock-Based Compensation - continued

PAVmed Restricted Stock Awards

PAVmed restricted stock awards granted under the PAVmed 2014 Equity Plan and restricted stock awards granted outside such plan are summarized as follows:

	Number of Restricted Stock Awards		Weighted Average Grant Date Fair Value
Outstanding restricted stock awards as of December 31, 2021[2]	111,109	$	35.40
Granted	—	$	—
Vested	(36,111)	$	17.94
Forfeited	(10,000)	$	30.60
Unvested restricted stock awards as of December 31, 2022[1]	64,998	$	45.76
Granted	12,195		5.79
Vested	(6,666)		46.50
Forfeited	—		—
Unvested restricted stock awards as of December 31, 2023	70,527	$	38.77

(1) The unvested restricted stock awards presented in the table above, are inclusive of 6,666 restricted stock awards granted outside the PAVmed 2014 Equity Plan as of December 31, 2022. These 6,666 restricted stock awards were fully vested during the period ended December 31, 2023.

(2) Share activity and weighted average grant date fair values include immaterial rounding due to the Company's 1-for-15 reverse stock split.

Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan

The Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan ("Lucid Diagnostics 2018 Equity Plan") is separate and apart from the PAVmed 2014 Equity Plan discussed above. The Lucid Diagnostics 2018 Equity Plan is designed to enable Lucid Diagnostics to offer employees, officers, directors, and consultants, an opportunity to acquire shares of common stock of Lucid Diagnostics. The types of awards that may be granted under the Lucid Diagnostics 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 compensation committee.

A total of 11,644,000 shares of common stock of Lucid Diagnostics are reserved for issuance under the Lucid Diagnostics 2018 Equity Plan, with 2,832,133 shares available for grant as of December 31, 2023. The share reservation is not diminished by a total of 423,300 stock options and 50,000 restricted stock awards granted outside the Lucid Diagnostics 2018 Equity Plan, as of December 31, 2023. In January 2024, the number of shares available for grant was increased by 2,680,038 in accordance with the evergreen provisions of the plan.

Note 14 — Stock-Based Compensation - continued

Lucid Diagnostics Stock Options

Lucid Diagnostics stock options granted under the Lucid Diagnostics 2018 Equity Plan and stock options granted outside such plan are summarized as follows:

	Number of Stock Options	Weighted Average Exercise Price	Remaining Contractual Term (Years)	Intrinsic Value[2]
Outstanding stock options at December 31, 2021	1,419,242	$ 0.73	7.0	
Granted[1]	2,365,000	$ 3.68		
Exercised	(965,342)	$ 0.72		
Forfeited	(253,523)	$ 3.83		
Outstanding stock options at December 31, 2022	2,565,377	$ 3.14	8.3	$ 428
Granted[1]	3,618,000	$ 1.32		
Exercised	—	$ —		
Forfeited	(678,994)	$ 2.75		
Outstanding stock options at December 31, 2023[3]	5,504,383	$ 2.00	8.5	$ 765
Vested and exercisable stock options at December 31, 2023	2,339,527	$ 2.30	7.8	$ 529

(1) Stock options granted under the Lucid Diagnostics 2018 Equity Plan and those granted outside such plan generally vest one-third in one year then ratably over the next eight quarters, 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 Lucid Diagnostics common stock on each of December 31, 2023 and December 31, 2022 and the exercise price of the underlying Lucid Diagnostics stock options, to the extent such quoted price is greater than the exercise price.

(3) The outstanding stock options presented in the table above, are inclusive of 423,300 stock options granted outside the Lucid Diagnostics 2018 Equity Plan, as of December 31, 2023 and December 31, 2022.

Subsequent to December 31, 2023, on February 22, 2024, Lucid granted 2,895,000 stock options under the Lucid Diagnostics Inc 2018 Equity Plan with a weighted average exercise price of $1.25 for which will generally vest one-third after one year then ratably over the next eight quarters.

Lucid Diagnostics Restricted Stock Awards

Lucid Diagnostics restricted stock awards granted under the Lucid Diagnostics 2018 Equity Plan and restricted stock awards granted outside such plan are summarized as follows:

	Number of Restricted Stock Awards	Weighted Average Grant Date Fair Value
Unvested restricted stock awards as of December 31, 2021	1,940,740	$ 12.76
Granted	320,000	4.53
Vested	(169,320)	13.48
Forfeited	—	—
Unvested restricted stock awards as of December 31, 2022[1]	2,091,420	$ 11.44
Granted	550,000	1.29
Vested	(303,980)	11.95
Forfeited	—	—
Unvested restricted stock awards as of December 31, 2023	2,337,440	$ 8.99

(1) The unvested restricted stock awards presented in the table above, are inclusive of 50,000 restricted stock awards granted outside the Lucid Diagnostics 2018 Equity Plan as of December 31, 2022. These 50,000 restricted stock awards were fully vested during the period ended December 31, 2023.

Note 14 — Stock-Based Compensation - continued

Consolidated Stock-Based Compensation Expense

The consolidated stock-based compensation expense recognized by each of PAVmed and Lucid Diagnostics for both the PAVmed 2014 Equity Plan and the Lucid Diagnostics 2018 Equity Plan, with respect to stock options and restricted stock awards as discussed above, for the periods indicated, was as follows:

	Years Ended December 31,	
	2023	2022
Cost of revenue	$ 122	$ 16
Sales and marketing expenses	1,715	2,464
General and administrative expenses	7,935	16,001
Research and development expenses	1,367	1,051
Total stock-based compensation expense	$ 11,139	$ 19,532

Stock-Based Compensation Expense Recognized by Lucid Diagnostics

As noted, the consolidated stock-based compensation expense presented above is inclusive of stock-based compensation expense recognized by Lucid Diagnostics, inclusive of each of: stock options granted under the PAVmed 2014 Equity Plan to the three physician inventors of the intellectual property underlying the Amended CWRU License Agreement; and stock options and restricted stock awards granted to employees of PAVmed and non-employee consultants under the Lucid Diagnostics 2018 Equity Plan. The stock-based compensation expense recognized by Lucid Diagnostics for both the PAVmed 2014 Equity Plan and the Lucid Diagnostics 2018 Equity Plan, with respect to stock options and restricted stock awards as discussed above, for the periods indicated, was as follows:

	Years Ended December 31,	
	2023	2022
Lucid Diagnostics 2018 Equity Plan – cost of revenue	$ 63	$ 13
Lucid Diagnostics 2018 Equity Plan – sales and marketing	948	968
Lucid Diagnostics 2018 Equity Plan – general and administrative	4,455	12,691
Lucid Diagnostics 2018 Equity Plan – research and development	296	187
PAVmed 2014 Equity Plan - cost of revenue	37	3
PAVmed 2014 Equity Plan - sales and marketing	463	654
PAVmed 2014 Equity Plan - general and administrative	173	262
PAVmed 2014 Equity Plan - research and development	387	213
Total stock-based compensation expense – recognized by Lucid Diagnostics	$ 6,822	$ 14,991

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 2014 Equity Plan and the Lucid Diagnostics 2018 Equity Plan, as discussed above, is as follows:

	Unrecognized Expense	Weighted Average Remaining Service Period (Years)
PAVmed 2014 Equity Plan		
Stock Options	$ 3,799	1.8
Restricted Stock Awards	$ 185	1.1
Lucid Diagnostics 2018 Equity Plan		
Stock Options	$ 3,566	2.0
Restricted Stock Awards	$ 1,167	2.2

Note 14 — Stock-Based Compensation - continued

Stock-based compensation expense recognized with respect to stock options granted under the PAVmed 2014 Equity Plan was based on a weighted average estimated fair value of such stock options of $4.90 per share and $16.50 per share during the years ended December 31, 2023 and 2022, respectively, calculated using the following weighted average Black-Scholes valuation model assumptions:

	Years Ended December 31,	
	2023	2022
Expected term of stock options (in years)	5.6	5.8
Expected stock price volatility	88%	88%
Risk free interest rate	3.8%	2.2%
Expected dividend yield	—%	—%

Stock-based compensation expense recognized with respect to stock options granted under the Lucid Diagnostics 2018 Equity Plan was based on a weighted average estimated fair value of such stock options of $0.88 per share and $2.30 per share during the years ended December 31, 2023 and 2022, respectively, calculated using the following weighted average Black-Scholes valuation model assumptions:

	Years Ended December 31,	
	2023	2022
Expected term of stock options (in years)	5.6	5.6
Expected stock price volatility	74%	71%
Risk free interest rate	3.9%	2.1%
Expected dividend yield	—%	—%

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

A total of 38,216 shares and 12,950 shares of common stock of the Company were purchased for proceeds of approximately $182 and $218, on March 31, 2023 and 2022, respectively, under the PAVmed ESPP. A total of 20,267 shares and 12,780 shares of common stock of the Company were purchased for proceeds of approximately $76 and $140, on September 30, 2023 and 2022, respectively, under the PAVmed ESPP. The March 31, 2023 purchase was partially settled through the redeployment of 12,590 shares of treasury stock. The September 30, 2022 purchase was settled through the redeployment of treasury stock. The PAVmed ESPP has a total reserve of 133,334 shares of common stock of PAVmed of which 7,528 shares are available for issue as of December 31, 2023. In January 2024, the number of shares available-for-issue was increased by 166,667 in accordance with the evergreen provisions of the plan.

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

A total of 231,987 shares of common stock of Lucid Diagnostics were purchased for proceeds of approximately $276 on March 31, 2023 under the Lucid ESPP. A total of 276,213 and 84,030 shares of common stock of Lucid Diagnostics were purchased for proceeds of approximately $275 and $109 on September 30, 2023 and 2022, respectively, under the Lucid ESPP.The Lucid ESPP has a total reserve of 1,000,000 shares of common stock of Lucid Diagnostics of which 407,770 shares are available for issue as of December 31, 2023. In January 2024, the Lucid board authorized an increase in the number of shares available for issue by 500,000.

Note 15 — Preferred Stock

As of December 31, 2023 and December 31, 2022, there were 1,305,213 and 1,205,759 shares of PAVmed Series B Convertible Preferred Stock, classified in permanent equity, issued and outstanding, respectively.

PAVmed Series B Convertible Preferred Stock Dividends

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 was immediately convertible upon its issuance. At the holders' election, fifteen shares of Series B Convertible Preferred Stock are currently convertible into one share of common stock of the Company, subject to further adjustment for the effect of future 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.

Note 15 — Preferred Stock - continued

The PAVmed Inc. Series B Convertible Preferred Stock dividends are 8.0% 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. Such dividends may be settled, at the discretion of the board of directors, through any combination of the issue of additional shares of Series B Convertible Preferred Stock, the issue shares of common stock of the Company, and /or cash payment.

PAVmed Series B Convertible Preferred Stock Dividends Earned

The Series B Convertible Preferred Stock dividends earned are included in the calculation of basic and diluted net loss attributable to PAVmed common stockholders for each of the respective corresponding periods presented in the accompanying consolidated statement of operations, inclusive of $304 of such dividends earned in the year ended December 31, 2023; and $281 of such dividends earned in the year ended December 31, 2022.

PAVmed Series B Convertible Preferred Stock Dividends Declared

During the year ended December 31, 2023, the Company's board of directors declared an aggregate of approximately $298 of Series B Convertible Preferred Stock dividends, earned as of December 31, 2022; March 31, 2023; June 30, 2023; and September 30, 2023, which have been settled by the issue of an additional aggregate 99,454 shares of Series B Convertible Preferred Stock.

During the year ended December 31, 2022, the Company's board of directors declared an aggregate of approximately $276 of Series B Convertible Preferred Stock dividends, earned as of December 31, 2021; March 31, 2022; June 30, 2022; and September 30, 2022, which have been settled by the issue of an additional aggregate 91,885 shares of Series B Convertible Preferred Stock.

Subsequent to December 31, 2023, in January 2024, the Company's board of directors declared a PAVmed Series B Convertible Preferred Stock dividend, earned as of December 31, 2023, of $78, to be settled by the issue of 26,123 additional shares of Series B Convertible Preferred Stock.

The PAVmed Series B Convertible Preferred Stock dividends are recognized as a dividend payable liability only upon the dividend being declared payable by the Company's board of directors. Accordingly, the dividends declared payable subsequent to the date of the accompanying consolidated balance sheet were not recognized as a dividend payable liability as the Company's board of directors had not declared the dividends payable as of each such date.

Note 16 — Common Stock and Common Stock Purchase Warrants

Common Stock

In February 2023, the Company distributed a proxy statement for a special meeting of shareholders that was held on March 31, 2023 (the "Special Meeting"), at which the Company sought approval of an amendment to the Company's Certificate of Incorporation, to effect, (i) a reverse split of the Company's outstanding shares of common stock at a specific ratio, ranging from 1-for-5 to 1-for-15, to be determined by the board of directors of the Company in its sole discretion, and (ii) an associated reduction in the number of shares of common stock the Company is authorized to issue, from 250,000,000 shares to 50,000,000 shares. On March 31, 2023, the shareholders approved the above proposal to amend the Company's Certificate of Incorporation, to effect, at any time prior to the one-year anniversary date of the Special Meeting. On November 28, 2023 the Company's board of directors, unanimously authorized management to effect the reverse split at the ratio of 1-for-15. The reverse stock split became effective on December 7, 2023. At the effective date, every 15 shares of the Company's common stock that were issued and outstanding were automatically combined into one issued and outstanding share, without any change in par value of such shares. No fractional shares were issued in connection with the reverse stock split. Instead, each fractional share remaining after completion of the reverse stock split that was less than a whole share was rounded up to one whole share. The reverse stock split also correspondingly affected all outstanding PAVmed equity awards and outstanding convertible securities.

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

A total of 100,000 shares of PAVmed common stock were issued to an unrelated service provider as the consideration for the services rendered under a research and development agreement dated May 31, 2023 ("May 31, 2023 R&D Agreement"). The shares were issued as consideration for a contractual minimum fair market value of $750, with such derived fair market value computed using a contractual formula based on the PAVmed Inc. common stock volume weighted average price per share ("VWAP") during the last ten days of the six month anniversary of the May 31, 2023 R&D Agreement. If the such fair market value was less than $750, then, the Company would incur an additional contractual consideration obligation in amount equal to the difference between the required minimum fair market value of $750 and the contractual formula based computed fair market value. On the six month anniversary, November 30, 2023, the contingent reconciliation payment was calculated to be $390, based on the prior 10 day VWAP calculation, with the change in the estimated fair value recognized as other income (expense).

During the year ended December 31, 2023 a total of 58,483 shares of common stock of the Company were issued under the PAVmed ESPP. See Note 14, *Stock-Based Compensation*, for a discussion of each of the PAVmed 2014 Equity Plan and the PAVmed ESPP.

In the year ended December 31, 2023, 1,745,824 shares of the Company's common stock were issued upon conversion, at the election of the holder, of the April 2022 Senior Convertible Note and the September 2022 Senior Convertible Note, for $6,083 face value principal repayments, as discussed in Note 13, *Debt*.

In the year ended December 31, 2023, the Company sold 321,288 shares through their at-the-market equity facility for net proceeds of approximately $1,823, after payment of 3% commissions. As of December 31, 2023, the Company had $291 of net proceeds due from broker. Subsequent to December 31, 2023, as of March 21, 2024, the Company sold 133,299 shares through their at-market equity facility for net proceeds of approximately $495, after payment of 3% commissions.

PAVmed Distribution of Lucid Diagnostics Common Stock to Shareholders

On February 15, 2024, the Company distributed by special dividend to the Company stockholders 3,331,747 shares of Lucid Diagnostics common stock held by the Company. On such date, each PAVmed shareholder as of the January 15, 2024 record date received a stock dividend of approximately 38 shares of Lucid common stock for every 100 shares of PAVmed common stock they held as of such date. The shares distributed were approximately equal to the number of shares of common stock that Lucid issued to PAVmed on or about January 26, 2024 in satisfaction of certain intercompany obligations due to Lucid from PAVmed.

Common Stock Purchase Warrants

As of December 31, 2023 and December 31, 2022, Series Z Warrants outstanding totaled 11,937,450 representing the right to purchase 795,830 shares of the Company's common stock. The Series Z Warrants are now exercisable to purchase one whole share of common stock of the Company at an exercise price of $23.48 ($24.00 post reverse-split, decreased by $0.52 due to distribution of Lucid common stock to PAVmed stockholders, discussed further below). On December 4, 2023, the Company announced the extension of the Company's Series Z Warrants, by 12 months, to April 30, 2025. The Company recognized the incremental value associated with the Z Warrants modification for the term extension as a deemed dividend charge of $1,791 and as an increase of net loss available to common stockholders on the consolidated statements of operations in 2023. The incremental value associated with the Z Warrants modification was determined using a Black-Scholes pricing model using the modified terms of the Z Warrants with the following assumptions: expected term of 1.41 years, dividend yield of 0%, volatility of 233%, and a risk-free rate of 4.79%, compared to the publicly traded closing price of PAVMZ on the date immediately preceding the modification. There were no Series Z Warrants exercised during the year ended December 31, 2023.

The Company's distribution of Lucid common stock to PAVmed stockholders, described above, constituted an "Extraordinary Dividend" as defined in the Warrant Agreement. Accordingly, as a result of the distribution, pursuant to Section 4.3 of the Warrant Agreement, the Warrant Price has been decreased by $0.52 (the fair market value of 0.37709668 of a share of Lucid Diagnostics' common stock) to $23.48 per share.

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:

	December 31, 2023	December 31, 2022
NCI – equity	$ 20,615	$ 17,752
Net loss attributable to NCI	(15,088)	(14,255)
Impact of subsidiary equity transactions	(1,983)	28
Lucid Diagnostics proceeds from issuance of preferred stock	18,625	—
Lucid Diagnostics proceeds from At-The-Market Facilities, net of deferred financing charges	284	1,767
Lucid Diagnostics issuance of common stock for settlement of APA-RDx installment and termination payment	713	653
Lucid Diagnostics issuance of common stock for settlement of vendor service agreement	147	—
Lucid Diagnostics 2018 Equity Plan stock option exercise	—	695
Lucid Diagnostics Employee Stock Purchase Plan Purchase	551	109
Conversion of Lucid Diagnostics common stock for Senior Secured Convertible Debt	167	—
Stock-based compensation expense - Lucid Diagnostics 2018 Equity Plan	5,762	13,859
Stock-based compensation expense - Veris Health 2021 Equity Plan	20	7
NCI – equity	$ 29,813	$ 20,615

The consolidated NCI presented above is with respect to the Company's consolidated majority-owned subsidiaries as a component of consolidated total stockholders' equity as of December 31, 2023 and December 31, 2022; and the recognition of a net loss attributable to the NCI in the consolidated statement of operations for the periods beginning on the acquisition date of the respective majority-owned subsidiaries.

Lucid Diagnostics

As of December 31, 2023, there were 42,329,864 shares of common stock of Lucid Diagnostics issued and outstanding, of which, PAVmed held 31,302,420 shares, representing a majority ownership equity interest and PAVmed has a controlling financial interest in Lucid Diagnostics, and accordingly, Lucid Diagnostics is a consolidated majority-owned subsidiary of PAVmed.

On March 7, 2023, Lucid issued 13,625 shares of newly designated Lucid Series A Convertible Preferred Stock (the "Lucid Series A Preferred Stock"). Each share of the Lucid Series A Preferred Stock has a stated value of $1,000 and a conversion price of $1.394. The Lucid Series A Preferred Stock is convertible into shares of Lucid Diagnostics' common stock at any time at the option of the holder from and after the six-month anniversary of its issuance, and automatically converts into shares of Lucid Diagnostics' common stock on the second anniversary of its issuance. The terms of the Lucid Series A Preferred Stock also include a one times preference on liquidation and a right to receive dividends equal to 20% of the number of shares of Lucid common stock into which such Lucid Series A Preferred Stock is convertible, payable on the one-year and two-year anniversary of the issuance date. The Lucid Series A Preferred Stock is a non-voting security, other than with respect to limited matters related to changes in terms of the Lucid Series A Preferred Stock. The aggregate gross proceeds from the sale of shares in such offering were $13.625 million.

On October 17, 2023, Lucid issued 5,000 shares of newly designated Lucid Series A-1 Convertible Preferred Stock (the "Lucid Series A-1 Preferred Stock"). The terms of the Lucid Series A-1 Preferred Stock are substantially identical to the terms of the Lucid Series A Preferred Stock, except that the Lucid Series A-1 Preferred Stock has a conversion price of $1.2592. The aggregate gross proceeds from the sale of shares in such offering were $5.0 million.

In November 2022, Lucid Diagnostics entered into an "at-the-market offering" for up to $6.5 million of its common stock that may be offered and sold under a Controlled Equity Offering Agreement between Lucid Diagnostics and Cantor Fitzgerald & Co. In the year ended December 31, 2023, Lucid Diagnostics sold 230,068 shares through their at-the-market equity facility for net proceeds of approximately $0.3 million, after payment of 3% commissions.

Note 17 — Noncontrolling Interest - continued

Subsequent to December 31, 2023, on January 26, 2024 PAVmed elected to receive payment of $4,675 of fees and reimbursements due from Lucid, through the issuance of 3,331,771 shares of Lucid Diagnostics common stock. On February 15, 2024, the Company distributed by special dividend to the Company stockholders, as of the record date noted above, 3,331,747 shares of Lucid Diagnostics common stock held by the Company.

On March 13, 2024, Lucid issued an additional 5,670 shares of Lucid Series A-1 Preferred Stock, for aggregate gross proceeds of $5.67 million.

On March 13, 2024, Lucid issued 44,285 shares of newly designated Lucid Series B Convertible Preferred Stock (the "Lucid Series B Preferred Stock"). The terms of the Lucid Series B Preferred Stock are substantially identical to the terms of the Lucid Series A Preferred Stock and the Lucid Series A-1 Preferred Stock, except that the Lucid Series B Preferred Stock has a conversion price of $1.2444, and the holders of the Lucid Series B Preferred Stock vote with the common stock on an as-converted basis (subject to any applicable ownership limitations). On the same day, Lucid issued an additional 5,670 shares of Lucid Series A-1 Preferred Stock, for aggregate gross proceeds of $5.67 million (all of which shares were immediately exchange for shares of Lucid Series B Preferred Stock). The aggregate gross proceeds from the sale of shares in such offering were $18.1 million.

As a result of 100% of the then-outstanding shares of Lucid Series A Preferred Stock and Lucid Series A-1 Preferred Stock being exchanged for shares of Lucid Series B Preferred Stock in the Lucid Series B Offering and Exchange, no shares of Lucid Series A Preferred Stock or Lucid Series A-1 Preferred Stock remain outstanding.

Veris Health

As of December 31, 2023, there were 8,000,000 shares of common stock of Veris Health issued and outstanding, of which PAVmed holds an 80.44% majority-interest ownership and PAVmed has a controlling financial interest, with the remaining 19.56% minority-interest ownership held by an unrelated third-party. Accordingly, Veris Health 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 accompanying consolidated balance sheets.

Note 18 — Income Taxes

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

	Years Ended December 31,	
	2023	2022
Current		
Federal, State and Local	$ —	$ —
Deferred		
Federal	(16,789)	(24,265)
State and Local	(19,323)	11,124
Current and Deferred tax (benefit) expense	(36,112)	(13,141)
Less: Valuation allowance reserve	36,112	13,141
Income tax expense (benefit)	$ —	$ —

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

	Years Ended December 31,	
	2023	2022
U.S. federal statutory rate	21.0%	21.0%
U.S. state and local income taxes, net of federal benefit	6.1%	6.6%
Permanent differences	(2.7)%	(1.0)%
Tax credits	2.2%	1.3%
Revaluation of state deferred taxes	—%	(15.2)%
Federal deferred true-up	5.8%	—%
State deferred true-up	13.2%	—%
Valuation allowance	(45.6)%	(12.7)%
Effective tax rate	—%	—%

Note 18 — Income Taxes - continued

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

	Years Ended December 31,	
	2023	2022
Deferred Tax Assets		
Net operating loss	$ 67,786	$ 37,032
Debt issue costs	537	922
Stock-based compensation expense	12,304	11,105
Lease liabilities	1,266	836
Research and development expenditures	8,234	6,193
Research and development tax credit carryforwards	3,481	1,719
Accrued expenses	385	311
Section 195 deferred start-up costs	17	15
Depreciation & amortization	$ 800	$ 221
Deferred tax assets	$ 94,810	$ 58,354
Deferred Tax Liabilities		
Operating lease right-of-use assets	(1,194)	(850)
Depreciation	—	—
Patent licenses	—	—
Deferred Tax Liabilities	$ (1,194)	$ (850)
Deferred tax assets, net of deferred tax liabilities	93,616	57,504
Less: valuation allowance	(93,616)	(57,504)
Deferred tax assets, net after valuation allowance	$ —	$ —

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

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, 2023 and 2022. As of December 31, 2023 and 2022, the deferred tax asset valuation allowance increased by $36,112 and $13,141, respectively.

The Company has total estimated federal net operating loss ("NOL") carryforward of approximately $236.3 million and $158.4 million as of December 31, 2023 and 2022, respectively, which is available to reduce future taxable income, of which approximately $13.8 million have statutory expiration dates commencing in 2037, and approximately $222.5 million which do not have a statutory expiration date. The Company has not yet conducted a formal analysis and the NOL carryforward and general business credits 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 $260.0 million have statutory expiration dates commencing in 2037. The Company has total estimated research and development ("R&D") tax credit carryforward of approximately $3.4 million as of December 31, 2023 which are available to reduce future tax expense and have statutory expiration dates commencing in 2037.

Note 18 — Income Taxes - continued

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.

In August 2022, the U.S. Congress passed the Inflation Reduction Act, which included a corporate minimum tax on book earnings of 15%, an excise tax on corporate share repurchases of 1%, and certain climate change and energy tax credit incentives. The adoption of a corporate minimum tax of 15% is not expected to impact PAVmed's effective tax rate. The excise tax of 1% on corporate share buybacks will not have an impact on the Company's effective tax rate.

Note 19 — Net Loss Per Share

The Net loss per share - attributable to PAVmed Inc. - basic and diluted and Net loss per share - attributable to PAVmed Inc. common stockholders - basic and diluted - for the respective periods indicated - is as follows:

	Years Ended December 31,	
	2023	2022
Numerator		
Net loss - before noncontrolling interest	$ (79,263)	$ (103,238)
Net loss attributable to noncontrolling interest	15,088	14,255
Net loss - as reported, attributable to PAVmed Inc.	$ (64,175)	$ (88,983)
Deemed dividend on Series Z warrant modification	$ (1,791)	$ —
Series B Convertible Preferred Stock dividends – earned	$ (304)	$ (281)
Net loss attributable to PAVmed Inc. common stockholders	$ (66,270)	$ (89,264)
Denominator		
Weighted average common shares outstanding, basic and diluted	7,231,546	5,938,406
Net loss per share [(1)]		
Basic and diluted		
Net loss attributable to PAVmed Inc. common stockholders	$ (9.16)	$ (15.03)

(1)- Convertible Preferred Stock would potentially be considered a participating security under the two-class method of calculating net loss per share. However, the Company has incurred net losses to-date, and as such holders are not contractually obligated to share in the losses, there is no impact on the Company's net loss per share calculation for the periods indicated.

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 each of the respective years noted, are included in the calculation of basic and diluted net loss attributable to PAVmed 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.

Note 19 — Net Loss Per Share - continued

Basic weighted-average number of shares of common stock outstanding for the years ended December 31, 2023 and 2022 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 of 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 years 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:

	December 31,	
	2023	**2022**
Stock options and restricted stock awards	1,262,985	836,151
Series Z Warrants	795,830	795,830
Series B Convertible Preferred Stock	87,015	80,384
Total	2,145,830	1,712,365

The total stock options and restricted stock awards are inclusive of 60,057 and 33,391 stock options as of December 31, 2023 and 2022, respectively; and 6,666 restricted stock awards as of December 31, 2022 granted outside the PAVmed 2014 Equity Plan. These 6,666 restricted stock awards were fully vested during the year ended December 31, 2023.

BOARD OF DIRECTORS

Lishan Aklog, M.D.
Chairman and Chief Executive Officer of PAVmed Inc.

Michael J. Glennon
Vice Chairman of PAVmed Inc., Co-Founding Partner of Pavilion Holdings Group, a medical device holding company, Chairman and Chief Executive Officer of Pavilion Medical Innovations, a medical device incubator, and President and Chief Executive Officer of Saphena Medical and Cruzar Medsystems

Timothy E. Baxter
Operating Partner at Centre Partners Management LLC, a leading middle market private equity firm

James L. Cox, M.D.
Surgical Director of the Center for Heart Rhythm Disorders at the Bluhm Cardiovascular Institute and the Visiting Professor of Surgery at the Feinberg School of Medicine at Northwestern University

Joan Harvey
President of Care Solutions for Evernorth, Cigna Corporation's health services business

Ronald M. Sparks
Former Healthcare Industry Executive at Avista Capital Partners, a private equity firm

Debra J. White
Former Group Chief Executive Officer of Interserve Group, a UK-headquartered multinational group of support services and construction companies

CORPORATE OFFICERS

Lishan Aklog, M.D.
Chairman and Chief Executive Officer

Dennis M. McGrath
President and Chief Financial Officer

Shaun M. O'Neil
Chief Operating Officer

Michael A. Gordon
General Counsel and Secretary

CORPORATE INFORMATION

Transfer Agent

The transfer agent and registrar for PAVmed Inc.'s common stock is Continental Stock Transfer & Trust Company, 1 State Street, 30th Floor, New York, New York 10004.

Stock Listing

PAVmed Inc's. common stock and Series Z warrants trade on the Nasdaq Capital Market under the symbols PAVM and PAVMZ, respectively.

Annual Meeting

The annual meeting of stockholders will be held on June 20, 2024 at 10:00 a.m., Eastern time, solely over the Internet by means of a live audio webcast.

Corporate Headquarters

360 Madison Avenue, 25th Floor
New York, New York 10017

Exhibits

The Company will provide stockholders with copies of the exhibits to its Form 10-K upon payment of a fee of $.25 per page, plus $5.00 postage and handling charge, if a request is sent in writing to the Secretary, PAVmed Inc., 360 Madison Avenue, 25th Floor, New York, New York 10017.