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: 001-40901

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

Delaware	**82-5488042**
(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	LUCD	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 $14.4 million, based on 10,331,863 shares of common stock held by non-affiliates and a last reported sales price per share of the registrant's common stock of $1.39 on such date.

As of March 21, 2024 there were 48,244,798 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 Lucid Diagnostics Inc. 2018 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;
- risks related to our relationship with PAVmed; 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

Lucid Diagnostics Inc. ("Lucid") is a commercial-stage medical diagnostics technology company focused on the millions of patients with gastroesophageal reflux disease ("GERD"), also known as chronic heartburn, acid reflux or simply reflux, who are at risk of developing esophageal precancer and cancer, specifically highly lethal esophageal adenocarcinoma ("EAC"). References in this Form 10-K to "we," "us" and "our" are to Lucid and, unless the context otherwise requires, its subsidiaries.

We believe that our flagship product, 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 EAC deaths, through early detection of esophageal precancer in at-risk GERD patients.

EsoGuard is a bisulfite-converted targeted 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). Analytical validation tests of EsoGuard demonstrated approximately 97% analytical sensitivity, 95% analytical specificity, approximately 98% analytical accuracy, and 100% inter-assay and intra-assay precision. Two independent clinical validation case control studies funded by the National Institute of Health utilized were performed using upper endoscopy with biopsies as the diagnostic comparator and confirmed EsoGuard accurately identifies BE. A pooled analysis of both studies demonstrated 84% sensitivity (95% confidence interval [CI] 76-90%), for detection of BE, and 86% specificity (95% CI 81-91%). Positive predictive value (PPV) and negative predictive value (NPV) were calculated using a BE prevalence of 10.6% published in a meta-analysis of U.S patients with GERD. This resulted in a PPV of approximately 42% and NPV of around 98%.

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 our 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 our 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 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 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, we are aggressively pursuing EsoGuard commercial insurer payment and coverage. Although the claim adjudication cycle can be prolonged during the early commercialization of a new test, we have received and are continuing 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.

We continue 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 evaluates 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.

Additionally, 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. Combined interim results from the PREVENT and PREVENT-FF registries focusing on provider decision impact have previously been accepted for peer review publication in Journal of Gastroenterology & Digestive Systems (ISSN: 2640-7477). 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 our license agreement with CWRU (as amended to date, the "Amended CWRU License Agreement"), we acquired an exclusive worldwide right to use the intellectual property rights to the EsoGuard and EsoCheck technology for the detection of changes in the esophagus and on sample preservation. We are 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. We are 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"). Our subsidiary LucidDx Labs and RDx agreed to terminate the MSA RDx effective as of February 10, 2023, such that LucidDx Labs from and after such date has operated 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 for some time until it fully dissolves 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.

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.

EsoCure

The EsoCure Esophageal Ablation Device is a novel technology that allows 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.

In connection with our efforts to expand our presence in the EAC diagnostic market, in March 2022, PAVmed and Lucid entered into an intercompany license agreement whereby Lucid was granted the rights to commercialize EsoCure for the treating dysplastic BE. Under the intercompany license, Lucid will pay PAVmed a 5% royalty on all EsoCure sales up to $100 million per calendar year, and 8% above that threshold.

PAVmed has 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, PAVmed may conduct additional development work and animal testing of EsoCure to support a future FDA 510(k) submission.

Our Relationship with PAVmed

We are a majority-owned subsidiary of PAVmed, and PAVmed has a controlling financial interest. We continue to depend on PAVmed to provide us various management, technical, research and development, legal, accounting, and administrative services.

PAVmed owns approximately 70.1% as of December 31, 2023 and 64.9% as of March 21, 2024 of the combined voting power of our outstanding common stock (with such percentage inclusive of shares of our common stock underlying granted but unvested restricted stock awards), but excluding the voting power of any convertible securities. Presently, PAVmed controls more than 50% of the combined voting power of our common stock and our convertible securities. However, PAVmed's percentage of the combined voting power may decrease when dividends are paid on our convertible securities and to the extent our convertible securities are converted into shares of our common stock. For as long as PAVmed continues to control more than 50% of our voting securities, PAVmed will be able to direct the election of all the members of our board of directors. Similarly, PAVmed will have the power to determine matters submitted to a vote of our stockholders without the consent of our other stockholders, to prevent a change in control of us, and to take other actions that might be favorable to PAVmed, without prior notice to other stockholders. Even if PAVmed's ownership falls below 50%, PAVmed may retain substantial influence on such matters and may remain our controlling stockholder. PAVmed's controlling interest may discourage a change of control that other holders of our common stock may favor.

We are party to a management services agreement with PAVmed (the "MSA"), as well as a payroll benefits and expense reimbursement agreement (the "PBERA"). Under the MSA, PAVmed provides management, technical and administrative services to us, including without limitation services related to research and development, regulatory clearance, manufacture, and commercialization of our products, as well as services related to corporate financial, accounting and legal matters. The terms of this agreement are intended to be consistent with the terms that we could have negotiated with unaffiliated third parties; however, they may actually be more or less favorable. Under the PBERA, PAVmed has agreed to pay certain payroll and benefit-related expenses in respect of our personnel on our behalf, and we reimburse PAVmed for the same. PAVmed may elect that our obligations under each of the MSA and the PBERA are settled by the issuance of our stock (instead of cash), subject to applicable restrictions under securities laws (and, in the case of the PBERA, subject also to approval by our board). The MSA does not have a termination date, but may be terminated by our board of directors at any time. The PBERA likewise does not have a termination date, but may be terminated by PAVmed or Lucid at any time.

Recent Events

Business

Intercompany Agreements with PAVmed

In January 2024, in accordance with the MSA and the PBERA, PAVmed elected to receive payment of $4.7 million of fees and reimbursements accrued under the MSA and the PBERA through the issuance of 3,331,771 shares of the Company's common stock.

In March 2024, the Company entered into an eighth amendment to the MSA with PAVmed, increasing the monthly fee due thereunder from $0.75 million to $0.83 million, effective as of January 1, 2024. The eighth amendment to the MSA was executed on March 22, 2024. Pursuant to the MSA, as amended by the eighth amendment, the parties agreed PAVmed may elect to receive payment of the monthly MSA Fee in cash or in shares of our common stock, with such shares valued at the volume weighted average price ("VWAP") during the final ten trading days of the applicable month (subject to a floor price of $0.70 per share). However, in no event will PAVmed be entitled to receive under the MSA, as amended, from and after the effective date of the eighth amendment to the MSA, more than 9,644,135 shares of our common stock (representing 19.99% of our outstanding shares of common stock as of immediately prior to the execution of the eighth amendment).

Financing

Preferred Stock Offerings

On March 13, 2024, we 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 our newly designated Series B Convertible Preferred Stock, par value $0.001 per share (the "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 our Series A Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), and 10,670 shares of our Series A-1 Convertible Preferred Stock, par value $0.001 per share (the "Series A-1 Preferred Stock"), held by them for 31,790 shares of Series B Preferred Stock (collectively, the "Series B Offering and Exchange"). Prior to the execution of the Series B Subscription Agreements and the Exchange Agreements, we entered into subscription agreements with certain of the Series B Investors providing for the sale to such investors of 5,670 shares of 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 Series B Preferred Stock pursuant to the Exchange Agreements (and are included in the 10,670 shares of Series A-1 Preferred Stock set forth above). Each share of the Series B Preferred Stock has a stated value of $1,000 and a conversion price of $1.2444. The terms of the 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 our common stock into which such Series B Preferred Stock is convertible, payable on the one-year and two-year anniversary of the issuance date. The Series B Preferred Stock votes with our common stock on an as converted basis (subject to certain beneficial ownership and Nasdaq limitations described elsewhere in this Form 10-K). The aggregate gross proceeds of these transactions was $18.16 million (inclusive of $5.67 million of aggregate gross proceeds from the sale of the Series A-1 Preferred Stock that was immediately exchanged for Series B Preferred Stock in the transactions).

All the shares of Series A Preferred Stock and Series A-1 Preferred Stock were exchanged for shares of Series B Preferred Stock in the Series B Offering and Exchange and, as a result, no shares of Series A Preferred Stock or Series A-1 Preferred Stock remain outstanding.

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

Intellectual Property

Our business will depend on proprietary medical device and diagnostic technologies, including the EsoCheck and EsoGuard technology licensed by us. We intend to vigorously protect our proprietary technologies' intellectual property rights in patents, trademarks and copyrights, as available through registration in the United States and internationally. Patent protection and other proprietary rights are thus essential to our business. We currently have applied for, license or own 20 domestic and foreign patents covering the EsoGuard and EsoCheck products and related 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

The EsoCheck and EsoGuard technology is protected by patents in the United States and internationally, and our policy is to continue to aggressively file patent applications, both independently and in collaboration with CWRU, as appropriate, to protect this technology and other of our proprietary technologies relating to our business, including inventions and improvements to inventions. Under the CWRU License Agreement, CWRU has agreed to apply for patent coverage, at our expense, in any country requested by us, to the extent such protection is reasonably attainable. We seek patent protection, as appropriate, on:

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

In addition to filing and prosecuting patent applications in the United States, we intend to file counterpart patent applications in other countries 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, 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 the position of our business in the United States and internationally. Prior to acquiring or licensing a technology from a third party, we will evaluate the existing proprietary rights, our ability to adequately obtain and protect these rights and the likelihood or possibility of infringement upon competing rights of others.

We also rely upon trade secrets, know-how, continuing technological innovation, and may rely upon licensing opportunities, to develop and maintain our competitive position. We 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 assign to us all new and improved intellectual property that arise during the term of the agreement.

Lucid also has proprietary rights to a range of trademarks, including, among others, Lucid Diagnostics™, LUCID™, EsoCheck®, EsoGuard®, Collect + Protect®, and EsoCheck Cell Collection Device®. (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, Lucid 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.

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

Government Regulation

Key U.S. Regulation

FDA Regulation

For the purposes of FDA regulation a "medical device" is broadly defined in section 201(h) of the FDCA as "an instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, which is intended for use in humans for the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body, and which does not achieve its primary intended purposes through chemical action and which is not dependent upon being metabolized for the achievement of its primary intended purposes." Medical devices subject to FDA regulation include "in-vitro diagnostic medical devices" or IVD devices, defined in the same FDCA section as "reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae, which are intended for use in the collection, preparation, and examination of specimens taken from the human body".

Our marketing of any medical device product we may develop, license, or acquire, including traditional medical devices such as EsoCheck, and IVD products such as EsoGuard, is subject to FDA regulation.

- In June 2019, we received FDA 510(k) clearance for EsoCheck, permitting us to market it in the U.S. as a cell collection device indicated for use in the collection and retrieval of surface cells of the esophagus in the general population of adults, 22 years of age and older. In 2022, we received FDA clearance to expand EsoCheck's indications for use to include adults and adolescents, 12 years of age and older. In 2023, we further received FDA clearance to permit us to market EsoCheck as non-sterile.
- In December 2019, RDx, our then-CLIA-certified laboratory partner completed documentation of EsoGuard analytical validity allowing us to commercialize it as an LDT. In March 2022, we transferred EsoGuard testing to our own CLIA-certified laboratory, upon our acquisition of certain assets from RDx as described elsewhere in this report.

FDA defines an LDT as "an IVD product that is intended for clinical use and designed, manufactured and used within a single laboratory." FDA has long maintained that it has clear regulatory authority over LDTs and has chosen to fully exercise its authority for certain classes of "single laboratory" IVD products which would satisfy its definition of an LDT, such as direct-to-consumer tests that do not involve a health care provider. FDA, however, has generally not enforced these regulatory requirements for most LDTs not in one of these classes and has generally not required these LDTs to undergo FDA premarket review of analytical validity and clinical validity, as all other IVD products must.

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.

Since only EsoCheck is FDA cleared, we are not permitted to jointly market it with EsoGuard. This currently is not a significant obstacle to our commercialization efforts, which are almost entirely devoted to marketing EsoGuard. EsoCheck is merely offered, free of charge, as a generic esophageal cell collection device, which is FDA 510(k) cleared to be used to collect samples for any diagnostic test. We believe, however, over the long-term, once our commercialization efforts have gained significant traction, it would be useful to jointly market EsoGuard, used with EsoCheck, as a combined product. We therefore may, when resources permit, pursue FDA PMA approval for EsoGuard, when used on samples collected with EsoCheck, which will allow us to jointly market them as well as provide protection against changes to LDT regulation which could threaten our ability to market EsoGuard as an LDT.

FDA "Breakthrough Device" is highly-coveted special designation under FDA's Breakthrough Devices Program, established pursuant to the 21st Century Cures Act and the FDA Reauthorization Act of 2017, which seeks to offer patients and healthcare providers timely access to medical devices which "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions" by speeding up their development, assessment and review through (i) enhanced communications, (ii) more efficient and flexible clinical study design, including more favorable pre/post market data collection balance and (iii) priority review of regulatory submissions. Once effective, MCIT would provide each Breakthrough Device with four years of national Medicare coverage starting on the date of FDA market authorization. In February 2020 we were granted Breakthrough Device designation for EsoGuard on esophageal samples collected using EsoCheck. Pursuant to this designation and as defined by the final policy to be released by FDA in April 2024, we will be working with FDA to submit the premarket submission for EsoGuard.

Before and after approval or clearance in the United States, our products are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act, as well as by other regulatory bodies. FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, recordkeeping, market clearance or approval, advertising and promotion, import and export, marketing and sales, and distribution of medical devices and products.

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

Class I: general controls, such as labeling and adherence to quality system regulations;
Class II: special controls, pre-market notification (often referred to as a 510(k) application), specific controls such as performance standards, patient registries, post-market surveillance, additional controls such as labeling and adherence to quality system regulations; and
Class III: special controls and approval of a 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 approval, or even if they will clear or approve our products at all. It is our understanding that the data we are collecting for EsoGuard will be sufficient to support the analytical and clinical validity requirements for a premarket submission to the FDA as and when required by FDA's final policy anticipated to be released by the FDA in April 2024.

Clinical Trials of Medical Devices and Diagnostic Tests

One or more clinical trials may be necessary to support an FDA submission. Clinical studies of unapproved or uncleared medical devices or diagnostic tests 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 FDA prior to initiation of the clinical study. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device on humans and that the testing protocol is scientifically sound. The IDE is reviewed by FDA within 30 calendar days after receipt by FDA and FDA can issue a disapproval, conditional approval or full approval for the study to begin depending on the remaining FDA questions following review. Clinical studies of investigational devices may not begin until an IRB has approved the study.

During any study, the sponsor must comply with 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, FDA, or the IRB at each institution at which a clinical trial is being conducted may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable risk. During the approval or clearance process, 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:

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

Laboratory Certification, Accreditation and Licensing

Our 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, we will need to comply with New York's clinical laboratory regulations in order to offer our clinical laboratory products and services in New York.

We have 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 our CLIA-certified laboratory fails to meet any applicable requirements of CLIA or state law, that failure could adversely affect any future CMS consideration of our technologies, prevent their approval entirely, and/or interrupt the commercial sale of any products and services and otherwise cause us 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 for the Lucid Test Centers and other EsoGuard programs and related activities 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 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

We received CE Mark certification for EsoCheck under MDD and completed CE Mark self-certification for EsoGuard, which qualifies as a General IVD, under IVDD, indicating that both may be marketed in CE Mark European countries, namely the European Economic Area (the European Union, Norway, Iceland, and Lichtenstein), Switzerland, and, until July 1, 2023, the United Kingdom.

MDD refers to Medical Device Directive 93/42/EEC, which for nearly three decades provided the essential requirements and conformity assessment procedure that medical devices must undergo to be affixed with a CE Mark and sold in CE Mark European countries. MDD is now obsolete and has been replaced by MDR. MDR refers to Regulation (EU) 2017/745 and incorporates several new concepts and registrations, stricter oversight of manufacturers by notified bodies, universal device identification (UDI) marking, and increased post-market surveillance requirements.

Similarly, IVDD refers to In-Vitro Diagnostic Medical Devices Directive (98/79/EC), which for over twenty years has provided the essential requirements and conformity assessment procedure that in-vitro diagnostic medical devices must undergo to be affixed with a CE Mark and sold in CE Mark European countries. On May 26, 2022, IVDD will be replaced by IVDR, which refers to Regulation (EU) 2017/746, and has an expanded scope, risk-based classification, more rigorous clinical evidence and surveillance requirements, and more stringent documentation.

Both MDR and IVDR have sunset provisions for medical device and IVD certifications under MDD and IVD, respectively. Both EsoGuard and EsoCheck will require recertification under their stricter regulations in the coming years. Failure to secure these recertifications under MDR and IVDR will halt our ability to commercialize our products in the CE Mark European countries. As these are entirely new regulations, the cost, time and risk associated with these recertifications is difficult to predict.

In addition, the United Kingdom, which is a major target market for us, has left the European Union ("Brexit") and will transition from CE Mark certification to its own UKCA mark certification. We will need to secure UKCA mark certification for EsoGuard and EsoCheck before their CE Mark certifications expire in the UK. Since this is an entirely new process, it is difficult to predict the cost, time and risk associated with transitioning to UKCA certification.

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. 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.

Any action against us for violation of these or similar foreign 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.

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 our operations may require employees to use certain hazardous chemicals, we also must comply with regulations on hazard communication and hazardous chemicals in laboratories. These regulations require us, 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 us to regulations of the Department of Transportation, the United States Postal Service, and the Centers for Disease Control and Prevention that apply to the surface and air transportation of clinical laboratory specimens.

Environmental

The cost of compliance with federal, state and local provisions related to the protection of the environment has had no material effect on our Diagnostics business. There were no material capital expenditures for environmental control facilities in the years ended December 31, 2023 and 2022.

Employees

Currently, as of March 21, 2024 we have 70 employees (all of whom are full-time employees), inclusive of our executive officers –our Chairman of the Board of Directors and Chief Executive Officer ("CEO"), our President and Chief Operating Officer, ("President" or "COO"), our Chief Financial Officer ("CFO"), and our General Counsel and Secretary ("General Counsel"). In addition, we are obligated to reimburse PAVmed for certain payroll benefit and expenses related to our employees pursuant to the PBERA, which may be settled in shares of our common stock, at PAVmed's election. 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 May 8, 2018. Our corporate offices are located at 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.luciddx.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 (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.luciddx.com. The content of our website is not incorporated by reference into this Annual Report on Form 10-K, nor in any other report or document we file or furnish with and /or submit to the SEC, and any reference to our website are intended to be inactive textual references only.

Item 1A. Risk Factors

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

Risks 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 Associated with Our Financial Condition

- 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.
- To raise capital, we have issued a significant amount of convertible securities under which we expect to issue a correspondingly significant amount of shares of our common stock upon conversion thereof. In addition, we may issue shares of our capital stock or debt securities in the future in order to raise capital to fund our operations. All of the foregoing would dilute the equity interest of our stockholders and might cause a change in control of our ownership.
- We expect to need additional capital funding, which may be compounded by our obligations to our parent company, PAVmed, which requires its own additional capital funding.
- Our quarterly operating results could be subject to significant fluctuation, which could increase the volatility of our stock price and cause losses to our stockholders.
- 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.

Risks Associated with Our Business

- Since we have a limited operating history, and have not generated any significant revenues to date, you will have little basis upon which to evaluate our ability to achieve our business objective.
- The markets in which we operate are attractive and other companies or institutions may develop and market novel or improved technologies, which may make the EsoGuard or EsoCheck technologies less competitive or obsolete.
- We expect to derive substantially all of our revenues from the EsoGuard and EsoCheck products.
- We are highly dependent on our license agreement with CWRU, the termination of which would prevent us from commercializing our products, and which imposes significant obligations on us.
- Our products may never achieve market acceptance.
- The sizes of the markets for our current and future products have not been established with precision, and may be smaller than we estimate.
- Recommendations in published clinical practice guidelines issued by various organizations, including professional societies and federal agencies may significantly affect payors' willingness to cover, and physicians' willingness to prescribe, our products and services.
- We or our third-party manufacturers may not have the manufacturing and processing capacity to meet the production requirements of consumer demand or clinical testing in a timely manner.
- Our EsoGuard test is performed in a single commercial clinical 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 their equipment were damaged or destroyed, or if we experience a significant disruption in our commercial clinical laboratory operations for any reason, our ability to continue to operate our business could be materially harmed.
- Our results of operations can be adversely affected by labor shortages, turnover, and labor cost increases.
- We expect to rely on courier delivery services to transport EsoCheck devices and EsoGuard specimen kits to physicians and other medical professionals and samples back to laboratory facilities for analysis. If these delivery services are disrupted or become prohibitively expensive, customer satisfaction and our business could be negatively impacted.

- If we attempt to bring any other products or services to market in addition to the EsoGuard test and EsoCheck device, we likely will be required to make significant investments in research and development, which ultimately may prove unsuccessful. Our future performance may be affected by the success of products we have not yet developed, licensed, acquired.
- 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 may suffer if we are unable to manage our growth.
- 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.
- We may engage in acquisitions that are not successful and which could disrupt our business, cause dilution to our stockholders and reduce our financial resources.
- Adverse results in material litigation matters could have a material adverse effect upon our business.

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.
- If we fail to maintain CLIA-certification or otherwise meet the applicable requirements of federal or state law regulating commercial clinical laboratories, such failure could limit or prevent our ability to perform our EsoGuard test, or any other tests which we may develop, license or acquire, affect any payor consideration of such tests, prevent their clearance or approval entirely, and/or interrupt the commercial sale and/or marketing of any such tests, cause us to incur significant expense to remedy this failure and otherwise negatively impact our business.
- EsoGuard may not be jointly marketed as a combined product with EsoCheck without first securing FDA approval of the combined product as an IVD device. If FDA deems that we are jointly marketing such an IVD product with EsoCheck without FDA approval of the combined product as an IVD device, we would be subject to FDA enforcement action which could limit or halt commercialization of our products, and result in FDA sanctions which could severely impact our business.
- Securing FDA approval of EsoGuard as an IVD device, separately or as a combined product with EsoCheck, is a complex process requiring substantial time, commitment of resources and expense without any assurance that FDA will grant such approval.
- Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.
- Modifications to our cleared or approved products may require new clearances or premarket approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.
- Clinical trials necessary to support regulatory submission will be expensive and will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from expanding our commercial efforts and will adversely affect our business, operating results and prospects.
- The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.
- If our clinical studies do not satisfy providers, payors, patients and others as to the reliability and performance of our EsoGuard test and the EsoCheck device, or any other product or service we may develop and seek to commercialize, we may experience reluctance or refusal on the part of physicians to order, and third-party payors to pay for, such test.
- If the validity of an informed consent for a clinical trial of one of our products was challenged, we could be subject to fines, penalties, litigation, or regulatory sanctions, or other adverse consequences, including invalidating or requiring us to repeat clinical trials which could negatively affect our business and results of operations.
- EsoCheck and any other products we develop that receive regulatory clearance or approval 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.

- If we are found to be promoting the use of our devices for unapproved or "off-label" uses or engaging in other noncompliant activities, we may be subject to recalls, seizures, fines, penalties, injunctions, adverse publicity, prosecution, or other adverse actions, resulting in damage to our reputation and business.
- Clinical laboratories and medical diagnostic companies are subject to extensive and frequently changing federal, state, and local laws. We could be subject to significant fines and penalties if we fail (or if our prior unrelated third-party laboratory partner previously failed) to comply with these laws and regulations.
- We operate Lucid Test Centers where prescribing physicians can send patients for EsoGuard testing, including undergoing specimen collection using EsoCheck. These Lucid Test Centers are subject to federal and state regulations which may be burdensome, costly or difficult to comply with. Failure to comply with these regulations could result in sanctions, fines or other enforcement actions which may be costly, time-consuming and limit our ability to utilize them and adversely impact our business.
- We intend to engage with one or more third-party telemedicine companies to provide physicians to evaluate patients and, if clinically indicated, refer the patient to our Lucid Test Centers or to a #CheckYourFoodTube Precancer Testing Event, to undergo EsoCheck specimen collection for EsoGuard testing. Telemedicine is subject to numerous federal and state regulations and faces particularly intense scrutiny by these regulators. If we fail to comply with federal healthcare regulations, we could face substantial penalties, sanctions, fines or prosecution and our business, operations and financial condition could be adversely affected.
- Many aspects of our business, beyond the specific elements described above, are subject to complex, intertwined, costly and/or burdensome federal health care laws and regulations which may open to interpretation and be subject to varying levels of discretionary enforcement. If we fail to comply with these laws and regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.
- The regulations that govern pricing and reimbursement for new products vary widely from country to country, and may adversely affect the pricing, coverage and reimbursement rates of our products in other countries.
- Due to billing complexities in the diagnostic and laboratory service industry, we may not be able to collect payment for the EsoGuard tests we perform.
- Healthcare reform measures could hinder or prevent our products' commercial success.
- Our medical products may in the future be subject to product recalls that could harm our reputation, business, and financial results.
- If our medical products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.
- Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our products.
- Compliance with the HIPAA security, privacy and breach notification regulations may increase our costs.

Risks Associated with Our Intellectual Property and Technology Infrastructure

- We may not be able to protect or enforce the intellectual property rights for the technology used in, or expected to be used in, our products, 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 the intellectual property rights for the technology used in, or expected to be used in, our products, 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.
- Failure in our information technology 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 internal computer systems, or those used by our third-party research institution collaborators, vendors or other contractors or consultants, may suffer security breaches.

Risks Associated with Our Relationship with PAVmed

- PAVmed owns a majority of our voting stock and thus it (or any successor to its stake in the Company), may control certain actions requiring a stockholder vote.
- If PAVmed's debt is accelerated due to its default under the terms thereof, PAVmed could cease to have voting control of the Company.
- Certain conflicts of interest may arise between us and our affiliated companies, including PAVmed, and in some cases we have waived certain rights with respect thereto.

- Our ability to operate our business effectively may suffer if the MSA with PAVmed is insufficient to meet our needs or if, upon the termination of the MSA, we do not cost-effectively establish our own fully functional financial, administrative, operational and other support systems in order to operate as a stand-alone company.
- Any disputes that arise between us and PAVmed with respect to our past and ongoing relationships could harm our business operations.

Risks Associated with Ownership of Our Common Stock

- 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.
- Nasdaq may in the future delist our common stock, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.
- Our stock price may be volatile, and holders of our common stock could incur substantial losses.
- We do not intend to pay any dividends on our common stock at this time.
- We incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives.
- If we fail to establish and maintain proper and effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline significantly.
- We are subject to evolving corporate governance and public disclosure expectations and regulations that impact compliance costs and risks of noncompliance.
- We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.
- 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.
- Our charter provides, subject to limited exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.

Risks Associated with Our Financial Condition

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

We have incurred net losses since our inception. For the years ended December 31, 2023 and 2022, we had a net loss of $52.7 million and $56.2 million, respectively. Our ability to generate sufficient revenue from any of our products in development, and to transition to profitability and generate consistent positive cash flows is dependent upon factors that may be outside of our control. We expect that our operating expenses will continue to increase as we continue to develop, pursue regulatory clearance or approval for and commercialize our products, build our manufacturing, sales and other commercial infrastructure, 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 are subject to all of the risks and uncertainties typically faced by a medical device and diagnostic company devoting substantially all its efforts to the commercialization of its initial products and services and ongoing research and development activities and clinical trials.

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 our recurring losses from operations, recurring cash flows used in operations and the requirement we 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 in addition to the recently completed offering of Series B Preferred Stock (in which we raised over $18 million), seeking to restructure our 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.

To raise capital, we have issued a significant amount of convertible securities under which we expect to issue a correspondingly significant amount of shares of our common stock upon conversion thereof. In addition, we may issue shares of our capital stock or debt securities in the future in order to raise capital to fund our operations. All of the foregoing would dilute 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 200,000,000 shares of common stock, par value $.001 per share, and 20,000,000 shares of preferred stock, par value $.001 per share. There are 151,755,202 authorized but unissued shares of our common stock available for issuance as of March 21, 2024 (inclusive of granted but unvested restricted stock awards granted as of each such date under the Lucid Diagnostics 2018 Long-Term Incentive Equity Plan).

From March 2023 through March 2024, we issued shares of Series A Preferred Stock, Series A-1 Preferred, and Series B Preferred Stock that, in accordance with the terms thereof, could be converted into, in the aggregate, up to 49,822,240 shares of our common stock (which amount includes all future dividends that may be potentially payable in shares of our common stock).

As of March 21, 2024, 2,203,800 shares of our common stock were issuable under the March 2023 Senior Convertible Note, assuming the noteholder elected to convert the March 2023 Senior Convertible Note in full on such date at the fixed conversion price of $5.00 per share (based on $11.0 million in aggregate principal amount outstanding as of such date and no accrued and unpaid interest thereon). The number of shares of our common stock to be issued under the March 2023 Senior Convertible Note may be substantially greater than this amount if we make the required amortization payments in shares of our common stock (or upon conversion of the principal and interest in certain other circumstances as described elsewhere in this filing), because in such event the number of shares to be 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 $0.30 per share). 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 the March 2023 Senior Convertible Note. However, assuming that all amortization payments are made as scheduled in shares of common stock at a price equal to the current market price of $1.11 per share, we estimate that we would issue 9,927,027 shares to the noteholder.

In March 2024, we entered into an eighth amendment to the management services agreement with PAVmed (the "MSA"), pursuant to which PAVmed may elect to receive payment of the monthly fee under the management services agreement in cash or in shares of our common stock valued at a price based on the current market price, subject to a floor price and a maximum number of shares. Under the amendment, the monthly fee due from the Company to PAVmed was increased from $0.75 million to $0.83 million. In accordance with the MSA and the PBERA, on January 26, 2024, PAVmed elected to receive payment of $4.675 million of fees and reimbursements accrued under the MSA and the PBERA through the issuance of 3,331,771 shares of the Company's common stock. To the extent PAVmed elects for us to satisfy our obligations under the MSA and PBERA in shares of our common stock in the future, the interest of other shareholder of the Company would be diluted.

Furthermore, we have issued and expect to continue to issue equity awards, including stock options, under our 2018 Long-Term Incentive Equity Plan (the "Lucid Diagnostics Inc. 2018 Equity Plan") and our Employee Stock Purchase Plan (the "Lucid Diagnostics Inc. ESPP"). In addition, in March 2022, we entered into a committed equity facility with an affiliate of Cantor. Under the terms of the facility, Cantor has committed to purchase up to $50 million in shares of our common shares stock from time to time at the our request. In November 2022, we also entered into an "at-the-market offering" for up to $6.5 million of our common stock that may be offered and sold under a Controlled Equity Offering Agreement between us and Cantor. Also in November 2022, we entered into the PBERA with PAVmed, pursuant to which PAVmed will continue to pay certain payroll and benefit-related expenses on our behalf and we will reimburse PAVmed, in cash or, subject to approval by each of our boards of directors, in shares of our common stock valued at a price based on the current market price, subject to a floor price and a maximum number of shares.

In addition, we may issue a substantial number of additional shares of our common stock or preferred stock or incur indebtedness, or issue or incur a combination of common and preferred stock and indebtedness, to raise additional funds or in connection with any strategic acquisition or as compensation to our officers, directors, employees and consultants or to fund investments in our current operations.

The issuance of additional shares of our common stock or any number of shares of our preferred stock, and the availability for sale of such shares in the public markets:

- may significantly dilute the equity interest of our current investors;

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

Similarly, if we incur indebtedness, it could result in:

- default and foreclosure on our assets if our operating revenues are insufficient to pay our debt obligations and we are not able to refinance such obligations;
- acceleration of our obligations to repay the indebtedness even if we have made all principal and interest payments when due if the debt security contains covenants that require the maintenance of certain financial ratios or reserves, and any such covenant is breached without a waiver or renegotiation of that covenant;
- our immediate payment of all principal and accrued interest, if any, if the debt security is payable on demand and a demand is made;
- our inability to obtain additional financing, if necessary, if the debt security contains covenants restricting our ability to obtain additional financing while such security is outstanding; and
- our inability to conduct acquisitions, joint ventures or similar arrangements if the debt security contains covenants restricting such transactions or the funding thereof or requiring prior approval of the debt holders.

We expect to need additional capital funding, which may be compounded by our obligations to our parent company, PAVmed, which requires its own additional capital funding.

Our future capital requirements depend on many factors, including our research, development, and sales and marketing activities. We intend to continue to make investments to support our business growth. Because we have not generated significant revenue or cash flow to date, and despite our recently having raised approximately $18.1 million in the Series B Offering and Exchange, we may require additional funds to:

- continue our research and development including existing and new clinical trials;
- fund our operations;
- protect our intellectual property rights or defend, in litigation or otherwise, any claims that we infringe third-party patents or other intellectual property rights;
- manufacture and distribute our products; and
- promote market acceptance of our products.

Our need for additional funds may be affected by:

- the cost and timing of expanding our sales, marketing and distribution capabilities;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Under our existing management services agreement and payroll and benefit expense reimbursement agreement with PAVmed, PAVmed may determine the form and timing of our satisfaction of our obligations under such agreements. To the extent PAVmed elects for this obligation to be paid in cash, that would increase our need to raise additional capital. In this regard, because of the challenges PAVmed has faced in terms of raising capital itself, PAVmed has become highly dependent on us to fund its operations, primarily through electing for the payment in cash by us of our obligations under our management services agreement with PAVmed.

Debt or preferred stock financing, if available, may involve covenants restricting our operations or our ability to incur additional debt or issue additional preferred stock, and may contain other terms that are not favorable to us or our stockholders. Additional equity financing may result in substantial dilution to our existing stockholders. If we do not have, or are not able to obtain, sufficient funds, we may have to delay product development initiatives or license to third parties the rights to commercialize products or technologies that we would otherwise seek to market. We also may have to reduce manufacturing, distribution, marketing, customer support or other resources devoted to our products.

Our quarterly operating results could be subject to significant fluctuation, which could increase the volatility of our stock price and cause losses to our stockholders.

Our results of operations, including our revenue and profits, assuming we are able to successfully commercialize the EsoGuard and EsoCheck products, may fluctuate significantly, depending on a variety of factors, including the following:

- our success in marketing and selling, and changes in demand for, our products, and the level of reimbursement and collection obtained for our products;
- seasonal variations affecting physician recommendations for esophageal precancer and cancer screenings and patient compliance with physician recommendations, including without limitation holidays, weather events, and other circumstances that may limit patient access to medical practices for preventive services such as esophageal precancer and cancer screening;
- our success in collecting payments from third-party payors, patients and collaborative partners, variation in the timing of these payments and recognition of these payments as revenues;
- the pricing of our products, including potential changes in CMS reimbursement rates or other reimbursement rates;
- circumstances affecting our ability to provide our products, including weather events, supply shortages, or regulatory or other circumstances that adversely affect our ability to manufacture our products or process tests in our clinical laboratory;
- fluctuations in the amount and timing of our selling and marketing costs and our ability to manage costs and expenses and effectively implement our business; and
- our research and development activities, including the timing of costly clinical trials.

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

We may be required to repay or redeem, or to pay interest on, the March 2023 Senior Convertible Note or any future permitted indebtedness incurred by us or our subsidiaries, in cash. Despite our right to pay the interest and principal balance of the March 2023 Senior Convertible Note by issuing shares of our common stock, we may be required to repay such indebtedness in cash, if we do not meet certain customary equity conditions (including minimum price and volume thresholds) or in certain other circumstances. For example, we may be required to repay the outstanding principal balance and accrued but unpaid interest, along with a premium, upon the occurrence of certain changes of control or an event of default.

Our ability to make payments of the principal of, to pay interest on, or to redeem our indebtedness in cash, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We have not generated material revenue from operations to date, and our business may not generate cash flow from operations in the future sufficient to service our indebtedness and make necessary capital expenditures. In addition, the March 2023 Senior Convertible Note would contain, and any future indebtedness may contain, restrictive covenants, including financial covenants. These payment obligations and covenants could have important consequences on our business. In particular, they could:

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

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

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

If we are required to make payments under our indebtedness in cash and are unable to generate sufficient cash flow from operations, we may be required to sell assets, or we may seek to refinance the remaining balance, by either refinancing with the holder of the indebtedness, by raising sufficient funds through a sale of equity or debt securities or by obtaining a credit facility. No assurances can be given that we will be successful in making the required payments under our indebtedness, or in refinancing our obligations on favorable terms, or at all. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. A failure to refinance could have a material adverse effect on our liquidity, financial position, and results of operations. Should we refinance, it could be dilutive to shareholders or impose onerous terms on us.

Risks Associated with Our Business

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

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

The markets in which we operate are attractive and other companies or institutions may develop and market novel or improved technologies, which may make the EsoGuard or EsoCheck technologies less competitive or obsolete.

Given the large market opportunity for esophageal precancer testing we may face multiple competitors in the future, some of which possess significantly greater financial and other resources and development capabilities than us. Our EsoGuard test may face competition from new biomarkers also designed to detect esophageal precancer and conditions along the BE-EAC spectrum.

The Mayo Clinic and Exact Sciences Inc. (Nasdaq: EXAS) have published preliminary data on such biomarkers and have publicly expressed a commitment to advancing them to commercialization. Investigators at Johns Hopkins University associated with a privately held firm called Previse have published limited data on methylation biomarkers for BE. Of note, both groups used the EsophaCap "sponge-on-a-string" cell collection device.

Other manufacturers have developed noninvasive esophageal cell collection devices most notably "sponge-on-a-string" devices which may compete with EsoCheck. One such device, Cytosponge, previously marketed by in the U.S. by Medtronic Inc. (NYSE: MDT), which is similar to EsophaCap, the device we acquired in our acquisition of CapNostics LLC and is utilized almost exclusively for clinical research, is a spherical mesh sponge encapsulated in soluble gelatin that dissolves in the stomach. The expanded sponge brushes the lining of the esophagus as it is withdrawn and retrieved. 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 for some time until it fully dissolves and then is pulled thru the targeted region brushing the lining of the esophagus and then later retrieved. Although, unlike EsoCheck, these devices do not provide anatomic targeting nor protect their sample from dilution and contamination during device withdrawal, future biomarkers may have sufficient sensitivity to detect BE-EAC despite such dilution and contamination. Manufacturers may also be developing new tools that have not yet been announced that provide noninvasive esophageal cell sampling with the same or better protection from dilution and contamination as EsoCheck.

Several well-capitalized companies are developing "liquid biopsy" tests for early cancer detection based on circulating tumor DNA. Although none of these tests yet purport to detect early precancer in the bloodstream, technological advances could result in sufficient sensitivity to do so generally and for conditions along the BE-EAC spectrum. Such advances could put EsoGuard and EsoCheck at a significant competitive disadvantage in the esophageal precancer testing market as it would be logistically much simpler to send the patient for a routine blood draw instead of a specialized office procedure like EsoCheck, and patients would generally prefer such a blood draw over even a noninvasive procedure such as EsoCheck.

Additional, still unproven, technologies with the potential to compete with EsoGuard and EsoCheck in the future, include breath tests and oral tests which may be capable of identifying the presence of BE. For example, there is early data to suggest that an "electric nose" device which measures volatile organic compounds (VOCs) developed by The eNose Company, based in the Netherlands, may be able to identify patients with BE. Preliminary published data from Columbia University School of Medicine found that differences in the oral bacterial microbiome, obtained with a simple saliva sample or oral swab, may correlate with the presence of BE.

Although there can be no assurance that we will pursue the development of any products other than EsoGuard and EsoCheck, if we seek to develop other products, we may need to compete with a broad range of organizations in the U.S. and other countries that are engaged in the development, production and commercialization of diagnostic products and services. These competitors include biotechnology, diagnostic and other life science companies; academic and scientific institutions, governmental agencies, and public and private research organizations.

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. Our potential competitors may have substantially greater financial, marketing, sales, distribution, manufacturing, and technological resources. These competitors may also have broader product lines and greater name recognition than we do. Many of these competitors will have obtained FDA or other regulatory clearances or approvals, and patent protection, for their products, or are in the process of seeking such clearances, approvals, and protection. Certain of our potential competitors 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, especially given our focus on the EsoGuard and EsoCheck technology. Although there can be no assurance that we will pursue the development of any products other than EsoGuard and EsoCheck, even if we do develop new marketable products or services, our current and future competitors may develop products and services that are more commercially attractive than ours, and they may bring those products and services to market earlier or more effectively than us.

We expect to derive substantially all of our revenues from the EsoGuard and EsoCheck products.

Although we may develop additional products based on the technology underlying our EsoGuard and EsoCheck products, or other related technologies we develop, license, or acquire, we presently expect to derive substantially all of our revenues from sales of our EsoGuard and EsoCheck products. As such, any factor adversely affecting sales of our products, including the product development and release cycles, regulatory issues, intellectual property rights issues, market acceptance, product competition, performance and reliability, reputation, price competition and economic and market conditions, and the other factors discussed in this filing, could adversely affect our business prospects, financial condition and results of operations, and could threaten the viability of our business.

We are highly dependent on our license agreement with CWRU, the termination of which would prevent us from commercializing our products, and which imposes significant obligations on us.

We are highly dependent on the intellectual property licensed from CWRU, pursuant to which we license the technology underlying our EsoGuard and EsoCheck products. Other products or services we may develop also may rely on the same technology. In the event that we default in the payment of any amount when due under the License Agreement, and such amount is not paid within 30 days of notice of nonpayment, CWRU may terminate the exclusivity of the license or terminate the License Agreement in full. Furthermore, if we breach the agreement, and we do not cure such breach within the applicable time period, in addition to seeking damages, CWRU could terminate the License Agreement. Any termination of the License Agreement resulting in the loss of the licensed rights would prevent us from marketing and selling the EsoGuard and EsoCheck products and any other products or services we may develop based on the same underlying technology. Any termination of the exclusivity of the license could damage our competitive position within the marketplace. In addition, disputes may also arise between us and CWRU regarding the License Agreement. If any such dispute results in an impairment of our ability to use the intellectual property, we may be unable to commercialize the EsoGuard and EsoCheck products and any other product or service we may develop based on the same underlying technology. Accordingly, any such termination or dispute could threaten the viability of our business.

Our products may never achieve market acceptance.

To date, we have not generated any significant revenues. Our ability to generate revenues from product sales and to achieve profitability will depend upon our ability to successfully commercialize the EsoGuard and EsoCheck products and any other products, tests or services we develop. Because we have just begun to offer our products, tests or services for sale, we have no basis to predict whether any of our products will achieve market acceptance. A number of factors may limit the market acceptance of any of our products, including:

- the effectiveness, reliability and safety of our products, including any potential side effects, and the other competitive features of our products, including price, as compared to alternatives;
- the rate of adoption of our products by hospitals, doctors and nurses and acceptance by the health care community, and the ease of the ordering process for doctors;

- guidelines and other recommendations from medical societies and other similar organizations relating to screening for, monitoring, diagnosing and treating esophageal precancer and cancer or other medical conditions for which our products are used;
- the product labeling or product inserts required by regulatory authorities for each of our products;
- the availability and amount of insurance or other third-party reimbursement, such as Medicare, for patients using our products;
- the extent and success of our marketing efforts and those of our collaborators;
- unfavorable publicity concerning our products or similar products; and
- in the case of FDA PMA approval of the EsoGuard combined with EsoCheck as an IVD device, and in the case of any other products or services we may develop in the future, the timing of regulatory approvals of our products and market entry compared to competitive products.

The sizes of the markets for our current and future products have not been established with precision, and may be smaller than we estimate.

Our estimates of the annual total addressable markets for our current products are based on a number of internal and third-party estimates, including, without limitation, the number of patients with esophageal cancer and precancer, the number of individuals who are at a higher risk for developing cancer, and the assumed prices at which we can sell tests for markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell our products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

Recommendations in published clinical practice guidelines issued by various organizations, including professional societies and federal agencies may significantly affect payors' willingness to cover, and physicians' willingness to prescribe, our products and services.

Long-term adoption of our products as well as payment and coverage for them may depend on their recommendation in clinical practice guidelines. These include professional society guidelines published by gastroenterology specialty societies, such as the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), and the American Society for Gastrointestinal Endoscopy (ASGE), internal medicine and family practice societies such as the American College of Physicians (ACP) and American Academy of Family Physicians (AAFP), and oncology societies such as the American Cancer Society (ACS). These also include federal agencies and federally funded affiliates such as the U.S. Preventative Services Task Force ("USPSTF") and the Agency for Healthcare Research & Quality ("AHRQ"). The recommendations in these clinical practice guidelines may shape payors' coverage decisions.

The USPSTF, a panel of primary care physicians and epidemiologists and other national experts funded by the U.S. Department of Health and Human Services' AHRQ, makes influential recommendations on clinical preventative services. We may seek a USPSTF recommendation in the future. The process of USPSTF recommendation development is lengthy, requires high quality supporting evidence for a positive recommendation, and the outcome of any USPSTF process is uncertain.

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

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

For some of our products, we or our third-party manufacturers will need to have sufficient production and processing capacity in order to conduct human clinical trials, to produce products for commercial sale at an acceptable cost. We have limited experience in large-scale product manufacturing, nor do we have the resources or facilities to manufacture most of our products on a commercial scale. We cannot guarantee that we or our third-party manufacturers will be able to increase capacity in a timely or cost-effective manner, or at all.

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.

Our EsoGuard test is performed in a single commercial clinical 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 their equipment were damaged or destroyed, or if we experience a significant disruption in our commercial clinical laboratory operations for any reason, our ability to continue to operate our business could be materially harmed.

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

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

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

Our results of operations can be adversely affected by labor shortages, turnover, and labor cost increases.

Labor is a significant component of operating our business. A number of factors may adversely affect the labor force available to us or increase labor costs, including high employment levels, federal unemployment subsidies, increased wages offered by other employers, vaccine mandates and other government regulations and our responses thereto. As more employers offer remote work, we may have more difficulty recruiting for jobs that require on-site attendance, such as certain clinical laboratory and sales roles. Although we have not experienced any material labor shortage to date, we have recently observed an overall tightening and increasingly competitive labor market. A sustained labor shortage or increased turnover rates within our employee base could lead to increased costs, such as increased overtime or financial incentives to meet demand and increased wage rates to attract and retain employees, and could negatively affect our ability to efficiently operate our clinical laboratories and overall business. If we are unable to hire and retain employees capable of performing at a high level, or if mitigating measures we may take to respond to a decrease in labor availability have unintended negative effects, our business could be adversely affected.

Additionally, the operations of our vendors and partners could also suffer from labor shortages, turnover, and labor cost increases which could result in supply chain disruptions and increases in the costs of the products and services we purchase, each of which could adversely affect our operations.

We expect to rely on courier delivery services to transport EsoCheck devices and EsoGuard specimen kits to physicians and other medical professionals and samples back to laboratory facilities for analysis. If these delivery services are disrupted or become prohibitively expensive, customer satisfaction and our business could be negatively impacted.

In most cases, we expect to ship EsoCheck devices EsoGuard specimen kits to physicians and have the physician's office ship samples by air express courier delivery service to our CLIA-certified laboratory for EsoGuard testing. Disruptions in delivery service, whether due to bad weather, natural disaster, labor disruptions, terrorist acts or threats, or for other reasons, can adversely affect customer satisfaction, specimen quality and our ability to provide our services on a timely basis. If the courier delivery services that transport EsoCheck devices or EsoGuard specimen kits institute significant price increases, our profitability would be negatively affected and we may need to identify alternative delivery methods, if possible, modify our service model, or attempt to raise our pricing, which may not be possible with regard to Medicare claims or commercially practicable with regard to commercial claims.

If we attempt to bring any other products or services to market in addition to the EsoGuard test and EsoCheck device, we likely will be required to make significant investments in research and development, which ultimately may prove unsuccessful. Our future performance may be affected by the success of products we have not yet developed, licensed, acquired.

Although there can be no assurance that we will pursue the development of any products or services other than the EsoGuard test and EsoCheck device, we may develop additional products or services based on the same underlying technologies or other technologies we develop, license, or acquire. If we attempt to bring any other such products or services to market, we likely will incur significant expenses on research and development efforts, which ultimately may prove unsuccessful.

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

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

Our ability to successfully carry out our business plan is dependent upon the efforts of our key personnel. We cannot assure you that any of our key personnel will remain with us for the immediate or foreseeable future. The unexpected loss of the services of our key personnel could have a detrimental effect on us. We may also be unable to attract and retain additional key personnel in the future. 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 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 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 (although our near-term focus is on our U.S. operations). These factors include:

- challenges associated with cultural differences, languages and distance;
- differences in clinical practices, needs, products, modalities and preferences;
- longer payment cycles in some countries;
- credit risks of many kinds;
- legal and regulatory differences and restrictions;
- currency exchange fluctuations;
- foreign exchange controls that might prevent us from repatriating cash earned in certain countries;
- political and economic instability and export restrictions;
- variability in sterilization requirements for multi-usage surgical devices;
- potential adverse tax consequences;
- higher cost associated with doing business internationally;
- challenges in implementing educational programs required by our approach to doing business;
- negative economic developments in economies around the world and the instability of governments, including the threat of war, terrorist attacks, epidemic or civil unrest;
- adverse changes in laws and governmental policies, especially those affecting trade and investment;
- health epidemics and /or pandemics, such as the epidemics resulting from the Ebola virus, or the enterovirus, or the avian influenza virus, or the pandemic resulting from a novel strain of a coronavirus designated “Severe Acute Respiratory Syndrome Coronavirus 2” - or “SARS-CoV-2”, which may adversely affect our workforce as well as our local suppliers and customers;
- import or export licensing requirements imposed by governments;
- differing labor standards;
- differing levels of protection of intellectual property;
- the threat that our operations or property could be subject to nationalization and expropriation;
- varying practices of the regulatory, tax, judicial and administrative bodies in the jurisdictions where we operate; and
- potentially burdensome taxation and changes in foreign tax.

We may engage in acquisitions that are not successful and which could disrupt our business, cause dilution to our stockholders and reduce our financial resources.

We may in the future enter into transactions to acquire other businesses, products, services or technologies. Because we have not made any major acquisitions to date, our ability to do so successfully is unproven. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms or at all. Any acquisitions we make in the future may not strengthen our products, technologies or businesses or otherwise improve our competitive position, and these transactions may be viewed negatively by investors, healthcare providers, patients and others. For example, we may be unable to timely and effectively integrate the acquired businesses into our business; we may lose key employees; we may encounter potential unknown liabilities and unforeseen risks, including liabilities associated with contracts containing consent and/or other provisions that may be triggered by the acquisitions; we may be unable to realize the anticipated benefits of the acquisitions or do so within the anticipated timeframe; or we may be unable to effectively manage our expanded operations. In addition to the risks outlined above, we may decide to incur debt in connection with an acquisition or issue our common stock or other securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results. For the foregoing reasons, the market price of our common stock may decline as a result of any acquisitions.

Adverse results in material litigation matters could have a material adverse effect upon our business.

We may become subject in the ordinary course of business to material legal actions related to, among other things, intellectual property disputes, contract disputes, data and privacy issues, professional liability and employee-related matters. We may also receive inquiries and requests for information from governmental agencies and bodies, including CMS or private payors, requesting comment and/or information on allegations of billing irregularities, billing and pricing arrangements, or privacy practices that are brought to our attention through audits or third parties. Legal actions could result in substantial monetary damages, as well as damage to our reputation with customers and diversion of the attention of our management, which could have a material adverse effect upon its business.

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 our 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." We expect to submit EsoGuard for Technical Assessment under this foundational LCD later this year. However, even if we do submit EsoGuard for Technical Assessment as currently planned, there can be no assurance that MolDx will determine that we meet the criteria for coverage as specified in the LCD. If we are not granted coverage, or if a determination is substantially delayed, that could have a material adverse effect on our 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 will be eligible for coverage by third-party payors or, if eligible for coverage, what the reimbursement rates will be. 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 our 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, 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 for our EsoGuard test and EsoCheck device 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 at an adequate reimbursement rate, other factors may have a significant impact on the actual reimbursement we receive for an EsoGuard test or EsoCheck device 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 EsoGuard test or EsoCheck device 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 EsoGuard or EsoCheck is out of network for a given payor, physicians may be less likely to prescribe EsoGuard and EsoCheck 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 an EsoGuard test or EsoCheck device 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 EsoGuard and EsoCheck for their patients, and may make patients less likely to comply with physician orders for EsoGuard and EsoCheck, 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 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 FDA. However, there can be no assurance that we will be able to successfully transition the platform to fulfill the QS requirements, if and when required by FDA, and our failure to do so could have a material impact on our ability to commercialize EsoGuard and on our business as a whole.

If we fail to maintain CLIA-certification or otherwise meet the applicable requirements of federal or state law regulating commercial clinical laboratories, such failure could limit or prevent our ability to perform our EsoGuard test, or any other tests which we may develop, license or acquire, affect any payor consideration of such tests, prevent their clearance or approval entirely, and/or interrupt the commercial sale and/or marketing of any such tests, cause us to incur significant expense to remedy this failure and otherwise negatively impact our business.

We perform the EsoGuard test in our own CLIA-certified commercial clinical laboratory, and like all clinical laboratories which perform non-research laboratory testing on human samples in the U.S., it is regulated by CMS through CLIA and associated federal regulations set forth in 42 CFR § 493, as well as through other federal and state laws and regulations. Federal CLIA requirements and laws of certain states impose certification requirements for clinical laboratories, establish standards for quality assurance and quality control, among other things. Some state laws restrict laboratory marketing activities, which may adversely affect our ability to market our laboratory services. Clinical laboratories are subject to inspection by regulators, and to sanctions for failing to comply with applicable requirements. Sanctions available under CLIA include prohibiting a laboratory from running tests, requiring a laboratory to implement a corrective plan, and imposing civil monetary penalties. If we fail to maintain CLIA-certification or otherwise meet the applicable requirements of federal or state law, that failure could adversely limit or prevent its ability to perform our EsoGuard test, or any other diagnostic tests which we may develop, license or acquire, affect any payor consideration of such tests, prevent their clearance or approval entirely, and/or interrupt the commercial sale and/or marketing of any such tests, cause us to incur significant expense to remedy this failure and otherwise negatively impact our business.

EsoGuard may not be jointly marketed as a combined product with EsoCheck without first securing FDA approval of the combined product as an IVD device. If FDA deems that we are jointly marketing such an IVD product with EsoCheck without FDA approval of the combined product as an IVD device, we would be subject to FDA enforcement action which could limit or halt commercialization of our products, and result in FDA sanctions which could severely impact our business.

EsoCheck has received FDA 510(k) clearance permitting us to market it in the U.S. as a cell collection device indicated for use in the collection and retrieval of surface cells of the esophagus in the general population of adults, 22 years of age and older. EsoGuard, on the other hand, has not received FDA approval to be marketed as an IVD device and is being marketed as an LDT. As such we must market EsoGuard and EsoCheck as separate products. Jointly marketing EsoGuard as a combined product with EsoCheck would require us to secure FDA approval of the combined product as an IVD device. If we were to jointly market such products, even inadvertently, without such FDA approval we would be subject to FDA enforcement actions which could result in fines, unanticipated compliance expenditures, recall or seizures of our products, total or partial suspension of production or distribution, restrictions on labeling and promotion, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution. Responding to such actions could cause us to incur significant expense, limit or halt commercialization of our products and severely impact our business.

Securing FDA approval of EsoGuard as an IVD device, separately or as a combined product with EsoCheck, is a complex process requiring substantial time, commitment of resources and expense without any assurance that FDA will grant such approval.

FDA has indicated to us through its pre-submission process that jointly marketing EsoGuard combined with EsoCheck as an IVD device would be subject to PMA premarket approval, the most stringent FDA premarket medical device scientific and regulatory review process, which requires sufficient valid scientific evidence in addition to general and special controls to assure that it is safe and effective for its intended use(s). If we choose, or are required, as a result of changes in LDT regulation, to secure FDA approval of EsoGuard as an IVD device, even if not combined with EsoCheck, we expect we would this require FDA PMA approval.

The process of securing FDA PMA approval is complex and requires substantial time, commitment of resources and expense. The process may take many years to complete, and approval may never be obtained. It requires us to demonstrate with substantial evidence, gathered in preclinical and large, complex well-controlled clinical trials, that the planned product is safe and effective for use for as intended. We may not conduct such a trial or may not successfully enroll or complete any such trial, if required. 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.

There can be no assurance that FDA will ever permit us to market EsoGuard, used with EsoCheck, as a combined product. Also, any regulatory clearance or approval of a product, once obtained, may be withdrawn. If we are unable to successfully obtain or maintain regulatory clearance or approval to sell any products we may develop in the U.S., our business, financial condition, results of operations and growth prospects could be adversely affected. Furthermore, delays in receipt of clearances or approvals could materially delay or prevent us from commercializing our products and services or result in substantial additional costs that could decrease our profitability. Even if we were to successfully obtain and maintain regulatory clearance or approval for a product, any clearance or 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.

FDA can delay, limit, or deny clearance or approval of a future product for many reasons, including but not limited to:

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

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

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

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

Modifications to our cleared or approved products may require new clearances or premarket approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.

For any product approved pursuant to a PMA, we are required to seek supplemental approval for many types of changes to the approved product, for which we will need to determine whether a PMA supplement or other regulatory filing is needed or whether the change may be reported via the PMA Annual Report. Similarly, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires new 510(k) clearance or, possibly, approval of a new PMA. If the FDA requires us to seek approvals or clearances for modifications to our previously approved or cleared products, for which we concluded that new approvals or clearances are unnecessary, we may be required to cease marketing or distribution of our products or to recall the modified product until we obtain the approval or clearance, and we may be subject to significant regulatory fines or penalties. Foreign regulatory regimes may have comparable requirements, which present the same or substantially similar risks.

Clinical trials necessary to support regulatory submission will be expensive and will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from expanding our commercial efforts and will adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support regulatory submission will be time-consuming and expensive and their outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in early or later clinical trials. For example, the results of the studies to date on EsoGuard may not be replicated by the clinical trials being undertaken to obtain PMA approval of the use of EsoGuard and EsoCheck together as an IVD device.

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, discomforts or expenditures. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy may be required and we may not adequately develop such protocols to support clearance and approval. Further, FDA may require us 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. FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

We expect to depend on clinical investigators, medical institutions and contract research organizations to perform the clinical trials. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for EsoGuard and any other products we may develop. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market EsoGuard and any other products we may develop, license or acquire, or to achieve sustained profitability.

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

Even if any of our clinical trials are completed as planned, it cannot be certain that study results will support product candidate claims or that 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. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues (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—Clinical Utility and Clinical Trials*".

If our clinical studies do not satisfy providers, payors, patients and others as to the reliability and performance of our EsoGuard test and the EsoCheck device, or any other product or service we may develop and seek to commercialize, we may experience reluctance or refusal on the part of physicians to order, and third-party payors to pay for, such test.

Although we have received FDA 510(k) clearance to market EsoCheck, and EsoGuard may be performed in our own CLIA-certified commercial clinical laboratory and marketed as an LDT, if the results of any research and clinical studies conducted by us, including those conducted for the purpose of obtaining FDA approval of the combined EsoGuard and EsoCheck product as an IVD device, and our sales and marketing activities relating to communication of these results, do not convince guidelines organizations, physicians and other healthcare providers, third-party payors and patients that EsoGuard and EsoCheck are safe and effective, we may experience reluctance or refusal on the part of physicians to order, and third-party payors to pay for, EsoGuard or EsoCheck, which could adversely affect our business prospects.

If the validity of an informed consent for a clinical trial of one of our products was challenged, we could be subject to fines, penalties, litigation, or regulatory sanctions, or other adverse consequences, including invalidating or requiring us to repeat clinical trials which could negatively affect our business and results of operations.

Our products are the subject of multiple clinical trials and we anticipate they will continue to be so in the future. We have implemented measures to ensure that data and biological samples that we receive have been collected from, and any procedures that have been performed using our products have been on, subjects who have provided appropriate informed consent. When we utilize clinical research contractor or partner with other third parties in connection with our studies, we rely upon them to comply with the requirements to obtain the subject's informed consent and to comply with applicable laws and regulations. The collection of data and samples in many different countries results in complex legal questions regarding the adequacy of informed consent and the status of genetic material under a large number of different legal systems. Those informed consents could be challenged and prove invalid, unlawful, or otherwise inadequate for our purposes. Any such findings against us, could force us to stop accessing or using data and samples or servicing or conducting clinical trials, which would hinder our product offerings or development. We could also become involved in legal actions, which could consume our management and financial resources.

EsoCheck and any other products we develop that receive regulatory clearance or approval 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.

Even after regulatory clearance or approval has been obtained for our products, the cleared or approved product and its manufacturer remain subject to continual review by FDA or non-U.S. regulatory authorities. Our cleared or approved products may be subject to limitations on the indicated uses for which the product may be marketed, as in the case of the FDA 510(k) marketing clearance for our EsoCheck cell collection device. Furthermore, future approvals may contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the approved product. There is a risk that FDA may modify or withdraw the approval of a product if the results of a post-approval study are not satisfactory or are inconsistent with previous studies. We may rely on third parties, such as contract research organizations, medical institutions and clinical investigators to conduct any post-approval studies. We will have limited control over the activities of these third parties and any post-approval studies may be delayed or halted prior to its completion for reasons outside our control.

In addition, we and our cleared or approved products will be subject to extensive and ongoing regulatory requirements by FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. We and our contract manufacturers also will be required to comply with current good manufacturing practice ("cGMP") regulations regarding the manufacture of our products, 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 medical devices, and these facilities are subject to continual review and periodic inspections by FDA and other regulatory authorities for compliance with cGMP regulations. Operations at these facilities could be interrupted or halted if FDA or other governmental agency deems the findings of such inspections unsatisfactory.

Failure to comply with FDA or other regulatory requirements could result in fines, unanticipated compliance expenditures, recall or seizures of our products, total or partial suspension of production or distribution, restrictions on labeling and promotion, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution. 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 recall of the product from the market or suspension of manufacturing. We also may voluntarily recall a product. Any recalls could have an adverse effect on our ability to provide our products, which in turn would adversely affect our financial condition.

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

Our labeling, advertising, promotional materials and user training materials must comply with 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 FDA. Obtaining 510(k) clearance or PMA approval only permits us to promote our products for the uses specifically cleared by FDA. Use of a device outside its cleared or approved indications is known as "off-label" use. Physicians and consumers may use our products off-label because 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 we may request additional cleared indications for our current products, 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 FDA determines that our labeling, advertising, promotional materials, or user training materials, or representations made by our personnel, include the promotion of an off-label use for the device, or that we have 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 our devices and request that we modify our labeling, advertising, or user training or promotional materials and/or subject us 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 our 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 our reputation could be damaged and adoption of the products would be impaired. Although we intend to refrain from statements that could be considered off-label promotion of our products, FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, any such off-label use of our 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 our management's attention and result in substantial damage awards against us.

Clinical laboratories and medical diagnostic companies are subject to extensive and frequently changing federal, state, and local laws. We could be subject to significant fines and penalties if we fail (or if our prior unrelated third-party laboratory partner previously failed) to comply with these laws and regulations.

As a provider of clinical diagnostic products and services, we are subject (and our prior third-party laboratory partner previously was subject) to extensive and frequently changing federal, state, and local laws and regulations governing various other aspects of our business. In particular, the clinical laboratory industry is subject to significant governmental certification and licensing regulations, as well as federal and state laws regarding:

- test ordering and billing practices;
- marketing, sales and pricing practices;
- health information privacy and security, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and comparable state laws;
- insurance;
- anti-markup legislation; and
- consumer protection.

We are also required to comply with FDA regulations, including with respect to our labeling and promotion activities. In addition, advertising of our tests is subject to regulation by the Federal Trade Commission, ("FTC") and advertising of laboratory services is regulated by certain state laws. Violation of any FDA requirement could result in enforcement actions, such as seizures, injunctions, civil penalties and criminal prosecutions, and violation of any FTC or state law requirement could result in injunctions and other associated remedies, all of which could have a material adverse effect on our business. Most states also have similar regulatory and enforcement authority for devices. Additionally, most foreign countries have authorities comparable to FDA and processes for obtaining marketing approvals. Obtaining and maintaining these approvals, and complying with all laws and regulations, may subject us to similar risks and delays as those we could experience under FDA, FTC and state regulation. We incur various costs in complying and overseeing compliance with these laws and regulations.

Healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments and healthcare laws and regulations are subject to change. Development of the existing commercialization strategy for our EsoGuard test and EsoCheck device has been based on existing healthcare policies. We cannot predict what additional changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations.

If we or our partners fail to comply with these laws and regulations, we could incur significant fines and penalties and our reputation and prospects could suffer. Additionally, any such partners could be forced to cease offering our products and services in certain jurisdictions, which could materially disrupt our business.

We operate Lucid Test Centers where prescribing physicians can send patients for EsoGuard testing, including undergoing specimen collection using EsoCheck. These Lucid Test Centers are subject to federal and state regulations which may be burdensome, costly or difficult to comply with. Failure to comply with these regulations could result in sanctions, fines or other enforcement actions which may be costly, time-consuming and limit our ability to utilize them and adversely impact our business.

As part of our commercialization efforts for EsoGuard, we are operating Lucid Test Centers in jurisdictions where a licensed health care professional, employed or contracted by us, will perform the esophageal cell collection procedure using EsoCheck and then package the specimen for transport to our CLIA-certified commercial clinical laboratory. The Lucid Test Centers may be deemed laboratory draw stations or outpatient centers or clinics, which may be subject to state licensure and operating requirements. In addition, states may require personnel performing the specimen collection procedure to be licensed and may require collaboration with or supervision by a physician. The health care professionals may also be subject to malpractice claims. We will need to purchase insurance policies to cover such claims but the coverage limits on such policies may be insufficient to cover any monetary awards for damages granted for such claims. In certain states, our Lucid Test Centers may trigger the corporate practice of medicine doctrine, a general prohibition in some jurisdictions against non-licensed individuals or corporations owning medical practices or employing physicians and other licensed HCPs. In many states, a general business corporation cannot directly employ health care professionals or enter any arrangement where the physicians or the healthcare professional is in any way controlled or directed by the corporation. Complying with these state regulations can be complex, burdensome and costly and we may be unable to do so in certain states, limiting our commercialization efforts and business in those states. The Lucid Test Centers may be subject to additional state regulations relating to the distribution of the collection devices, test orders, patient consents, medical necessity requirements and billing regulations.

We have invested heavily in regulatory and compliance infrastructure in an effort to ensure compliance with this regulatory framework, however, we cannot guarantee that we will remain in compliance with these rules at all times. Our failure to comply with these regulations in the operation of these Lucid Test Centers or in managing the personnel interacting with patients at these centers could subject us to sanctions, fines or other enforcement actions. Responding to these actions may be costly and time-consuming and may require us to cease operations at these centers which may limit our commercialization efforts and adversely impact our business.

We intend to engage with one or more third-party telemedicine companies to provide physicians to evaluate patients and, if clinically indicated, refer the patient to our Lucid Test Centers or to a #CheckYourFoodTube Precancer Testing Event, to undergo EsoCheck specimen collection for EsoGuard testing. Telemedicine is subject to numerous federal and state regulations and faces particularly intense scrutiny by these regulators. If we fail to comply with federal healthcare regulations, we could face substantial penalties, sanctions, fines or prosecution and our business, operations and financial condition could be adversely affected.

One element of our growth strategy is to expand EsoGuard commercialization across multiple channels, including by partnership with telemedicine providers. The logistics required to manage a patient's journey through a telemedicine program, in a manner which is compliant with all applicable regulations, are complex and require very careful coordination between us and our third-party telemedicine and laboratory partners broadly operating within our quality management system. Our activities and the activities of our third-party partners on our behalf within this telemedicine program are subject to numerous federal and state regulations. The telemedicine provider itself may be subject to additional state regulations relating to the corporate practice of medicine, test orders, patient consents, medical necessity requirements and billing regulations. Telemedicine faces particularly intense scrutiny from regulators due to numerous cases of companies failing to operate in this space with a properly functioning regulatory and compliance infrastructure.

We cannot guarantee that our personnel or those of our third-party partners will comply with the applicable regulations at all times. If any such personnel fail to comply with regulations, we could face substantial penalties, sanctions, fines or prosecution and our business, operations and financial condition could be adversely affected.

Many aspects of our business, beyond the specific elements described above, are subject to complex, intertwined, costly and/or burdensome federal health care laws and regulations which may open to interpretation and be subject to varying levels of discretionary enforcement. If we fail to comply with these laws and regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

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

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the U.S. Foreign Corrupt Practices Act, or "FCPA," which prohibits payments or the provision of anything of value to foreign officials for the purpose of obtaining or keeping business;
- the federal False Claims Act, or "FCA," which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information, and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

In 2018, Congress passed Eliminating Kickbacks in Recovery Act ("EKRA") as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. Similar to the Anti-Kickback Statute, EKRA imposes criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing (among other healthcare services) unless a specific exception applies. However, unlike the Anti-Kickback Statute, EKRA is not limited to services covered by federal or state healthcare programs but applies more broadly to services covered by "healthcare benefit programs," including commercial insurers. EKRA potentially expands the universe of arrangements that could be subject to government enforcement under federal fraud and abuse laws. In addition, while the Anti-Kickback Statute includes certain exceptions that are widely relied upon in the healthcare industry, not all of those same exceptions apply under EKRA. We cannot assure you that our relationships with healthcare providers, sales representatives, hospitals, customers, or any other party will not be subject to scrutiny or will survive regulatory challenge under EKRA.

If our operations or arrangements 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, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of these laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against that action and the underlying alleged violations, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If the physicians or other providers or entities with whom we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

The regulations that govern pricing and reimbursement for new products vary widely from country to country, and may adversely affect the pricing, coverage and reimbursement rates of our products in other countries.

The regulations that govern 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 clearance or 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 clearance or 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. In addition, 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. Adverse pricing limitations may hinder our ability to recoup our investment in the EsoGuard and EsoCheck products and any other products, tests or services we develop, even if our products obtain regulatory approval.

Due to billing complexities in the diagnostic and laboratory service industry, we may not be able to collect payment for the EsoGuard tests we perform.

Billing for diagnostic and laboratory services is a complex process. Laboratories bill many different payors including patients, private insurance companies, Medicare, Medicaid, and employer groups, all of which have different billing requirements. We are continuing to work with third-party payors to cover and reimburse EsoGuard tests. If we are unsuccessful, we may not receive payment for EsoGuard tests we perform for patients on a timely basis, if at all, and we may not be able to provide services for patients with certain healthcare plans. We may face lawsuits by government or commercial payors if they believe they have overpaid us for our EsoGuard test services. We may face write-offs of doubtful accounts, disputes with payors and patients, and long collection cycles. We may face patient dissatisfaction, complaints or lawsuits, including to the extent EsoGuard tests are not fully covered by insurers and patients become responsible for all or part of the price of the test. As a result, patient compliance in fulfilling prescriptions for EsoGuard could be adversely affected. To the extent patients express dissatisfaction with our billing practices to their physicians, those physicians may be less likely to prescribe EsoGuard for other patients, and our business would be adversely affected.

Even if payors do agree to cover EsoGuard, our billing and collections process may be complicated by the following and other factors, which may be beyond our control:

- disputes among payors as to which payor is responsible for payment;
- disparity in coverage among various payors or among various healthcare plans offered by a single payor;

- payer medical management requirements, including prior authorization requirements;
- differing information and billing requirements among payors; and
- failure by patients or physicians to provide complete and correct billing information.

Furthermore, our contracts with a commercial payor may not permit us to bill patients insured by that payor for amounts beyond deductibles, co-payments and co-insurance as prescribed in the coverage agreement between the payor and the patients. Moreover, when contracted payors do not cover an EsoGuard test, for example, for failure to satisfy prior-authorization or other payor medical management requirements, we may not be permitted to collect the balance from the patient and our business may be adversely impacted.

The uncertainty of receiving payment for our EsoGuard test and complex laboratory billing processes could negatively affect our business and our operating results.

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

There may well 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 an IRB 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 all 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 FDA or other regulatory authorities to clinical studies and the medical device approval process. Adverse event data from clinical studies may receive greater scrutiny with respect to product safety, which may make 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, 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.

Our medical products may in the future be subject to product recalls that could harm our reputation, business, and financial results.

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 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 us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. FDA requires that certain classifications of recalls be reported to FDA within ten working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of FDA. If FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect its sales. In addition, FDA could take enforcement action for failing to report the recalls when they were conducted. No recalls of our medical products have been reported to FDA.

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

Under FDA medical device reporting regulations, medical device manufacturers are required to report to 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 we fail to report these events to FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any such adverse event involving our 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 our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our products.

We face an inherent risk of product liability exposure related to the sale of the EsoGuard and EsoCheck products and any other products we develop. The marketing, sale and use of our products 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 a product we developed 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.

Compliance with the HIPAA security, privacy and breach notification regulations may increase our costs.

The HIPAA privacy, security and breach notification regulations, including the expanded requirements under HITECH, establish comprehensive federal standards with respect to the uses and disclosures of protected health information, or "PHI," by health plans, healthcare providers and healthcare clearinghouses, in addition to setting standards to protect the confidentiality, integrity and security of PHI. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payments for our services, and our healthcare operations activities;
- a patient's rights to access, amend and receive an accounting of certain disclosures of PHI;
- requirements to notify individuals if there is a breach of their PHI;
- the contents of notices of privacy practices for PHI;
- administrative, technical and physical safeguards required of entities that use or receive PHI; and
- the protection of computing systems maintaining electronic PHI.

We have implemented practices intended to meet the requirements of the HIPAA privacy, security and breach notification regulations, as required by law. We are required to comply with federal privacy, security and breach notification regulations as well as varying state privacy, security and breach notification laws and regulations, which may be more stringent than federal HIPAA requirements. In addition, for healthcare data transfers from other countries relating to citizens of those countries, we must comply with the laws of those countries. The federal privacy regulations restrict our ability to use or disclose patient identifiable data, without patient authorization, for purposes other than payment, treatment, healthcare operations and certain other specified disclosures such as public health and governmental oversight of the healthcare industry.

HIPAA provides for significant fines and other penalties for wrongful use or disclosure of PHI, including potential civil and criminal fines and penalties. Computer networks are always vulnerable to breach and unauthorized persons may in the future be able to exploit weaknesses in the security systems of our computer networks and gain access to PHI. Additionally, we share PHI with third-parties who are legally obligated to safeguard and maintain the confidentiality of PHI. Unauthorized persons may be able to gain access to PHI stored in such third-parties computer networks. Any wrongful use or disclosure of PHI by us or such third-parties, including disclosure due to data theft or unauthorized access to our or our third-parties computer networks, could subject us to fines or penalties that could adversely affect our business and results of operations. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we could also incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

Risks Associated with Our Intellectual Property and Technology Infrastructure

We may not be able to protect or enforce the intellectual property rights for the technology used in, or expected to be used in, our products, which could impair our competitive position.

Our success depends significantly on our ability to protect the patents, trademarks, trade secrets, copyrights and the other intellectual property rights for the technology used, or expected to be used, in our products. We rely primarily on patent protection and trade secrets, including the patents to the EsoGuard and EsoCheck technologies licensed by us from CWRU, as well as a combination of copyright and trademark laws and nondisclosure and confidentiality agreements to protect the technology and other intellectual property on which we rely. 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. In addition, although we have the right to direct CWRU to seek patent protection for the EsoGuard and EsoCheck technology in additional countries, we have limited control over the prosecution of any such application and have limited control over CWRU's other intellectual property practices as they relate to the EsoGuard and EsoCheck technologies. Despite our intellectual property rights practices, it may be possible for a third party to copy or otherwise obtain and use the technology on which we rely without authorization, develop similar technology independently or design around our patents. Furthermore, protecting intellectual property rights is costly and time consuming. We are responsible for the costs of CWRU in preparing, filing and prosecuting any patents related to the EsoGuard technology (subject to a provision for cost sharing in the event CWRU grants additional licenses to the technology, none of which would be permitted to overlap with our field of use).

Patents relied on by us may expire or may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related technologies. If any of the patents fails to protect the technology used by us, it would make it easier for our competitors to offer similar products. In addition, there is no assurance that competitors will not be able to design around the patents. Upon expiration of the 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. We cannot be assured that any pending or future patent applications for the technology on which we rely will result in the issuance of a patent to us. The U.S. Patent and Trademark Office, or the "PTO," may deny or require significant narrowing of claims in the patent applications, and patents issued as a result of the 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.

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 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 also rely on the use of registered and common law trademarks with respect to the brand names of some of our products. Common law trademarks provide less protection than registered trademarks.

Furthermore, we may not be able to obtain patent protection and other intellectual property rights in all the countries in which we operate, and under the laws of such countries, patents and other intellectual property rights may be unavailable or limited in scope.

Any inability on our part to adequately protect our intellectual property may have a material adverse effect on our business, financial condition and results of operations.

We 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 or CWRU their patent, copyright, trademark, and other intellectual property rights relating to technologies that are important to our business. Searches for existing intellectual property rights may not reveal important intellectual property and our competitors may also have filed for patent protection, information which is not publicly available, just as claimed trademark rights may not be revealed through our searches. We may be subject to claims that our team members or CWRU's personnel have disclosed, or that we have used, or CWRU has used, trade secrets or other proprietary information of our team members' or CWRU's personnel's former employers. Our efforts to identify and avoid infringing upon 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. In any infringement litigation against CWRU relating to the EsoGuard technology, we will have the right to assume the defense of such suit at our expense.

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

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

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

Competitors may violate the intellectual property rights for the technology used in, or expected to be used in, our products, and we may bring litigation to protect and enforce our intellectual property rights, which may result in substantial expense and may divert our attention from implementing our business strategy.

We believe that the success of our business will depend, in significant part, on obtaining patent protection for our products and technologies, defending our patents and preserving our trade secrets and other proprietary intellectual property rights. Our failure to pursue any potential claim could result in the loss of our proprietary intellectual property 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.

Failure in our information technology 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. We are substantially dependent on those IT systems to receive and process EsoGuard test orders, securely store patient health records and deliver the results of our EsoGuard tests. IT systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts including cyberattacks, and natural disasters. 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, and in particular to operate our clinical laboratory, could adversely affect our ability to operate our business. Any interruption in the operation of IT systems could have an adverse effect on our operations.

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.

Our internal computer systems, or those used by our third-party research institution collaborators, vendors or other contractors or consultants, may suffer security breaches.

In the ordinary course of our business, we and our contract manufacturers store sensitive data, including intellectual property, proprietary business information, personally identifiable information of our employees and patient health records, in our data centers and on our networks. 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. Despite the implementation of security measures by us and by our contractors, our internal computer systems and those of our contractors may be vulnerable to security breaches and damage from computer viruses, unauthorized access and ransomware attacks, including the unauthorized encryption of data stored on our computer network. Any such breach or attack could materially affect business operations and result in a loss of data, damage to our IT systems, or inappropriate disclosure of confidential or proprietary 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, damage to our reputation, and delays in the commercialization of our products. In addition, we could incur additional cost, expense and the diversion of time and resources to recover from such an attack, and any such attach could cause our management to conclude that our disclosure controls and procedures were not effective.

Risks Associated with Our Relationship with PAVmed

PAVmed owns a majority of our voting stock and thus it (or any successor to its stake in the Company), may control certain actions requiring a stockholder vote.

PAVmed owns approximately 70.1% as of December 31, 2023 and 64.9% as of March 21, 2024 of our issued common stock (with such percentage inclusive of shares of our common stock underlying granted but unvested restricted stock awards), but excluding the voting power of any convertible securities. Presently, PAVmed controls more than 50% of the combined voting power of our common stock and our convertible securities and for as long as PAVmed continues to control more than 50% of our voting securities, PAVmed will be able to direct the election of all the members of our board of directors. Thus, we are a majority-owned subsidiary of PAVmed, and PAVmed has a controlling financial interest. In addition, as long as PAVmed continues to control more than 50% of our voting securities, PAVmed will have the ability to take stockholder action without the vote of any other stockholder and without having to call a stockholder meeting. Similarly, PAVmed will have the ability to prevent the approval of any action submitted to the stockholders. If PAVmed does not provide any requisite consent allowing us to take any such action when requested, we will not be able to engage in the related activities and, as a result, our business and our operating results may be harmed.

PAVmed's interests and objectives as a stockholder may not align with, or may even directly conflict with, your interests and objectives as a stockholder. For example, PAVmed may be more or less interested in us entering into a transaction or conducting an activity due to the impact such transaction or activity may have on PAVmed as a company, independent of us. In such instances, PAVmed may exercise its control over us in a way that is beneficial to PAVmed, and you will not be able to affect the outcome so long as PAVmed continues to hold a majority of the shareholder votes.

In the event PAVmed is acquired or otherwise undergoes a change of control, any acquiror or successor will be entitled to exercise the voting control and contractual rights of PAVmed and may do so in a manner that could vary significantly from that of PAVmed.

With the goal of mitigating the risks flowing from PAVmed's control position, we have decided not to seek exemption as a "controlled company" from the corporate governance rules of Nasdaq, and therefore will be bound by the same corporate governance principles as other public companies, including the requirement that a majority of our directors be independent and that we maintain audit, compensation and nominating committees comprised of independent directors. However, our decision not to rely on the "controlled company" exemption could change. Although we do not anticipate changing our decision, for so long as a majority of our outstanding common stock is held by PAVmed (or by any other stockholder or group of stockholders), we could choose to rely on this exemption in the future to avoid complying with certain of the Nasdaq corporate governance rules, including the rules that require us to have a board comprised of at least 50% independent directors, to have board nominations either selected, or recommended for the board's selection, by either a nominating committee comprised solely of independent directors or by a majority of the independent directors and to have officer compensation determined, or recommended to the board for determination, either by a compensation committee comprised solely of independent directors or by a majority of the independent directors. Any decision to rely on the "controlled company" exemption will be disclosed in our annual proxy statement.

If PAVmed's debt is accelerated due to its default under the terms thereof, PAVmed could cease to have voting control of the Company.

PAVmed currently has a significant amount of convertible debt outstanding, which begins to mature in April 2025, and has from time to time been in default thereunder. PAVmed is currently in compliance with the financial and other covenants under such indebtedness, although 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), PAVmed was not in compliance with certain financial covenants thereunder. While the holder of such indebtedness agreed to waive any such non-compliance, there can be no assurance that it will do so in the future. If the debtholder elects to accelerate PAVmed's indebtedness rather than waiving any such non-compliance, it is likely PAVmed will not have sufficient cash on hand to pay the amounts due on an acceleration, in which case it may be required to satisfy its obligations through the transfer of its shares of common stock of the Company to such debtholder. In such event, the debtholder in turn would be entitled to exercise the voting control and contractual rights of PAVmed and may do so in a manner that could vary significantly from that of PAVmed.

Certain conflicts of interest may arise between us and our affiliated companies, including PAVmed, and in some cases we have waived certain rights with respect thereto.

Our certificate of incorporation includes a provision stating that we renounce any interest or expectancy in, or being offered an opportunity to participate in, any business opportunities, that are presented to our officers, directors, employees or stockholders, or affiliates thereof, who are also officers, directors, employees or stockholders of PAVmed or affiliates thereof, each a "PAVmed Party," and in which a PAVmed Party may have an interest or expectancy, a "PAVmed Opportunity," except as may be prescribed by any written agreement between us and PAVmed approved by our Board of Directors. In addition, no PAVmed Party will have any duty to communicate or present such business opportunities to us, and no PAVmed Party will be liable to our company or our stockholders for breach of any fiduciary duty, including by reason of a PAVmed Party pursuing or acquiring any PAVmed Opportunity. Pursuant to the management services agreement, no PAVmed Party will pursue any opportunity related to commercializing the EsoGuard diagnostic test and the EsoCheck cell collection device or developing and commercializing other products that use or enhance the same underlying technology.

As a result of the foregoing, a potential business opportunity may be presented by certain members of our management team to another entity prior to its presentation to us and we may not be afforded the opportunity to engage in such a transaction. In addition, if any PAVmed Party becomes aware of a potential business opportunity that is a PAVmed Opportunity (other than those specified in the management services agreement), including any such opportunity relating to any other diagnostic test or medical device, he or she will be entitled to present those opportunities to another PAVmed Party prior to presenting them to us. Accordingly, any conflicts of interest among us and our officers, directors, stockholders or their affiliates, including PAVmed and certain of our officers and directors, relating to business opportunities may not be resolved in our favor, and in cases where the business opportunity is a PAVmed Opportunity and it is presented to another PAVmed Party, we have waived our right to monetary damages in the event of any such conflict.

Our ability to operate our business effectively may suffer if the MSA with PAVmed is insufficient to meet our needs or if, upon the termination of the MSA, we do not cost-effectively establish our own fully functional financial, administrative, operational and other support systems in order to operate as a stand-alone company.

We will continue to use PAVmed's services under the MSA until such time as our Board of Directors determines it would be in our best interest to engage a dedicated management team. Upon termination or amendment of the MSA, we may need to create our own financial, administrative, operational and other support systems or contract with third parties to replace PAVmed's systems. As such systems will be new, it may take additional time to fully implement and stabilize these systems. In order to successfully implement our own systems and operate as a stand-alone business, we must be able to attract and retain a number of highly skilled employees.

The services provided under the MSA may not be sufficient to meet our needs and, after we terminate the MSA, we may not be able to replace these services or facilities at favorable costs and on favorable terms, if at all. Any gap in the services provided by PAVmed, or failure or significant downtime in our own financial or administrative systems once established, could result in unexpected costs, impact our results and/or prevent us from paying our suppliers and employees and performing other administrative services on a timely basis and could materially harm our business, financial condition, results of operations and cash flows.

We cannot assure you that such services are not available at lower cost from third parties. Any payments made to PAVmed will reduce our cash flow and profits.

Any disputes that arise between us and PAVmed with respect to our past and ongoing relationships could harm our business operations.

Disputes may arise between PAVmed and us in a number of areas relating to our past and ongoing relationships, including:

- employee allocation, retention and recruiting;
- the nature, quality, and pricing of the services PAVmed has agreed to provide us; and
- business opportunities that may be attractive to both PAVmed and us.

We may not be able to resolve any potential conflicts, and even if we do, the resolution may be less favorable than if we were dealing with an unaffiliated party.

Risks Associated with Ownership of Our Common Stock

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

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts currently publish research on our company, but there is no assurance that they will continue to do so. If no securities or industry analysts cover our company, the trading price for our common stock would likely be negatively impacted. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

Nasdaq may in the future delist our common stock, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

Our common stock is listed on the Nasdaq Capital Market. We are required to meet certain financial and liquidity criteria to maintain the listing of our common stock on Nasdaq. If we violate the Nasdaq continued listing requirements or fail to meet any of Nasdaq's continued listing standards, our common stock may be delisted. In addition, while we have no present intention to do so, our Board of Directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing.

If Nasdaq delists our common stock from trading on its exchange, or we voluntarily remove our common stock from listing, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- reduced liquidity with respect to our common stock;
- a determination that our shares of common stock are "penny stock" which will require brokers trading in our shares of common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares of common stock;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Our stock price may be volatile, and holders of our common stock 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. As a result of this volatility, investors may experience losses on their investment in our common stock. For example, on March 21, 2024, the last reported sale price of our common stock was $1.11. In the last six months, between September 21, 2023 and March 21, 2024, the intra-day sale price of our common stock fluctuated between a reported low sale price of $0.99 and a reported high sale price of $1.58. We may incur rapid and substantial increases or decreases in our stock price in the foreseeable future that may or may not coincide in timing with the disclosure of news or developments by us.

In addition, on February 15, 2024, PAVmed paid a distribution to its shareholders of approximately 3.3 million shares of our common stock, thereby increasing our public float and the size of our shareholder base, both of which could increase volatility of our common stock. PAVmed could make similar distributions in the future, which could further increase the volatility of our stock price.

The market price for our common stock may be influenced by many broad market and industry factors. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In addition, the market price for our common stock may be subject to price movements that 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. 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.

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

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

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

As a public company, we will incur significant legal, accounting and other expenses that we would not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the other rules and regulations of the Securities and Exchange Commission, or "SEC," and the rules and regulations of Nasdaq. The expenses that will be required in order to adequately prepare for being a public company will be material, and compliance with the various reporting and other requirements applicable to public companies will require considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. These rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly, and could also make it more difficult for us to attract and retain qualified personnel to serve on our Board of Directors, our board committees, or as executive officers.

If we fail to establish and maintain proper and effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline significantly.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. As a public company, we will be required to maintain internal controls over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires annual management assessment of the effectiveness of our internal control over financial reporting. However, our auditors will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until we are no longer an emerging growth company if we continue to take advantage of the exemptions available to us through the JOBS Act.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis could cause investors to lose confidence in the accuracy and completeness of our financial reports and could cause the market price of our common stock to decline significantly.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

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

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 will be 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 will have 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 will not permit cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; and
- our stockholders will be 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.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% 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% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our charter provides, subject to limited exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.

Our amended and restated certificate of incorporation will require, to the fullest extent permitted by law, subject to limited exceptions, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel in any action brought to enforce the exclusive forum provision. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our amended and restated certificate of incorporation.

Notwithstanding the foregoing, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision will provide that the Court of Chancery and the federal district court for the District of Delaware will have concurrent jurisdiction over any action arising under the Securities Act or the rules and regulations thereunder, and the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder or any other claim for which the federal courts have exclusive jurisdiction. To the extent the exclusive forum provision restricts the courts in which our stockholders may bring claims arising under the Securities Act and the rules and regulations thereunder, there is uncertainty as to whether a court would enforce such provision. Investors cannot waive compliance with the federal securities laws and the rules and regulations promulgated thereunder.

This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. By requiring a stockholder to bring such a claim in the Court of Chancery (or the federal district court for the District of Delaware, in the case of an action under the Securities Act or the rules and regulations thereunder), the exclusive forum provision also may increase the costs to a stockholder of bringing such a claim. Alternatively, if a court were to find the exclusive forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

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 president and 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, which is leased through our parent corporation PAVmed Inc. 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 has a lease agreement for its CLIA laboratory in California with 21,019 square feet, which has a remaining term expiring December 31, 2024. We also have lease agreements for our Lucid Test Centers in various locations in Arizona, California, Colorado, Florida, Idaho, Illinois, Nevada, Ohio, 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 office space in the future, as warranted by our business operations.

Item 3. Legal Proceedings

In the ordinary course of our business, particularly as it begins commercialization of its products, the Company may be subject to certain other legal actions and claims, including product liability, consumer, commercial, tax and governmental matters, which may arise from time to time. 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 - Other Information

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 “LUCD”.

Holders

As of March 21, 2024, there were 48,244,798 shares of our common stock issued. Our shares of common stock are held by an estimated 256 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 dividends will be made by our board of directors. We do not anticipate paying dividends in the foreseeable future but expect to retain earnings to finance the growth of our business. Subject to the restrictions described below and applicable law, our board of directors has complete discretion on whether to pay dividends. Even if our board of directors decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions, amongst and other factors deemed relevant.

As long as the Senior Convertible Note (see “*Liquidity and Capital Resources*” in Item 7 below) is 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 Note. Furthermore, our common stock is junior to our preferred stock with respect to certain in-kind dividends payable to the holders of such preferred stock.

Series B Preferred Stock

The holders of Series B Preferred Stock are entitled to dividends payable as follows: (i) a number of shares of common stock equal to 20% of the number of shares of common stock issuable upon conversion of the Series B Preferred Stock then held by such holder on March 13, 2025, and (ii) a number of shares of common stock equal to 20% of the number of shares of common stock issuable upon conversion of the Series B Preferred Stock then held by such holder on March 13, 2026. Under the terms of the Series B Preferred Stock, a holder that converts its Series B Preferred Stock prior to March 13, 2025 or March 13, 2026, as the case may be, will not receive the dividend that accrues on such date with respect to such converted Series B Preferred Stock. The holders of the Series B Preferred Stock also will be entitled to dividends equal, on an as-if-converted to shares of common stock basis, to and in the same form as dividends actually paid on shares of the common stock when, as, and if such dividends are paid on shares of the common stock.

Recent Sales of Unregistered Securities and Use of Proceeds

Except as previously disclosed in our current reports on Form 8-K and quarterly reports on Form 10-Q, and except as disclosed 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", "Lucid" and "Lucid Diagnostics" refer to Lucid Diagnostics Inc. and its subsidiaries LucidDx Labs Inc. ("LucidDx Labs") and CapNostics, LLC ("CapNostics"), (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, (v) "CE Mark" refers to a "Conformité Européenne" Mark, a mark indicating that a product such as a medical device conforms to the essential requirements of the relevant European directive, and (vi) "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

We are a commercial-stage medical diagnostics technology company focused on the millions of patients who are at risk of developing esophageal precancer and cancer, specifically highly lethal EAC.

We believe that our flagship product, 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 tool for the early detection of esophageal precancer, including Barrett's Esophagus ("BE"), in at-risk patients. Early detection of esophageal precancer allows patients to undergo appropriate monitoring and treatment, as indicated by clinical practice guidelines, in an effort to prevent progression to esophageal cancer.

EsoGuard is a bisulfite-converted targeted 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). Analytical validation tests of EsoGuard demonstrated approximately 97% analytical sensitivity, 95% analytical specificity, approximately 98% analytical accuracy, and 100% inter-assay and intra-assay precision. Two independent clinical validation case control studies funded by the National Institute of Health utilized were performed using upper endoscopy with biopsies as the diagnostic comparator and confirmed EsoGuard accurately identifies BE. A pooled analysis of both studies demonstrated 84% sensitivity (95% confidence interval [CI] 76-90%), for detection of BE, and 86% specificity (95% CI 81-91%). Positive predictive value (PPV) and negative predictive value (NPV) were calculated using a BE prevalence of 10.6% published in a meta-analysis of U.S patients with GERD. This resulted in a PPV of approximately 42% and NPV of around 98%.

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 an accurate, non-invasive, patient-friendly test for the early detection of EAC and BE, including dysplastic BE and related precursors to EAC in patients with GERD, commonly known as chronic heart burn, acid reflux, or just reflux.

Recent Developments

Business

Intercompany Agreements with PAVmed

In January 2024, in accordance with the MSA and the PBERA, PAVmed elected to receive payment of $4.7 million of fees and reimbursements accrued under the MSA and the PBERA through the issuance of 3,331,771 shares of the Company's common stock.

In March 2024, the Company entered into an eighth amendment to the MSA with PAVmed, increasing the monthly fee due thereunder from $0.75 million to $0.83 million, effective as of January 1, 2024.

Financing

Preferred Stock Offerings

On March 13, 2024, we 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 our newly designated Series B Convertible Preferred Stock, par value $0.001 per share (the "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 our Series A Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), and 10,670 shares of our Series A-1 Convertible Preferred Stock, par value $0.001 per share (the "Series A-1 Preferred Stock"), held by them for 31,790 shares of Series B Preferred Stock (collectively, the "Series B Offering and Exchange"). Prior to the execution of the Series B Subscription Agreements and the Exchange Agreements, we entered into subscription agreements with certain of the Series B Investors providing for the sale to such investors of 5,670 shares of 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 Series B Preferred Stock pursuant to the Exchange Agreements (and are included in the 10,670 shares of Series A-1 Preferred Stock set forth above). Each share of the Series B Preferred Stock has a stated value of $1,000 and a conversion price of $1.2444. The terms of the 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 our common stock into which such Series B Preferred Stock is convertible, payable on the one-year and two-year anniversary of the issuance date. The Series B Preferred Stock is a voting security. The aggregate gross proceeds of these transactions was $18.16 million (inclusive of $5.67 million of aggregate gross proceeds from the sale of the Series A-1 Preferred Stock that was immediately exchanged for Series B Preferred Stock in the transactions).

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

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

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 Company and RDx, a CLIA certified commercial laboratory service provider. On February 25, 2022, the EsoGuard Commercialization Agreement was terminated upon our acquisition, pursuant to the APA-RDx, of certain assets necessary to operate our own CLIA certified laboratory. For a fuller description of the APA-RDx, see Note 6, *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 the portion of the MSA Fee (as defined in Note 5, *Related Party Transactions*, to our accompanying consolidated financial statements) allocated to sales and marketing expenses, which are principally costs related to PAVmed employees who are performing services for the Company. 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 professional fees for accounting, tax, audit and legal services (including those fees incurred as a result of our being a public company), consulting fees, expenses associated with obtaining and maintaining patents within our intellectual property portfolio, and certain employee costs, along with the portion of the MSA Fee allocated to general and administrative expenses.

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 technologies and conducting clinical trials, including:

- costs associated with regulatory filings;
- patent license fees;
- cost of laboratory supplies and acquiring, developing, and manufacturing preclinical prototypes; and
- MSA Fee allocated to research and development.

We plan to incur research and development expenses for the foreseeable future as we continue the development of our existing products as well as new innovations. Our research and development activities, including our clinical trials, are focused principally on facilitating insurer reimbursement, encouraging physician adoption and developing product improvements or extending the utility of the lead products in our pipeline, including EsoCheck and EsoGuard.

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.

Results of Operations - continued

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

Revenue

In the year ended December 31, 2023, revenue was $2.4 million as compared to $0.4 million in the prior year. The $2.0 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 prior year period, which 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 $6.0 million as compared to $3.6 million in the prior year. The $2.4 million increase was principally related to:

- approximately $1.6 million increase in EsoCheck and EsoGuard supplies costs; and
- approximately $0.8 million increase in compensation related costs, including stock-based compensation.

Sales and marketing expenses

In the year ended December 31, 2023, sales and marketing costs were approximately $16.4 million as compared to $16.1 million in the prior year. The net increase of $0.3 million was principally related to:

- approximately $2.0 million increase in compensation related costs principally as a result of an increase in headcount, including stock-based compensation; and
- approximately $1.7 million decrease in third party marketing expenses.

General and administrative expenses

In the year ended December 31, 2023, general and administrative costs were approximately $19.3 million as compared to $24.0 million in the prior year. The net decrease of $4.7 million was principally related to:

- approximately $8.3 million decrease in stock-based compensation;
- approximately $3.3 million increase related to the amended MSA with PAVmed due to the growth and expansion of our business and the services incurred through PAVmed; and
- approximately $0.3 million increase related to outside professional services and facility related costs.

Research and development expenses

In the year ended December 31, 2023, research and development costs were approximately $7.3 million, compared to $11.3 million in the prior year. The net decrease of $4.0 million was principally related to:

- approximately $5.5 million decrease in development costs, particularly in clinical trial activities and outside professional and consulting fees with respect to EsoCure;
- approximately $0.7 million increase related to the amended MSA with PAVmed due to the growth and expansion of our business and the services incurred through PAVmed; and
- approximately $0.8 million increase in compensation related costs, including stock-based compensation.

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 $1.6 million in the prior year. The increase of $0.4 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 note was approximately $3.0 million of expense, related to the March 2023 Senior Convertible Note. The March 2023 Senior Convertible Note was initially measured at its issue date estimated fair value and subsequently remeasured at estimated fair value as of each reporting period date. The Company initially recognized a $0.8 million fair value non-cash expense on the issue date.

Loss on Issue and Offering Costs - Senior Secured Convertible Note

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

See Note 13, Debt, to our accompanying consolidated financial statements, for additional information with respect to the March 2023 Senior Convertible Note.

Liquidity and Capital Resources

Our current operational activities are principally focused on the commercialization of EsoGuard. We are pursuing commercialization across multiple sales channels, including: the communication to and education of medical practitioners and clinicians regarding EsoGuard; the establishment of Lucid Test Centers for the collection of cell samples using EsoCheck; the launch of the mobile testing unit; ongoing #CheckYourFoodTube testing days; and our direct contracting strategic initiative. Additionally, we are developing expanded clinical evidence to support insurance reimbursement adoption by government and private insurers. Further, as resources permit, the Company also intends to pursue development of other products and services.

Our ability to generate revenue depends upon our ability to successfully advance the commercialization of EsoGuard, including significantly expanding insurance reimbursement coverage, while also completing the clinical studies, product and service development, and necessary regulatory approval thereof. There are no assurances, however, we will be able to obtain an adequate level of financial resources required for the long-term commercialization and development of our products and services.

We are 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. We experienced a net loss of approximately $52.7 million and used approximately $32.8 million of cash in operations during the year ended December 31, 2023. Financing activities provided $29.5 million of cash during the year ended December 31, 2023. We ended the year with cash on-hand of $18.9 million as of December 31, 2023. We expect to continue to experience recurring losses and negative cash flow from operations, and will continue to fund our operations with debt and/or equity financing transactions, including current obligations on our 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

Preferred Stock Offerings

On March 13, 2024, we 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 our newly designated Series B Convertible Preferred Stock, par value $0.001 per share (the "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 our Series A Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), and 10,670 shares of our Series A-1 Convertible Preferred Stock, par value $0.001 per share (the "Series A-1 Preferred Stock"), held by them for 31,790 shares of Series B Preferred Stock (collectively, the "Series B Offering and Exchange"). Prior to the execution of the Series B Subscription Agreements and the Exchange Agreements, we entered into subscription agreements with certain of the Series B Investors providing for the sale to such investors of 5,670 shares of 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 Series B Preferred Stock pursuant to the Exchange Agreements (and are included in the 10,670 shares of Series A-1 Preferred Stock set forth above). Each share of the Series B Preferred Stock has a stated value of $1,000 and a conversion price of $1.2444. The terms of the 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 our common stock into which such Series B Preferred Stock is convertible, payable on the one-year and two-year anniversary of the issuance date. The Series B Preferred Stock is a voting security. The aggregate gross proceeds of these transactions was $18.16 million (inclusive of $5.67 million of aggregate gross proceeds from the sale of the Series A-1 Preferred Stock that was immediately exchanged for Series B Preferred Stock in the transactions).

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

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

Private Placement - Securities Purchase Agreement

Effective as of March 13, 2023, we entered into the SPA with an accredited institutional investor, pursuant to which we agreed to sell, and the investor agreed to purchase the March 2023 Senior Convertible Note with a face value principal of $11.1 million. We issued the March 2023 Senior Convertible Note on March 21, 2023 pursuant to the SPA. The March 2023 Senior Convertible Note proceeds were $9.925 million after deducting a $1.186 million lender fee and offering costs.

The March 2023 Senior Convertible Note has a 7.875% annual stated interest rate, a contractual conversion price of $5.00 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 the two-year anniversary of the date of issuance. The principal of the March 2023 Senior Convertible Note and accrued interest thereon is convertible at the option of the holder into the Company's common stock at the contractual conversion price. In addition, the principal of the March 2023 Senior Convertible Note amortizes over 18 months commencing six months after its issuance. The amortization payments and accrued interest on the March 2023 Senior Convertible Note are payable in shares of the Company's common stock (subject to the satisfaction of certain customary equity conditions and except for interest payable prior to September 21, 2023), at prices based on the then current market price.

Under the March 2023 Senior Convertible Note, the Company is subject to certain customary affirmative and negative covenants regarding the incurrence of indebtedness, the existence of liens, the repayment of indebtedness 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 March 2023 Senior Convertible Note, the Company is also subject to financial covenants requiring that (i) the amount of the Company's available cash shall equal or exceed $5.0 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, as of the last day of any fiscal quarter commencing with September 30, 2023 to (b) the Company's average market capitalization over the prior ten trading days, shall not exceed 30%, and (iii) the Company's market capitalization shall at no time be less than $30 million (the "Financial Tests"). As of December 31, 2023, the Company was in compliance, and as of the date hereof, the Company is in compliance, with the Financial Tests.

During the year ended December 31, 2023, approximately $0.1 million of principal repayments along with less than $0.1 million of interest expense thereon, were settled through the issuance of 115,388 shares of common stock of the Company, with such shares having a fair value of approximately $0.2 million (with such fair value measured as the respective conversion date quoted closing price of the common stock of the Company).

Committed Equity Facility and ATM Facility

In March 2022, we 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 our common stock from time to time at our 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 us 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 common stock of the Company 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, we sold 230,068 shares through our at-the-market equity facility for net proceeds of approximately $0.3 million, after payment of 3% commissions.

Intercompany Agreements with PAVmed

From our inception in May 2018 through our IPO in October 2021, our operations were funded by PAVmed providing working capital cash advances and by PAVmed paying certain operating expenses on our behalf. Additionally, our daily operations have been and continue to be conducted in part by personnel employed by PAVmed, for which we incur an MSA Fee expense. The MSA Fee is charged on a monthly basis and is subject-to periodic adjustment corresponding with changes in the services provided by PAVmed personnel to the Company, with any such change in the MSA Fee being subject to approval of the Company and PAVmed boards of directors. In this regard, in January 2024, the respective companies' boards of directors approved a eighth amendment to the MSA to increase the MSA Fee to $0.83 million per month, effective January 1, 2024. The eighth amendment to the MSA was executed on March 22, 2024. Pursuant to the MSA, as amended by the eighth amendment, the parties agreed PAVmed may elect to receive payment of the monthly MSA Fee in cash or in shares of our common stock, with such shares valued at the volume weighted average price ("VWAP") during the final ten trading days of the applicable month (subject to a floor price of $0.70 per share). However, in no event will PAVmed be entitled to receive under the MSA, as amended, from and after the effective date of the eighth amendment to the MSA, more than 9,644,135 shares of our common stock (representing 19.99% of our outstanding shares of common stock as of immediately prior to the execution of the eighth amendment).

In addition, on November 30, 2022, we entered into a payroll and benefit expense reimbursement agreement (the "PBERA") with PAVmed. Historically, PAVmed has paid for certain payroll and benefit-related expenses in respect of our personnel on our behalf, and we have reimbursed PAVmed for the same. Pursuant to the PBERA, PAVmed will continue to pay such expenses, and we will continue to reimburse PAVmed for the same. The PBERA provides that the expenses will be reimbursed on a quarterly basis or at such other frequency as the parties may determine, in cash or, subject to approval by PAVmed's and our boards of directors, in shares of our common stock, with such shares valued at the volume weighted average price of such stock during the final ten trading days preceding the later of the two dates on which such stock issuance is approved by PAVmed's and our boards of directors (subject to a floor price of $0.40 per share), or in a combination of cash and shares. However, in no event will we issue any shares of our common stock to PAVmed in satisfaction of all or any portion of the expenses if the issuance of such shares of our common stock would exceed the maximum number of shares of common stock that we may issue under the rules or regulations of Nasdaq, unless we obtain the approval of our stockholders as required by the applicable rules of the Nasdaq for issuances of shares of our common stock in excess of such amount.

As of December 31, 2023, we had a Due To: PAVmed Inc. payment obligation liability of approximately $9.3 million, which liability is primarily comprised of our obligations under the PBERA and the MSA, as well other operating expenses paid by PAVmed on our behalf. See our accompanying consolidated financial statements Note 5, *Related Party Transactions.* In accordance with the MSA and the PBERA, on January 26, 2024, 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 the Company's common stock.

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 13, 2023, the Company issued a Senior Secured Convertible Note dated March 21, 2023, referred to herein as the "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 March 2023 Senior Convertible Note is 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 March 2023 Senior Convertible Note).

The estimated fair values reported utilized the Company's common stock price 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 Company's common stock price, the Company's dividend yield, the risk-free rates based on U.S. Treasury security yields, and certain other Level-3 inputs including, assumptions regarding the estimated volatility in the value of the Company's common stock price and the volatility of similar entities within the medical device industry. Changes in these assumptions can materially affect the 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 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 non-employees, under each of the Lucid Diagnostics Inc. 2018 Equity Plan and the PAVmed Inc. 2014 Equity Plan.

The grant-date estimated fair value of the stock-based award is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective stock-based award, with such straight-line recognition adjusted, as applicable, so the cumulative expense recognized is at-least equal-to-or-greater-than the estimated fair value of the vested portion of the respective stock-based award as of the reporting date.

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

- With respect to the PAVmed Inc. 2014 Equity Plan, the expected stock price volatility is based on the historical stock price volatility of PAVmed Inc. common stock 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 Inc. 2018 Equity Plan, the expected stock price volatility is based on the historical stock price volatility of Lucid Diagnostics Inc. common stock and the volatilities of similar entities within the medical device industry over the period commensurate with the expected term with respect to stock options granted to 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 Lucid Diagnostics Inc. common stock used in the computation of estimated fair value of stock options and restricted stock awards granted under the Lucid Diagnostics Inc. 2018 Equity Plan is its quoted closing price per share.

The price per share of PAVmed Inc. common stock used in the computation of estimated fair value of stock options and restricted stock awards granted under the PAVmed Inc. 2014 Equity Plan is its quoted closing price per share.

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

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	2.1	3/3/2022
3.1.1	Amended and Restated Certificate of Incorporation	S-1/A	3.1	10/7/2021
3.1.2	Amendment to Amended and Restated Certificate of Incorporation	8-K	3.1	6/21/2023
3.1.3	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock	8-K	3.1	3/14/2024
3.2	Amended and Restated Bylaws	S-1/A	3.2	10/7/2021
4.1	Description of Registrant's Securities	*		
4.2	Common Stock Certificate	S-1/A	4.1	10/7/2021
4.3	Form of Senior Secured Convertible Note	8-K	4.1	3/14/23
10.1#	Lucid Diagnostics Inc. Amended and Restated 2018 Long-Term Incentive Equity Plan.	S-8		2/10/2023
10.2†	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	10.2	10/1/2021
10.3	License Agreement, dated as of May 20, 2019, by and between PAVmed Inc. and Lucid Diagnostics Inc.	S-1/A	10.3	10/1/2021
10.4.1	Management Services Agreement, dated as of May 12, 2018, by and between PAVmed Inc. and Lucid Diagnostics Inc.	S-1/A	10.4.1	10/7/2021
10.4.2	Amendment to Management Services Agreement, dated as of March 1, 2019, by and between PAVmed Inc. and Lucid Diagnostics Inc.	S-1/A	10.4.2	10/7/2021
10.4.3	Second Amendment to Management Services Agreement, dated as of June 5, 2019, by and between PAVmed Inc. and Lucid Diagnostics Inc.	S-1/A	10.4.3	10/7/2021
10.4.4	Third Amendment to Management Services Agreement, dated as of July 20, 2020, by and between PAVmed Inc. and Lucid Diagnostics Inc.	S-1/A	10.4.4	10/7/2021
10.4.5	Fourth Amendment to Management Services Agreement, dated as of February 1, 2021, by and between PAVmed Inc. and Lucid Diagnostics Inc.	S-1/A	10.4.5	10/7/2021
10.4.6	Fifth Amendment to Management Services Agreement, dated as of November 10, 2021, by and between PAVmed Inc. and Lucid Diagnostics Inc.	10-K	10.4.6	3/14/2023

Exhibit No.	Description	Incorporation by Reference		
		Form	Exhibit No.	Date
10.4.7	Sixth Amendment to Management Services Agreement, dated as of August 11, 2022, by and between PAVmed Inc. and Lucid Diagnostics Inc.	8-K	10.1	12/2/2022
10.4.8	Seventh Amendment to Management Services Agreement, dated as of May 9, 2023, by and between PAVmed Inc. and Lucid Diagnostics Inc.	10-Q	10.7	5/15/2023
10.4.9	Eighth Amendment to Management Services Agreement, dated as of March 22, 2024, by and between PAVmed Inc. and Lucid Diagnostics Inc.	*		
10.5	Payroll and Benefit Expense Reimbursement Agreement, dated as of November 30, 2022, by and between PAVmed Inc. and Lucid Diagnostics Inc.	8-K	10.2	12/2/2022
10.6#	Form of Stock Option Agreement.	10-K	10.9	3/14/2023
10.7#	Form of Indemnification Agreement.	S-1/A	10.9	10/8/2021
10.8	Quality & Manufacturing Master Services Agreement, dated as of September 1, 2021, by and between Coastline International, Inc. and Lucid Diagnostics Inc.	S-1/A	10.11	10/1/2021
10.9#	Form of Restricted Stock Agreement.	S-1/A	10.12#	10/8/2021
10.10#	Employment Agreement with Lishan Aklog, M.D.	8-K	10.1	1/20/2022
10.11#	Employment Agreement with Dennis M. McGrath	8-K	10.2	1/20/2022
10.12.1#	Employment Agreement with Shaun O'Neil	8-K	10.1	3/23/2022
10.12.2#	Amendment to Employment Agreement with Shaun O'Neil	*		
10.13#	Employment Agreement with Michael Gordon	10-K	10.16	3/14/2023
10.14.1‡	Common Stock Purchase Agreement, dated as of March 28, 2022, by and between CF Principal Investments LLC and Lucid Diagnostics Inc.	8-K	10.1	4/1/2022
10.14.2‡	Registration Rights Agreement, dated as of March 28, 2022, by and between CF Principal Investments LLC and Lucid Diagnostics Inc.	8-K	10.2	4/1/2022
10.15	Controlled Equity Offering℠, dated as of November 23, 2022, by and between Cantor Fitzgerald & Co. and Lucid Diagnostics Inc.	S-3	1.2	11/23/2022
10.16.1	Form of Securities Purchase Agreement	8-K	10.2	3/14/23
10.16.2	Form of Guaranty	8-K	10.3	3/14/23
10.16.3	Form of Registration Rights Agreement	8-K	10.1	3/24/23
10.17.1	Exchange Agreement, dated as of March 13, 2023, by and between Lucid Diagnostics Inc. and the purchasers of Series B Preferred Stock party thereto	8-K	10.1	3/14/2024
10.17.2	Registration Rights Agreement Agreement, dated as of March 13, 2023, by and between Lucid Diagnostics Inc. and the purchasers of Series B Preferred Stock party thereto	8-K	10.2	3/14/2024
10.18#	Lucid Diagnostics Inc. Employee Stock Purchase Plan	S-8	10.1	3/15/2022
14.1	Code of Ethics	10-K	14.1	3/14/2023
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	*		

Exhibit No.	Description	Incorporation by Reference		
		Form	Exhibit No.	Date
101	Inline XBRL Document Set for the consolidated financial statements and accompanying notes in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.	*		
104	Inline XBRL for the cover page of this Annual Report on Form 10-K, included in the Exhibit 101 Inline XBRL Document Set.	*		

* Filed herewith.
# Indicates management contract or compensatory plan.
† Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.
‡ Certain exhibits and schedules have been omitted pursuant to Item 601(b)(10) of Regulation S-K. The registrant hereby undertakes to furnish a copy of any omitted exhibit or schedule upon request by the Securities and Exchange Commission.

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.

Lucid Diagnostics Inc.

March 25, 2024

By: */s/ Dennis M. McGrath*
Dennis M. McGrath
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	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 25, 2024
/s/ Stanley N. Lapidus Stanley N. Lapidus	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/ Jacque J. Sokolov, M.D. Jacque J. Sokolov, M.D.	Director	March 25, 2024
/s/ Ronald M. Sparks Ronald M. Sparks	Director	March 25, 2024

LUCID DIAGNOSTICS INC.
and SUBSIDIARIES
(a majority-owned subsidiary of PAVmed Inc.)
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Lucid Diagnostics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Lucid Diagnostics 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.

/s/ Marcum LLP

Marcum LLP

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

New York, NY
March 25, 2024

LUCID DIAGNOSTICS INC.
and SUBSIDIARIES
(a majority-owned subsidiary of PAVmed Inc.)
CONSOLIDATED BALANCE SHEETS
(in thousands except number of shares and per share data)

	December 31, 2023	December 31, 2022
Assets:		
Current assets:		
Cash	$ 18,896	$ 22,474
Accounts receivable	45	17
Inventory	278	111
Prepaid expenses, deposits, and other current assets	2,854	1,754
Total current assets	22,073	24,356
Fixed assets, net	1,334	1,592
Operating lease right-of-use assets	1,307	2,008
Intangible assets, net	1,424	3,445
Other assets	1,132	1,108
Total assets	$ 27,270	$ 32,509
Liabilities, Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,146	$ 1,056
Accrued expenses and other current liabilities	3,841	1,447
Operating lease liabilities, current portion	1,106	962
Senior Secured Convertible Note - at fair value	13,950	—
Due To: PAVmed Inc. - MSA Fee and operating expenses	9,339	4,960
Total current liabilities	29,382	8,425
Operating lease liabilities, less current portion	199	1,037
Total liabilities	29,581	9,462
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.001 par value, 20,000,000 shares authorized; Series A and Series A-1 Convertible Preferred Stock, issued and outstanding 18,625 at December 31, 2023 and no shares issued and outstanding at December 31, 2022	18,625	—
Common stock, $0.001 par value, 200,000,000 shares authorized; 42,329,864 and 40,518,792 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	42	41
Additional paid-in capital	129,763	121,081
Accumulated deficit	(150,741)	(98,075)
Total Stockholders' Equity (Deficit)	(2,311)	23,047
Total Liabilities and Stockholders' Equity (Deficit)	$ 27,270	$ 32,509

See accompanying notes to the consolidated financial statements.

LUCID DIAGNOSTICS INC.
and SUBSIDIARIES
(a majority-owned subsidiary of PAVmed Inc.)
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except number of shares and per share data)

	Years Ended December 31,	
	2023	**2022**
Revenue	$ 2,428	$ 377
Operating expenses:		
Cost of revenue	5,979	3,614
Sales and marketing	16,404	16,134
General and administrative	19,254	23,974
Amortization of acquired intangible assets	2,021	1,649
Research and development	7,252	11,257
Total operating expenses	50,910	56,628
Operating loss	(48,482)	(56,251)
Other income (expense):		
Interest income	424	88
Interest expense	(416)	(8)
Change in fair value - Senior Secured Convertible Note	(2,980)	—
Loss on issue and offering costs - Senior Secured Convertible Note	(1,186)	—
Debt extinguishments loss - Senior Secured Convertible Note	(26)	—
Other income (expense), net	(4,184)	80
Loss before provision for income tax	(52,666)	(56,171)
Provision for income taxes	—	—
Net loss	$ (52,666)	$ (56,171)
Net loss per share - basic and diluted	$ (1.26)	$ (1.55)
Weighted average common shares outstanding, basic and diluted	41,756,129	36,172,421

See accompanying notes to the consolidated financial statements.

LUCID DIAGNOSTICS INC.
and SUBSIDIARIES
(a majority-owned subsidiary of PAVmed Inc.)
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
for the YEARS ENDED December 31, 2023 and 2022
(in thousands except number of shares and per share data)

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance as of December 31, 2021	—	$ —	34,917,907	$ 35	$ 96,608	$ (41,904)	$ 54,739
Exercise - stock options - Lucid Diagnostics Inc. 2018 Equity Plan	—	—	965,341	1	694	—	695
Stock-based compensation - Lucid Diagnostics Inc. 2018 Equity Plan	—	—	—	—	13,859	—	13,859
Stock-based compensation - PAVmed Inc. 2014 Equity Plan	—	—	—	—	1,132	—	1,132
Vest - restricted stock awards	—	—	169,320	—	—	—	—
CapNostics, LLC transfer	—	—	—	—	(211)	—	(211)
Issuance common stock - APA-RDx - Termination payment	—	—	326,701	—	653	—	653
Issuance - Committed Equity Facility, net of financing charges	—	—	680,263	1	1,766	—	1,767
Purchase - Employee Stock Purchase Plan	—	—	84,030	—	109	—	109
Issuance - Due To: PAVmed Inc. Settlement in Common Stock	—	—	3,375,230	4	6,471	—	6,475
Net loss	—	—	—	—	—	(56,171)	(56,171)
Balance as of December 31, 2022	—	$ —	40,518,792	$ 41	$ 121,081	$ (98,075)	$ 23,047
Stock-based compensation - Lucid Diagnostics Inc. 2018 Equity Plan	—	—	—	—	5,762	—	5,762
Stock-based compensation - PAVmed Inc. 2014 Equity Plan	—	—	—	—	1,060	—	1,060
Vest - restricted stock awards	—	—	303,980	—	—	—	—
Conversions - Senior Secured Convertible Note	—	—	115,388	—	166	—	166
Issuance common stock - APA-RDx - Termination payment	—	—	553,436	—	713	—	713
Issuance - At-The-Market Facility, net of financing charges	—	—	230,068	1	283	—	284
Purchase - Employee Stock Purchase Plan	—	—	508,200	—	551	—	551
Issuance - Series A and Series A-1 Preferred Stock	18,625	18,625	—	—	—	—	18,625
Issue common stock - vendor service agreement	—	—	100,000	—	147	—	147
Net loss	—	—	—	—	—	(52,666)	(52,666)
Balance as of December 31, 2023	18,625	$ 18,625	42,329,864	$ 42	$ 129,763	$ (150,741)	$ (2,311)

See accompanying notes to the consolidated financial statements.

LUCID DIAGNOSTICS INC.
and SUBSIDIARIES
(a majority-owned subsidiary of PAVmed Inc.)
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	$ (52,666)	$ (56,171)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	2,499	1,936
Stock-based compensation - Lucid Diagnostics Inc. 2018 Equity Plan	5,762	13,859
Stock-based compensation - PAVmed Inc. 2014 Equity Plan	1,060	1,132
Change in fair value - Senior Secured Convertible Note	2,980	—
Loss on issue - Senior Secured Convertible Note	1,111	—
Debt extinguishment loss - Senior Secured Convertible Note	26	—
APA-RDx: Issue common stock - termination payment	713	653
Issue common stock - vendor service agreement	23	—
Changes in operating assets and liabilities:		
Accounts receivable	(28)	183
Prepaid expenses and other current assets	(1,160)	1,163
Accounts payable	89	(445)
Accrued expenses and other current liabilities	2,394	333
Due To: PAVmed Inc. - operating expenses, employee related costs, MSA Fee	4,380	7,672
Net cash flows used in operating activities	(32,817)	(29,685)
Cash flows from investing activities		
Purchase of equipment	(221)	(908)
Asset acquisition	—	(3,200)
Net cash flows used in investing activities	(221)	(4,108)
Cash flows from financing activities		
Proceeds – issue of preferred stock	18,625	—
Proceeds – issue of Senior Convertible Note	10,000	—
Proceeds – issue of common stock – Committed Equity Facility	—	1,807
Proceeds – issue of common stock – At-The-Market Facility	284	—
Proceeds – exercise of stock options	—	695
Proceeds – issue common stock – Employee Stock Purchase Plan	551	109
Net cash flows provided by financing activities	29,460	2,611
Net increase (decrease) in cash	(3,578)	(31,182)
Cash, beginning of period	22,474	53,656
Cash, end of period	$ 18,896	$ 22,474

See accompanying notes to the consolidated financial statements.

LUCID DIAGNOSTICS INC.
and SUBSIDIARIES
(a majority-owned subsidiary of PAVmed Inc.)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(amounts in these accompanying notes are presented in thousands, except number of shares and per-share amounts.)

Note 1 — The Company

Description of the Business

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

The Company believes that its flagship product, 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 tool for the early detection of esophageal precancer in at-risk GERD patients. Early detection of esophageal precancer allows patients to undergo appropriate monitoring and treatment, as indicated by clinical practice guidelines, in an effort to prevent progression to esophageal cancer.

EsoGuard is a bisulfite-converted next-generation sequencing (NGS) DNA assay performed on surface esophageal cells collected with EsoCheck. 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 a FDA 510(k) and CE Mark cleared noninvasive swallowable balloon capsule catheter device capable of sampling surface esophageal cells in a less than a 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, when inflated, 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. The Company believes that 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 an accurate, non-invasive, patient-friendly test 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.

Note 2 — Liquidity and Going Concern

The Company's management is required to assess an entity's ability to continue as a going concern within one year of 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, 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 $2.4 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 of approximately $52.7 million and had net cash flows used in operating activities of approximately $32.8 million for the year ended December 31, 2023. As of December 31, 2023, the Company had negative working capital of approximately $7.3 million, with such working capital inclusive of the Senior Secured Convertible Note classified as a current liability of an aggregate of approximately $14.0 million and approximately $18.9 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 subsidiaries, LucidDx Labs Inc and CapNostics LLC. All intercompany transactions and balances have been eliminated in consolidation. The Company is a majority-owned consolidated subsidiary of PAVmed, which has a majority equity ownership interest and has financial control of the Company. The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions.

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

Use of Estimates

In preparing the consolidated financial statements in conformity with U.S. GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets 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 and estimate of fair value of debt obligations. 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.

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.

Note 3 — Summary of Significant Accounting Policies - continued

Offering Costs

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

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.

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.

Note 3 — Summary of Significant Accounting Policies - continued

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.

Note 3 — Summary of Significant Accounting Policies - continued

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 10, *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 non-employees, under each of the Lucid Diagnostics 2018 Equity Plan and the PAVmed 2014 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 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 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.

Note 3 — Summary of Significant Accounting Policies - continued

The price per share of PAVmed 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.

Financial Instruments Fair Value Measurements

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

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

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

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

As of December 31, 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 13, 2023, the Company issued a Senior Secured Convertible Note dated March 21, 2023, referred to herein as the "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 March 2023 Senior Convertible Note is 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 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 March 2023 Senior Convertible Note.

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.

Note 3 — Summary of Significant Accounting Policies - continued

Patent Costs and Purchased Patent License Rights

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

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

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.

Note 3 — Summary of Significant Accounting Policies - continued

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, stock options and unvested restricted stock awards granted under the Lucid Diagnostics 2018 Long-Term Incentive Equity Plan.

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 for each reporting period presented.

JOBS Act EGC Accounting Election

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

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 ("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.

Note 3 — Summary of Significant Accounting Policies - continued

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. The Company is currently evaluating the potential impact of this guidance on its consolidated financial statements.

Note 4 — Revenue from Contracts with Customers

EsoGuard Commercialization Agreement

The Company 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, a wholly-owned subsidiary of the Company, and RDx, with such agreement further discussed in Note 6, *Asset Purchase Agreement and Management Services Agreement*.

Revenue Recognized

In the year ended December 31, 2023, the Company recognized revenue of $2,428, 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, 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 $5,979, 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 through its termination on February 25, 2022.

Note 5 — Related Party Transactions

The aggregate Due To: PAVmed Inc. for the periods indicated is summarized as follows:

	MSA Fees	Employee-Related Costs	PAVmed Inc. OBO Payments	Total
Balance - December 31, 2022	$ 1,650	$ 3,026	$ 284	$ 4,960
MSA fees	9,000	—	—	9,000
ERC - Benefits	—	1,828	—	1,828
On Behalf Of (OBO) activities	—	—	1,035	1,035
Cash payments to PAVmed Inc.	(4,500)	(1,691)	(1,293)	(7,484)
Balance - December 31, 2023	$ 6,150	$ 3,163	$ 26	$ 9,339

PAVmed - Management Services Agreement

The Company's daily operations are also managed in part by personnel employed by PAVmed, for which the Company incurs a service fee, referred to as the "MSA Fee", according to the provisions of a Management Services Agreement ("MSA") with PAVmed. The MSA does not have a termination date, but may be terminated by the Company's board of directors. The MSA Fee is charged on a monthly basis and is subject-to periodic adjustment corresponding with changes in the services provided by PAVmed personnel to the Company, with any such change in the MSA Fee being subject to approval of the boards of directors of each of the Company and PAVmed. The respective companies' boards of directors approved an amendment to the MSA to increase the MSA Fee to $750 per month, effective January 1, 2023, which was entered into by PAVmed and the Company on May 9, 2023. During the six months ended December 31, 2022, MSA fees were $550 per month. During the six months ended June 30, 2022, MSA Fees were $390 per month.

Subsequent to December 31, 2023, in March 2024, we entered into an eighth amendment to the MSA. Under the amendment, the monthly fee due from the Company to PAVmed was increased from $750 to $833. 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.

The MSA Fee expense classification in the consolidated statement of operations for the periods noted is as follows:

	Years Ended December 31,	
	2023	2022
Sales & Marketing	$ 436	$ 1,043
General & Administrative	6,350	3,066
Research & Development	2,214	1,531
Total MSA Fee	$ 9,000	$ 5,640

The classification of the MSA Fee as presented above is based on the PAVmed classification of employee salary expense and other operating expenses. In this regard, PAVmed classifies employee salary expense as sales and marketing expenses for employees performing sales, sales support and marketing activities, research and development expenses for those employees who are engaged in product and services engineering development and design and /or clinical trials activities, and other employees and activities classified as general and administrative.

Note 6 — Asset Purchase Agreement and Management Services Agreement

Asset Purchase Agreement and Management Services Agreement - ResearchDx Inc.

Through its wholly-owned subsidiary, LucidDx Labs Inc. ("LucidDx Labs"), the Company 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 other property and equipment to establish a Company-owned CLIA certified, 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 Inc. 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.

Note 6 — Asset Purchase Agreement and Management Services Agreement - continued

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 10, *Intangible Assets, net.*

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

On February 14, 2023, through LucidDx Labs Inc, the Company 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.

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 the Company's common stock in February 2023. The Company was not required to make any cash payments in connection with the termination.

Note 7 — 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	$ 266	$ 371
Prepaid insurance	607	52
Deposits	1,981	1,331
Total prepaid expenses, deposits and other current assets	$ 2,854	$ 1,754

Note 8 — 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	$ 252	$ 223
Laboratory equipment	3-7 years	1,702	1,526
Furniture and fixtures	3-5 years	146	131
Leasehold improvements	(1)	1	1
Total Fixed Assets		2,101	1,881
Less Accumulated Depreciation		(767)	(289)
Total Fixed Assets, net		$ 1,334	$ 1,592

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

Depreciation expense of $478 and $287 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 9 — 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 for additional Lucid Test Centers.

The components of lease expense were as follows:

	Years Ended December 31,	
	2023	2022
Operating lease cost	$ 1,214	$ 951
Short-term lease cost	87	95
Variable lease cost	58	20
Total lease cost	$ 1,359	$ 1,066

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	$ 1,161
2025	127
2026	63
2027	24
Total lease payments	$ 1,375
Less: imputed interest	(70)
Present value of lease liabilities	$ 1,305

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	$ 1,207	$ 949
Non-cash investing and financing activities		
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 380	$ 2,763
Weighted-average remaining lease term - operating leases (in years)	1.39	2.03
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 $1,307 and $2,008, respectively, which are reported in operating lease right-of-use assets in the consolidated balance sheets. As of December 31, 2023 and 2022, the Company had outstanding operating lease obligations of $1,305 and $1,999, respectively, of which $1,106 and $962, respectively, are reported in operating lease liabilities, current portion and $199 and $1,037, 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.

Note 10 — Intangible Assets, net

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

	Estimated Useful Life	December 31, 2023	December 31, 2022
Defensive technology	60 months	$ 2,105	$ 2,105
Laboratory licenses and certifications and laboratory information management software	24 months	3,200	$ 3,200
Total Intangible assets		5,305	5,305
Less Accumulated Amortization		(3,881)	(1,860)
Intangible Assets, net		$ 1,424	$ 3,445

The defensive technology intangible asset of $2.1 million (and approximately $0.2 million of accumulated amortization) was recognized by the Company as of the April 1, 2022 effective date of the transfer of CapNostics, LLC ("CapNostics") to the Company from PAVmed Subsidiary Corp (a wholly-owned subsidiary of PAVmed). The transfer was accounted for as entities under common control. The defensive technology intangible asset was recognized by PAVmed Subsidiary Corp 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.

As noted in Note 6, *Asset Purchase Agreement and Management Services Agreement*, the asset purchase agreement between the Company and ResearchDx Inc. ("APA-RDx"), is being accounted for as an asset acquisition. 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 transferred 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 $1,649 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 11 — 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	$ 1,178	$ 879
CWRU Amended License Agreement - Royalty fee	96	10
Operating expenses	2,018	558
Other	549	—
Total accrued expenses and other current liabilities	$ 3,841	$ 1,447

Note 12 — Financial Instruments Fair Value Measurements

Recurring Fair Value Measurements

The fair value hierarchy table for the reporting date noted is as follows:

	Fair Value Measurement on a Recurring Basis at Reporting Date Using[1]			
	Level-1 Inputs	Level-2 Inputs	Level-3 Inputs	Total
December 31, 2023				
March 2023 Senior Convertible Note	$ —	$ —	$ 13,950	$ 13,950
Totals	$ —	$ —	$ 13,950	$ 13,950

[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 a Senior Secured Convertible Note dated March 21, 2023 with a $11.1 million face value principal ("March 2023 Senior Convertible Note"). The convertible note is 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.

The estimated fair value of the March 2023 Senior Convertible Note as of each of March 21, 2023 (date of issuance) and 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:

	March 2023 Senior Convertible Note: March 21, 2023	March 2023 Senior Convertible Note: December 31, 2023
Fair Value	$ 11,900	$ 13,950
Face value principal payable	$ 11,111	$ 11,019
Required rate of return	11.00%	10.00%
Conversion Price	$ 5.00	$ 5.00
Value of common stock	$ 1.54	$ 1.41
Expected term (years)	2.00	1.22
Volatility	75.00%	60.00%
Risk free rate	4.09%	4.56%
Dividend yield	—%	—%

The estimated fair values reported utilized the Company's common stock price along with certain Level 3 inputs (as discussed in the table 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 Company's common stock price, the Company's dividend yield, the risk-free rates based on U.S. Treasury security yields, and certain other Level-3 inputs including, assumptions regarding the estimated volatility in the value of the Company's common stock price and the volatility of similar entities within the medical device industry. Changes in these assumptions can materially affect the estimated fair values.

Note 13 — Debt

The fair value and face value principal outstanding of the March 2023 Senior Convertible Note as of the dates indicated are as follows:

	Contractual Maturity Date	Stated Interest Rate	Conversion Price per Share	Face Value Principal Outstanding	Fair Value
March 2023 Senior Convertible Note	March 21, 2025	7.875%	$ 5.00	$ 11,019	$ 13,950
Balance as of December 31, 2023				$ 11,019	$ 13,950

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

	March 2023 Senior Convertible Note	Other Income (expense)
Fair Value - December 31, 2022	$ —	$ —
Face value principal – issue date	11,111	$ —
Fair value adjustment – issue date	789	(789)
Installment repayments – common stock	(92)	—
Non-installment payments – common stock	(49)	—
Change in fair value	2,191	(2,191)
Fair Value at December 31, 2023	$ 13,950	
Other Income (Expense) - Change in fair value – year ended December 31, 2023		$ (2,980)

March 2023 Senior Secured Convertible Note

Lucid Diagnostics entered into a Securities Purchase Agreement ("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.

Under the SPA, Lucid issued in a registered direct offering under its effective shelf registration statement a Senior Secured Convertible Note dated March 21, 2023, referred to herein as the "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 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 March 21, 2025. The March 2023 Senior Convertible Note may be converted into shares of common stock of the Company at the Holder's election.

The 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, the Company 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. The Company 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, the Company 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 the Company, subject to customary equity conditions, including minimum share price and volume thresholds, or at the election of the Company, 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 all of Lucid Diagnostics' subsidiaries; and the obligations under this senior convertible note are secured by all of the assets of Lucid Diagnostics 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) the Company'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) the Company'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 the Financial Tests.

The 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 the Company, 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 the Company). 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 Company, 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 the Company).

Note 14 — Stock-Based Compensation

Lucid Diagnostics 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 below. 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, the company granted 2,895,000 stock options to employees and directors 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 year ended December 31, 2023.

Note 14 — Stock-Based Compensation - continued

PAVmed Inc. 2014 Equity Plan

The PAVmed 2014 Long-Term Incentive Equity Plan (the "PAVmed 2014 Equity Plan"), is separate and apart from the Lucid Diagnostics 2018 Equity Plan (as such equity plan is discussed above).

Stock-Based Compensation Expense

The stock-based compensation expense recognized by the Company for both the Lucid Diagnostics 2018 Equity Plan and the PAVmed 2014 Equity Plan, 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	$ 6,822	$ 14,991

The stock-based compensation expense, as presented above, is inclusive of: stock options and restricted stock awards granted under the Lucid Diagnostics 2018 Equity Plan to employees of PAVmed, the physician inventors of the technology licensed under the Amended CWRU License Agreement, and members of the board of directors of Lucid Diagnostics, as well as the stock options granted under the PAVmed 2014 Equity Plan to the physician inventors.

As of December 31, 2023, 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 Lucid Diagnostics 2018 Equity Plan and the PAVmed 2014 Equity Plan, as discussed above, is as follows:

	Unrecognized Expense	Weighted Average Remaining Service Period (Years)
Lucid Diagnostics 2018 Equity Plan		
Stock Options	$ 3,566	2.0
Restricted Stock Awards	$ 1,167	2.2
PAVmed 2014 Equity Plan		
Stock Options	$ 432	2.1

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	—%	—%

Note 14 — Stock-Based Compensation - continued

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 reservation of 1,000,000 shares of common stock of which 407,770 shares are available for issue as of December 31, 2023. In January 2024, our board authorized an increase in the number of shares available for issue by 500,000.

Note 15 — Stockholders' Equity

Series A Preferred Stock Offering

On March 7, 2023, the Company issued 13,625 shares of newly designated Series A Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), to accredited investors at a purchase price of $1,000 per share, for aggregate gross proceeds to the Company of $13.625 million. In connection with the issuance the Company filed a Certificate of Designation of Preferences, Rights and Limitations of the Series A Preferred Stock with the Secretary of State of the State of Delaware (the "Certificate of Designation"). The key terms of the Series A Preferred Stock are as follows:

Each share of Series A Preferred Stock is convertible at the option of the holder, subject to certain beneficial ownership limitations into such number of shares of the Company's common stock, equal to the number of Series A Preferred Shares to be converted, multiplied by the stated value of $1,000 (the "Stated Value"), divided by the conversion price in effect at the time of the conversion. The initial conversion price is $1.394, subject to adjustment in the event of stock splits, stock dividends, and similar transactions. The Series A Preferred Stock is convertible into shares of our 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 our common stock on March 7, 2025, the second anniversary of its issuance.

The Series A Preferred Stock will be senior to the Common Stock and any other class of the Company's capital stock that is not by its terms senior to or pari passu with the Series A Preferred Stock.

The holders of Series A Preferred Stock will be entitled to dividends payable as follows: (i) a number of shares of Common Stock equal to 20% of the number of shares of Common Stock issuable upon conversion of the Series A Preferred Stock then held by such Holder on March 7, 2024, and (ii) a number of shares of Common Stock equal to 20% of the number of shares of Common Stock issuable upon conversion of the Series A Preferred Stock then held by such Holder on March 7, 2025. A holder that converts its Series A Preferred Stock prior to March 7, 2024 or March 7, 2025, as the case may be, will not receive the dividend that accrues on such date with respect to such converted Series A Preferred Stock. The holders of the Series A Preferred Stock also will be entitled to dividends equal, on an as-if-converted to shares of Common Stock basis, to and in the same form as dividends actually paid on shares of the Common Stock when, as, and if such dividends are paid on shares of the Common Stock.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company (or any Deemed Liquidation Event as defined in the Certificate of Designation), the holders of shares of Series A Preferred Stock then outstanding will be entitled to be paid out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the Stated Value, plus any dividends accrued but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series A Preferred Stock been converted into Common Stock immediately prior to such event.

The Series A Preferred Stock is a non-voting security, other than with respect to limited matters related to changes in terms of the Series A Preferred Stock.

The Company will not effect any conversion of the Series A Preferred Stock, and a holder will not have the right to receive dividends or convert any portion of the Series A Preferred Stock, to the extent that, after giving effect to the receipt of dividends or the conversion, the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of the holder's affiliates) would beneficially own in excess of 4.99% of the Company's outstanding common stock (or, upon election of the holder, 9.99% of the Company's outstanding common stock).

Note 15 — Stockholders' Equity - continued

The Company and the investors in the offering also executed a registration rights agreement (the "Series A Registration Rights Agreement"), pursuant to which the Company agreed to file a registration statement covering the resale of the shares of Common Stock issuable pursuant to the Series A Preferred Stock.

Series A-1 Preferred Stock Offering

On October 17, 2023, the Company issued 5,000 shares of newly designated Series A-1 Convertible Preferred Stock (the "Series A-1 Preferred Stock"). The terms of the Series A-1 Preferred Stock are substantially identical to the terms of the Series A Preferred Stock, except that the 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.

The Company and the investors in the offering also executed a registration rights agreement (the "Series A-1 Registration Rights Agreement"), pursuant to which the Company agreed to file a registration statement covering the resale of the shares of Common Stock issuable pursuant to the Series A-1 Preferred Stock.

Subsequent to December 31, 2023, on March 13, 2024, the Company issued an additional 5,670 shares of Series A-1 Preferred Stock, all of which was subsequently exchanged for Series B Preferred Stock (as described below).

Series B Preferred Stock Offering and Exchange

Subsequent to December 31, 2023, on March 13, 2024, the Company issued 44,285 shares of newly designated Series B Convertible Preferred Stock (the "Series B Preferred Stock"). The terms of the Series B Preferred Stock are substantially identical to the terms of the Series A Preferred Stock, except that the Series B Preferred Stock has a conversion price of $1.2444, and the Series B Preferred Stock is a voting security (subject to applicable ownership limitations). In addition, the Series B Preferred Stock issued in exchange for Series A Preferred Stock and Series A-1 Preferred Stock may be converted, at the election of the Company at any time after the six-month anniversary of the issuance of such shares of Series B Preferred Stock, upon written notice given to the holders of such shares, if the volume weight average price of our common stock has been at least $8.00 per share (subject to adjustment in the event of stock splits, stock dividends, and similar transactions) on 20 out of 30 consecutive trading days ending within 15 trading days prior to the date on which such notice is given (subject to certain limited exceptions). 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 Series A Preferred Stock and Series A-1 Preferred Stock being exchanged for shares of Series B Preferred Stock in the Series B Preferred Stock Offering and Exchange, no shares of Series A Preferred Stock or Series A-1 Preferred Stock remain outstanding.

Lucid Diagnostics Common Stock

In June 2023, the Company received shareholder approval to issue up to 200 million shares of its common stock, an increase of 100 million shares.

As of December 31, 2023 and 2022 there were 42,329,864 and 40,518,792 shares of common stock issued and outstanding, respectively. As of December 31, 2023, PAVmed holds 31,302,420 shares, representing a majority-interest equity ownership and PAVmed has a controlling financial interest in the Company.

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. Substantially all of such shares were distributed by PAVmed to its shareholders on February 15, 2024. Following such distribution PAVmed holds 31,302,444 shares of Lucid Diagnostics common stock.

Note 15 — Stockholders' Equity - continued

Committed Equity Facility and ATM Facility

On March 28, 2022, the Company entered into a committed equity facility with an affiliate of Cantor Fitzgerald ("Cantor"). Under the terms of the committed equity facility, Cantor has committed to purchase up to $50 million of the Company's common stock from time to time at the request of the Company. While there are distinct differences, the facility is structured similarly to a traditional at-the-market equity facility, insofar as it allows the Company 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, the Company entered into an "at-the-market offering" ("ATM") for up to $6.5 million of its common stock that may be offered and sold under a Controlled Equity Offering Agreement between the Company and Cantor. In the year ended December 31, 2023, the Company sold 230,068 shares through the at-the-market equity facility for net proceeds of approximately $0.3 million, after payments of 3% commissions.

Note 16 — 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	(9,281)	(12,703)
State and Local	(6,897)	1,209
Current and Deferred tax (benefit) expense	(16,178)	(11,494)
Less: Valuation allowance reserve	16,178	11,494
Income tax (benefit) expense	$ —	$ —

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	6.4%	7.2%
Permanent differences	(1.3)%	0.6%
Tax credits	1.5%	0.5%
Revaluation of state deferred taxes	—%	(8.8)%
Federal deferred true-up	(0.7)%	—%
State deferred true-up	3.8%	—%
Valuation allowance	(30.7)%	(20.5)%
Effective tax rate	—%	—%

Note 16 — 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	$ 29,059	$ 16,015
Debt issue costs	55	—
Stock-based compensation expense	7,984	6,920
Accrued expenses	111	80
Depreciation & amortization	790	240
Research and development expenditures	3,109	2,442
Research and development tax credit carryforwards	1,062	295
Deferred tax assets	$ 42,170	$ 25,992
Deferred Tax Liabilities		
Depreciation	—	—
Deferred Tax Liabilities	$ —	$ —
Deferred tax assets, net of deferred tax liabilities	42,170	25,992
Less: valuation allowance	(42,170)	(25,992)
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.

Lucid Diagnostics has federal and state net operating loss ("NOL") carryforwards, available to reduce future taxable income, if any, as of December 31, 2023 and 2022, as follows: federal NOL carryforward of approximately $103.5 million and $65.1 million, respectively, with such federal NOL carryforward not having a statutory expiration date; and state NOL carryforward of approximately $103.5 million and $65.1 million, respectively, with such state NOL carryforward having statutory expiration dates commencing in 2037. The Company has not yet conducted a formal analysis and the NOL carryforward may be subject-to limitation under U.S. Internal Revenue Code ("IRC") Section 382 (provided there was a greater than 50% ownership change, as computed under such IRC Section 382).

As discussed herein, on October 14, 2021, Lucid Diagnostics completed its initial public offering ("IPO") of its common stock. While PAVmed Inc. holds a majority-interest equity ownership and has a controlling financial interest, its ownership interest was reduced from 81.8477% before the IPO to 79.9796% after the IPO. Accordingly, Lucid Diagnostics is included in the PAVmed consolidated income tax returns through October 13, 2021, and effective October 14, 2021, Lucid Diagnostics will file its income tax returns on a stand-alone legal entity basis. The Lucid Diagnostics stand-alone legal entity estimated income tax provision was computed on an assumed separate income tax return for the periods presented through October 13, 2021, wherein, the estimated income tax provision of Lucid Diagnostics is computed as if its income tax returns were filed by Lucid Diagnostics on a stand-alone legal entity basis. Notwithstanding the absence of a formal tax sharing agreement between PAVmed and Lucid Diagnostics, the Lucid Diagnostics stand-alone legal entity current tax expense and /or tax refund, if any, would be settled with PAVmed(as opposed with the respective tax authority) through October 13, 2021. The deferred tax asset and /or deferred tax liability; a valuation allowance on the deferred tax asset, net; and /or an uncertain tax position, if any; each as discussed above, is determined based on Lucid Diagnostics stand-alone legal entity assumed filing of separate income tax returns.

Note 16 — 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 2018 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 Lucid'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 17 — Net Loss Per Share

The Net loss per share basic and diluted for the respective periods indicated is as follows:

	Years Ended December 31,	
	2023	**2022**
Numerator		
Net loss	$ (52,666)	$ (56,171)
Denominator		
Weighted average common shares outstanding, basic and diluted	41,756,129	36,172,421
Net loss per share [(1)]		
Net loss per share - basic and diluted	$ (1.26)	$ (1.55)

(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.

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 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	5,504,383	2,565,377
Unvested restricted stock awards	2,337,440	2,091,420
Preferred stock	13,744,812	—
Total	21,586,635	4,656,797

BOARD OF DIRECTORS

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

Stanley N. Lapidus
Chairman of Mercy Bioanalytics, a company developing early detection tests for cancer based on exosomes, Binx Health, a provider of point-of-care diagnostics tests, and Mirvie, a maternal-fetal health diagnostic company, Executive-in-Residence at the University of Colorado Anschutz Medical Campus, Co-Founding Pillar of Pillar VC, and former Chief Executive Officer of Exact Sciences Corp. and Cytyc Corp.

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

Jacque J. Sokolov
Chairman and Chief Executive Officer of SSB Solutions, Inc., a diversified healthcare management, development, and financial services company

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
Chief Financial Officer

Shaun M. O'Neil
President and Chief Operating Officer

Michael A. Gordon
General Counsel and Secretary

CORPORATE INFORMATION

Transfer Agent

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

Stock Listing

Lucid Diagnostic Inc's. common stock trades on the Nasdaq Global Market under the symbol LUCD.

Annual Meeting

The annual meeting of stockholders will be held on June 20, 2024 at 11:00 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, Lucid Diagnostics Inc., 360 Madison Avenue, 25th Floor, New York, New York 10017.