

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

For the transition period from \_\_\_\_ to \_\_\_\_

Commission File Number: 001-40901

**LUCID DIAGNOSTICS INC.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

82-5488042  
(IRS Employer  
Identification No.)

One Grand Central Place  
60 E. 42nd Street  
Suite 4600  
New York, NY 10165  
(Address of Principal Executive Offices)

10165  
(Zip Code)

(212) 949-4319

(Registrant's Telephone Number, Including Area Code)

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

Title of each Class	Trading Symbol(s)	Name of each Exchange on which Registered
Common Stock, \$0.001 par value per share	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 the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

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

Large Accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

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

The registrant's common stock commenced trading on the Capital Market of The Nasdaq Stock Market LLC on October 14, 2021. Accordingly, as of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, there was no public market for the registrant's voting stock. As of October 14, 2021, the aggregate market value of the registrant's voting stock held by non-affiliates was approximately \$81.1 million, based on a last reported sales price per share of the registrant's common stock of \$11.60 on such date, and 6,990,717 shares of common stock held by non-affiliates (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).

As of March 29, 2022 there were 37,432,536 shares of the registrant's Common Stock, par value \$0.001 per share, issued (with such number of shares inclusive of shares of

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive proxy statement for its 2022 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K where indicated. Such definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the year ended December 31, 2021.

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## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this “Form 10-K”) of Lucid Diagnostics Inc. (“we”, “us”, “our” or “Lucid” or the “Company”) 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 the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in Item 1A of Part I of this Form 10-K under the heading “Risk Factors,” which are incorporated herein by reference.

Important factors that may affect our actual results include:

- our limited operating history;
- our financial performance, including our ability to generate revenue;
- our ability of our products to achieve market acceptance;
- our success in retaining or recruiting, or changes required in, our officers, key employees or directors;
- our potential ability to obtain additional financing when and if needed;
- our ability to protect our intellectual property;
- our ability to complete strategic acquisitions;
- our ability to manage growth and integrate acquired operations;
- the potential liquidity and trading of our securities;
- regulatory and operational risks;
- cybersecurity risks;
- risks related to SARS-CoV-2 /COVID-19 pandemic;
- the impact of the material weakness identified by our management;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- the time during which we will be an Emerging Growth Company (“EGC”) under the Jumpstart Our Business Startups Act of 2012 – (“JOBS Act”).

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

We may not actually achieve the plans, intentions, and /or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. You should read this 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 lead products, the EsoGuard® Esophageal DNA Test performed on samples collected with the EsoCheck® Esophageal Cell Collection Device, constitute the first and only commercially available diagnostic test capable of serving as a widespread screening tool to prevent EAC deaths, through early detection of esophageal precancer in at-risk GERD patients. The technologies were highlighted in the NCI’s Annual Plan and Budget Proposal for FY2020 to Congress as one of the year’s significant advances in cancer prevention. We believe EsoGuard could have as great an impact in preventing EAC deaths as widespread Pap test screening has had in preventing cervical cancer deaths.

Lucid was formed in May 2018 as a subsidiary of our parent company, PAVmed Inc. (Nasdaq: PAVM) (“PAVmed”), to license the technologies underlying EsoGuard and EsoCheck from Case Western Reserve University (“CWRU”). For a description of the license agreement with CWRU, as amended to date (the “License Agreement”), please refer to “*Business—License Agreement*.” Since our inception we have been managed pursuant to a management services agreement with PAVmed and have financed our operations through working capital advances from PAVmed. For a description of the PAVmed management services agreement and financing of our operations, please refer to “*Certain Transactions—Related Party Transactions*.”

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

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

The proceeds of the IPO offering and transitioning to a public company was aimed at driving a growth strategy focused on expanding commercialization across multiple channels, including expanding the number of our own testing centers, and expanding the clinical evidence of our products’ efficacy to support our ongoing regulatory, reimbursement and commercial efforts, as well as recommendation of our products in clinical practice guidelines.

The EsoCheck device received 510(k) marketing clearance from the FDA, in June 2019 and European CE Mark Certification in May 2021 as an esophageal cell collection device. EsoGuard has been established as a Laboratory Developed Test (“LDT”), completed European CE Mark Certification in June 2021, and was launched commercially in December 2019 after Clinical Laboratory Improvement Amendment (“CLIA”) certification and College of American Pathologists (“CAP”) accreditation of the test at Lucid Diagnostics commercial diagnostic laboratory partner ResearchDx Inc. (“RDx”), headquartered in Irvine, California. In August 2021, Lucid Diagnostics launched a strategic partnership with direct-to-consumer telemedicine company UpScriptHealth to support our commercialization efforts. Also in August 2021, we tested our first patients referred by primary care physicians (“PCPs”) in three Lucid Test Centers opened in the Phoenix metropolitan area.

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Subsequently, on February 25, 2022, our new, wholly owned subsidiary, LucidDx Labs Inc. (“LucidDx Labs”), acquired from 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 owned laboratory.

#### *EsoGuard, and EsoCheck and EsoCure*

EsoGuard and EsoCheck are based on patented technology licensed from CWRU, and have been developed to provide an accurate, non-invasive, patient-friendly screening 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.

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

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

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

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

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

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

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

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

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

In February 2020, we received FDA “Breakthrough Device Designation” for EsoGuard as an in-vitro diagnostic (“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.

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

#### *EsoCure*

EsoCure is in development as an Esophageal Ablation Device, with the intent to allow a clinician to treat dysplastic BE before it can progress to EAC, a highly lethal esophageal cancer, and to do so without the need for complex and expensive capital equipment. We have successfully completed a pre-clinical feasibility animal study of EsoCure demonstrating excellent, controlled circumferential ablation of the esophageal mucosal lining. We have also completed an acute and survival animal study of EsoCure™ Esophageal Ablation Device, demonstrating successful direct thermal balloon catheter ablation of esophageal lining through the working channel of a standard endoscope. We plan to conduct additional development work and animal testing of EsoCure to support a future FDA 510(k) submission.

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

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## **Diagnosics – Opportunity, Solution, and Strategy**

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

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

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

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

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

Unfortunately, for a variety of reasons, less than 10% of at-risk GERD patients who are recommended for screening undergo traditional invasive upper gastrointestinal

endoscopy (“EGD”). We believe that the profound tragedy of an EAC diagnosis is that likely death could have been prevented if the at-risk GERD patient had been screened and then undergone surveillance and curative endoscopic esophageal ablation of dysplastic BE.

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

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

## **Current Status of EsoGuard and EsoCheck**

### *Regulatory*

In June 2019, we received FDA 510(k) clearance to market EsoCheck in the U.S. as a device indicated for use in the collection and retrieval of surface cells of the esophagus in adults. In December 2019, Research Dx Inc. (“RDx”), our CLIA-certified commercial clinical laboratory services partner, completed documentation of EsoGuard analytical validity allowing us to commercialize it as an LDT. In March 2022, we transferred testing to our own laboratory, upon our acquisition of certain assets from RDx as described elsewhere in this report. In May 2021, we received CE Mark certification for EsoCheck, and in June 2021, we completed CE Mark self-certification for EsoGuard, indicating both may be marketed in CE Mark European countries.

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

### *Manufacturing & Logistics*

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

### *Reimbursement*

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

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

### *Commercialization*

Our initial EsoGuard commercialization efforts on gastroenterology (“GI”) physicians who have generally embraced our message that EsoGuard has the potential to expand the funnel of BE-EAC patients who will need long-term EGD surveillance and, potentially, treatment with endoscopic esophageal ablation. At the outset of our commercialization, we utilized a hybrid sales model with full-time sales management but have since transitioned and significantly expanded our full-time commercial team in 2021 and are actively recruiting full-time territory market develop managers and sales representatives nationwide. EsoGuard testing has begun accelerating as pandemic-related healthcare facility limitations have eased.

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

### *Clinical Research & Development*

Our active clinical research and development program seeks to expand the clinical evidence of our products’ efficacy to support our ongoing regulatory, reimbursement and commercial efforts. We are actively enrolling patients in two international multicenter clinical trials to support FDA PMA approval of EsoGuard, used with EsoCheck, as an IVD device indicated to detect NDBE. ESOGUARD-BE-1 is a screening study which will enroll approximately 500 to 900 male GERD patients over 50 years of age with one other risk factor. ESOGUARD-BE-2 is a case control study which will enroll approximately 500 male GERD patients with a previous diagnosis of NDBE, LGD, HGD, or

EAC, along with normal controls. Approximately one-half of the U.S. sites and one European site are actively enrolling. We expect to complete enrollment in both trials by the end of 2022 or the early part of 2023 and submit our PMA to FDA by mid-2023.

## **Our Growth Strategy**

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

### *Expand EsoGuard Commercialization Across Multiple Channels*

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

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

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

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

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

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

### *Expand Our Manufacturing and Laboratory Testing Capacity*

We are in the process of scaling our operational capacity, enhance efficiency and improve operating margins as demand for our products grows. We will complete transfer of EsoCheck manufacturing to a high-volume partner in 2022, which will provide sufficient long-term manufacturing capacity and substantially lower per-unit cost of goods. We anticipate doing the same for EsoGuard Specimen Kit manufacturing as demand dictates. We previously relied on the CLIA-certified commercial clinical laboratory at RDx to meet EsoGuard testing needs. However, we believed it was in our long-term interest to secure our own CLIA-certified laboratory, to increase capacity further, streamline billing and claims management, and decrease per-test cost of goods. In that regard, on February 25, 2022, our new, wholly owned subsidiary, LucidDx Labs, acquired from 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 owned laboratory.

### *Expand Our Product Portfolio*

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

### *Longer-Term Strategy*

Our longer-term strategy is to secure a specific indication, based on published guidelines, for BE screening in certain at-risk populations using EsoGuard on samples collected with EsoCheck. This use of EsoGuard together with EsoCheck as a screening system must be cleared or approved by the FDA as an IVD, device. In September 2019, we entered into an agreement with a clinical research organization to assist us with two ongoing clinical trials for EsoGuard as an IVD device, which are actively enrolling patients and consist of a screening study (ESOGUARD-BE-1) and a case control study (ESOGUARD-BE-2).

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

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### *FDA Breakthrough Device*

The U.S. Food and Drug Administration "Breakthrough Device" designation relates to the FDA's Breakthrough Device Program that was created to offer patients more timely access to breakthrough technologies which provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions by expediting their development, assessment and review through enhanced communications and more efficient and flexible clinical study design, including more favorable pre- and post-market data collection. Breakthrough Devices receive priority FDA review, and the Centers for Medicare and Medicaid Services and the United States Congress continue to work to provide an expedited coverage pathway for emerging technologies.

Pursuant to our Breakthrough Device discussions with FDA, we intend to extend enrollment in the ESOGUARD-BE-1 screening study until it is sufficiently powered to support expansion to the above proposed indication for use to include detection of dysplastic BE. FDA indicated that although they would have preferred to a study powered for HGD, they understood that the study size would be impracticable and that they would be open to including LGD. It also indicated that it would consider study designs with

some enrichment and, potentially, interim analysis and approval to mitigate sample size. We will be working with FDA to finalize an extension of our current screening study to support such an expanded dysplastic BE indication once FDA resumes Breakthrough Device meetings for IVD devices, which are currently on hold as the branch works to clear a Covid-19 pandemic related backlog. This study will be a substantial, capital-intensive, but potentially highly rewarding undertaking. Although the study size is yet to be determined and will depend on negotiations with FDA, it will be in the thousands.

#### *EsoGuard Clinical Utility Studies*

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

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

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

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

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

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

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#### *Eosinophilic Esophagitis Using EsoCheck*

We are exploring additional EsoCheck applications beyond our core focus of BE-EAC. The application with the greatest potential may be the monitoring of patients with Eosinophilic Esophagitis ("EoE"). EoE is a rapidly emerging allergy-mediated inflammatory condition of the esophagus similar to, and often associated with, inflammatory bowel disease ("IBD"). Although underappreciated by the medical community and frequently confused with GERD, EoE has a prevalence comparable to IBD and exacts a significant burden on patients. It can lead to swallowing difficulties, esophageal scarring, food impaction and pain. Current treatment includes oral steroids and an elimination diet. Several anti-inflammatory biologics are being evaluated to treat EoE. Since inflammation can persist despite resolution of symptoms, treatment courses can be very difficult and costly for patients, requiring multiple and frequent invasive endoscopies with biopsies. To date, efforts to replace endoscopy with a noninvasive diagnostic device have proven unsuccessful.

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

#### *EsoGuard and EsoCheck Intellectual Property*

Our Diagnostics business will depend on proprietary medical device and diagnostic technologies, including the EsoCheck and EsoGuard technology licensed by us. We intend to vigorously protect our proprietary technologies' intellectual property rights in patents, trademarks and copyrights, as available through registration in the United States and internationally. Patent protection and other proprietary rights are thus essential to our Diagnostics business. The EsoCheck and EsoGuard technology is protected by patents in the United States and internationally, and our policy is to continue to aggressively file patent applications, both independently and in collaboration with CWRU, as appropriate, to protect this technology and other proprietary technologies of ours relating to our Diagnostics business, including inventions and improvements to inventions. Under the CWRU License Agreement, CWRU has agreed to apply for patent coverage, at our expense, in any country requested by us, to the extent such protection is reasonably attainable. We seek patent protection, as appropriate, on:

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

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

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

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

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

### ***EsoGuard and EsoCheck Competition***

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

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

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

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

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

### ***License Agreement***

On May 12, 2018, we entered into the License Agreement with CWRU, which was amended on November 19, 2019, February 12, 2021 and August 23, 2021. Under the terms of the License Agreement, we acquired an exclusive worldwide right to use the intellectual property rights to the EsoGuard and EsoCheck technology for the detection of changes in the esophagus. CWRU retains the right to grant licenses to the EsoGuard technology outside this field of use. The November 2019 amendment to the License Agreement also incorporates technology on sample preservation, jointly developed by us and CWRU, as licensed technology under the agreement, on mutually agreeable terms and conditions.

CWRU is entitled to receive royalties based on net sales by us of licensed products utilizing the EsoGuard and EsoCheck technology. When determining net sales in circumstances where samples collected using a device based on EsoCheck technology are evaluated in a test other than one based on EsoGuard technology, the unit sales price of the device will be deemed to be 200% of the direct unit manufacturing cost (or 400%, if the test is for the detection of EAC or its precursors). 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. The minimum yearly royalty payment is credited against the royalties otherwise due. We are also required to pay CWRU a specified portion of any other non-royalty proceeds received by us pursuant to a sublicense of the EsoGuard and EsoCheck technology.

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.

Under the License Agreement, we are responsible for the costs incurred by CWRU in preparing, filing and prosecuting any patents related to the EsoGuard and EsoCheck

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

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

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. The EsoGuard patents begin to expire in August 2024. However, we are pursuing applications of the clinical utility to extend the patent protection with more recently filed families of cases that have a twenty-year term and, if issued, will expire in the mid to late 2030s. The EsoCheck patents, which are currently the last to expire, begin to expire in May 2035.

In addition, in the event that we defaults in the payment of any amount when due under the License Agreement, and such amount is not paid within 30 days of notice of nonpayment, CWRU may terminate the exclusivity of the license or terminate the CWRU License Agreement in full. In addition, either party may terminate the CWRU License Agreement upon the other party's default in the performance of its obligations under the License Agreement, subject to certain grace periods. Upon expiration of the CWRU License Agreement in the ordinary course, we expect to continue selling products using the EsoGuard and EsoCheck technology, as CWRU's proprietary intellectual property rights in the technology also will have expired.

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### ***Our Relationship with PAVmed Inc.***

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 75.8% as of December 31, 2021 and 74.6% as of March 29, 2022 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). For as long as PAVmed continues to control more than 50% of our common stock, 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. 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"). Under the agreement, 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. The MSA does not have a termination date, but may be terminated by the Lucid Diagnostics' board of directors at any time.

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### **Recent Events**

#### ***Committed Equity Financing***

Subsequent to December 31, 2021, in March 2022, we entered into a committed equity facility with an affiliate of Cantor Fitzgerald ("Cantor"). Under the terms of the facility, Cantor has committed to purchase up to \$50 million in shares of our common stock from time to time at our request. 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.

#### ***Asset Acquisition from RDx***

Subsequent to December 31, 2021, in February 2022, Lucid Diagnostics, Inc. through its wholly owned subsidiary LucidDx Labs, Inc. entered into an asset purchase agreement ("APA") with ResearchDx, Inc. ("RDx") Under the APA, LucidDx Labs acquired certain licenses and other related assets necessary to operate a CLIA-certified, CAP-accredited clinical laboratory. The acquired assets, together with certain additional assets necessary to commence laboratory operations that were separately purchased by LucidDx Labs, will be used by Lucid to perform the EsoGuard® Esophageal DNA assay, including without limitation DNA extraction, next generation sequencing ("NGS") and specimen storage, in its own laboratory located in Lake Forest, CA (the "Laboratory"). Prior to consummation of the Transactions, RDx provided such testing and related services for the EsoGuard assay at its own separate CLIA-certified, CAP-accredited laboratory. Lucid's EsoGuard assay is a bisulfite-converted NGS DNA methylation assay performed on surface esophageal cells, which is commercially available in the U.S. as a Laboratory Developed Test and has been shown to be accurate at detecting esophageal precancer and all conditions along the Barrett's Esophagus-Esophageal Adenocarcinoma spectrum. Under the APA, LucidDx Labs will pay RDx an aggregate purchase price of up to \$6.2 million for the acquired assets. Concurrent with the APA, LucidDx Labs and RDx also entered into a management services agreement ("MSA"). The MSA has a term of three years whereby LucidDx Labs will pay up to \$1.8 million in quarterly installments.

#### **CapNostics, LLC**

On October 5, 2021, PAVmed Subsidiary Corporation, a wholly-owned subsidiary of PAVmed Inc., acquired all of the outstanding common stock of CapNostics, LLC ("CapNostics") for total (gross) purchase consideration of approximately \$2.1 million of cash, paid at the closing of the transaction. In March 2022, both the PAVmed and Lucid board of directors approved entering into a purchase and sale of the CapNostics, LLC assets from PAVmed to Lucid as well as transferring the consulting agreement with the previous principal owner of CapNostics, LLC. The transfer price is \$2.1 million for the assets.

#### **EsoCure**

EsoCure has been in development as an Esophageal Ablation Device by PAVmed, with the intent to allow a clinician to treat dysplastic BE before it can progress to EAC, a highly lethal esophageal cancer, and to do so without the need for complex and expensive capital equipment. In March 2022, both the PAVmed and Lucid board of directors have approved entering into an intercompany license between PAVmed and Lucid such that Lucid will be granted the rights to commercialize EsoCure for the treating dysplastic Barrett's Esophagus, including a royalty arrangement whereby Lucid will pay PAVmed a 5% royalty on all EsoCure sales up to \$100 million per calendar year, and 8% above that threshold. Lucid will be obligated to fund ongoing development costs and cumulative patent expenses. EsoCure will become part of an integrated suite of Lucid products addressing BE-EAC.

## Government Regulation

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

### FDA and Similar 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 December 2019, our CLIA-certified laboratory partner ResearchDx Inc., dba PacificDx, 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. For over a decade, FDA has expressed its concern about insufficient regulatory oversight over increasingly high-risk LDTs. On multiple occasions from 2010 to 2020 it announced its intent to reconsider its long-standing policy of LDT enforcement discretion with respect to LDTs but never acted on this intent, limiting its actions to hosting a public workshop to gather feedback from industry stakeholders, publishing two draft guidance documents describing a proposed risk-based framework to LDTs, issuing a report citing evidence for the need for additional regulation of LDTs, and issuing a Discussion Paper on LDTs. FDA never issued a final guidance document on the regulation of LDTs and, in 2020, HHS announced that, effective immediately, it was rescinding all guidance, compliance manuals, website statements, or other informal issuances concerning FDA premarket review of LDTs, and that FDA may not require premarket review of LDTs absent a formal notice-and-comment rulemaking process.

This 2020 HHS directive notwithstanding, the regulatory status for LDTs such as EsoGuard remains somewhat ambiguous and uncertain. The current administration could rescind the HHS directive and allow FDA to return to its previous regime of enforcement discretion. The Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2020, which seeks to revamp the regulatory framework of diagnostic tests, including LDTs, is expected to be reintroduced in 2021 and could radically alter the landscape for LDTs. FDA may also choose to modify its enforcement discretion of elements of its “single laboratory” definition of LDTs which by strict interpretation would require the LDT to have been “designed” at the “single laboratory” and not transferred from another research laboratory, as EsoGuard was.

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 gain significant traction, it would be useful to jointly market EsoGuard, used with EsoCheck, as a combined product.

- We therefore have decided to 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. In October 2019, we participated in a FDA pre-submission meeting and received feedback on a proposed initial indication for use and the design of our two international multi-center clinical studies to support a PMA application for FDA approval of EsoGuard on samples collected with EsoCheck. We expect to complete enrollment by the end of 2022 and submit our PMA by early 2023.

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, we will be working with FDA to design an extension to our current screening study to support an expanded indication to detect dysplastic BE, once FDA resumes Breakthrough Device meetings for IVD products, which are currently on hold as the branch works to clear a Covid-19 pandemic related backlog.

Before and after approval or clearance in the United States, our products are subject to extensive regulation by 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 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 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. 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.

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

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

#### *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.

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#### *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.

Our CLIA-certified laboratory partner has current certificates to perform clinical laboratory testing. Clinical laboratories are subject to inspection by regulators and to sanctions for failing to comply with applicable requirements. Sanctions available under CLIA and certain state laws include prohibiting a laboratory from running tests, requiring a laboratory to implement a corrective plan, and imposing civil monetary penalties. If 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.

#### *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.

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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.

Managing the patient’s journey through our upcoming EsoGuard Telemedicine Program and our Lucid Test Centers consistent with the provisions of the Federal Anti-Kickback Statute requires very careful coordination between us and our third-party telemedicine partners, which each entity operating within numerous standard operating procedures incorporated in our quality management system. We have established a costly and substantial regulatory and compliance infrastructure for the Lucid Test Centers and EsoGuard Telemedicine Program, including retaining multiple legal and regulatory consultants with specific expertise in this space, establishing and a special Quality & Compliance Committee of our board of directors to provide board-level oversight, and assuring that our contracts with our third-party telemedicine partners comply with the law.

#### *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 processing of EsoGuard tests and submissions of claims consistent with the provisions of the Federal False Claims Act, especially for patients who pass through our EsoGuard Telemedicine Program and our Lucid Test Centers, requires very careful coordination between us and our third-party telemedicine partners broadly operating within numerous standard operating procedures incorporated in our quality management system. We have established a costly and substantial regulatory and compliance infrastructure for the Lucid Test Centers and EsoGuard Telemedicine Program, including retaining multiple legal and regulatory consultants with specific expertise in this space, establishing and a special Quality & Compliance Committee of our board of directors to provide board-level oversight, and assuring that our contracts with our third-party telemedicine comply with the law.

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.

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#### *Physician Payment Sunshine Act*

There has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. On February 8, 2013, the Centers for Medicare & Medicaid Services, or “CMS,” released its final rule implementing section 6002 of the Affordable Care Act known as the Physician Payment Sunshine Act that imposes new annual reporting requirements on device manufacturers for payments and other transfers of value provided by them, directly or indirectly, to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. A manufacturer’s failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of \$150,000 per year, and up to an aggregate of \$1 million per year for “knowing failures.”

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

#### *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 saving-for both payors and providers.

The Affordable Care Act is an example that has the potential to substantially change healthcare financing and delivery by both governmental and private insurers, and significantly impact the pharmaceutical and medical device industries. The Affordable Care Act implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2.0% per fiscal year, which went into effect on April 1, 2013, and will stay in effect through 2024 unless congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

### *HIPAA and Other Privacy Laws*

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HIPAA") established comprehensive protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or "Covered Entities": health plans, healthcare clearinghouses, and healthcare providers that conduct certain healthcare transactions electronically. Covered Entities and their business associates must have in place administrative, physical, and technical standards to guard against the misuse of individually identifiable health information. Some of our activities, including at our Lucid Test Centers and within our clinical trials, involve interactions with patients and their health information which implicate HIPAA. Our activities also involve us entering into specific kinds of relationships with Covered Entities and business associates of Covered Entities, which also implicate HIPAA. Penalties for violations of HIPAA include civil money and criminal penalties.

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

### *Self-Referral Law*

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

### *International Regulation*

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

### *European Union*

We recently 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, 2021, 2020 and 2019.

## **Employees**

The daily operations of Lucid Diagnostics are managed by personnel employed by PAVmed, for which Lucid Diagnostics Inc. incurs a service fee (the “MSA Fee”), according to the provisions of the MSA. Lucid Diagnostics recognized employee related costs for employees spending all of their time working for Lucid Diagnostics products, services and business activities. Additionally, the Company is charged a MSA Fee under the MSA for the percentage of other employees providing services to Lucid Diagnostics Inc.

## **Corporate Information**

Our executive offices are located at One Grand Central Place, Suite 4600, New York, NY 10165, and our telephone number is (212) 949-4319.

## **Available Information**

We make available free of charge through our website ([www.lucidxx.com](http://www.lucidxx.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.lucidxx.com](http://www.lucidxx.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 Business*

- Since we have a limited operating history, you will have little basis upon which to evaluate our ability to achieve our business objective.
- Our business may be adversely affected by health epidemics and/or pandemics, including the COVID-19 pandemic.
- 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 the License Agreement, 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 expect to be dependent on third-party manufacturers since we do not expect to directly manufacture our products in the foreseeable future.
- 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 laboratory facility.
- We may remain dependent on the sales and marketing efforts of third parties if we are unable to or choose not to develop an extensive sales and marketing staff and other resources.
- Our results of operations can be adversely affected by labor shortages, turnover, and labor cost increases.
- We heavily rely upon certain suppliers, including suppliers that are the sole source of certain products. The loss or interruption of supply from our suppliers could have a disruptive effect on our business.
- 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 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 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.
- We are party to agreements pursuant to which we may be required to make payments to certain of our affiliates, which may reduce our cash flow and profits.
- Our ability to be successful is dependent upon the efforts of our key personnel.
- Our business may suffer if we are unable to manage our growth.
- We may conduct business internationally, in which case our business, financial condition and results of operations could be adversely affected by the political and economic conditions of countries other than the U.S.
- 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*

- Our ability to market EsoGuard, or any other IVD that we may develop, license, or acquire, as LDTs without FDA approval, is entirely dependent on FDA continuing to exercise enforcement discretion with regard to requiring premarket review of LDTs.
- If our commercial clinical laboratory fails to maintain CLIA-certification or otherwise meet the applicable requirements of federal or state law regulating clinical laboratories, that failure could limit or prevent its ability to perform our EsoGuard test.
- EsoGuard, or any other IVD without FDA approval we may develop, license, or acquire and market as an LDT, may not be jointly marketed as a combined product with EsoCheck without first securing FDA approval of the combined product as an IVD.
- Securing FDA approval of EsoGuard, or any other IVD we may develop, license, or acquire, as an IVD, 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.
- 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.
- Our business and reputation will suffer if we are unable to establish and comply with, stringent quality standards to assure that the highest level of quality is observed in the performance of our tests.
- 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.
- Patient service centers, where prescribing physicians can send patients for EsoGuard testing, including undergoing specimen collection using EsoCheck, are subject to federal and state regulations which may be burdensome, costly or difficult to comply with.
- Telemedicine, and its specific use in conjunction with DTC, is subject to numerous federal and state regulations and faces particularly intense scrutiny by these regulators.
- 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 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.
- 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.
- We face uncertainty related to healthcare reform, pricing, coverage and reimbursement, which could reduce our revenue.
- Our products may cause serious adverse side effects or even death or have other properties that could delay or prevent their regulatory clearance or approval, limit the commercial desirability of an approved label or result in significant negative consequences following any marketing clearance or approval.
- We intend to market our products in Europe, however major changes in the EU regulation of medical devices and IVDs may make it burdensome, costly and impossible to successfully do so, which could adversely impact our business.

- 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.
- Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

*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, storage systems or our clinical laboratory equipment 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 Financial Condition*

- We have incurred operating losses since our inception and may not be able to achieve sustainable profitability.
- We have incurred recurring losses to date, which raised substantial doubt about our ability to continue as a going concern, although such doubt has been alleviated by PAVmed's agreement to continue to fund our operations.
- We may need substantial additional funding and may be unable to raise capital when needed, which could force us to delay, reduce, eliminate or abandon growth initiatives or product development programs.
- 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.

*Risks Associated with Our Relationship with PAVmed*

- PAVmed, our management, our initial stockholders and their respective affiliates control a substantial interest in us and thus may influence certain actions requiring a stockholder vote.
- Certain conflicts of interest may arise between us and our officers, directors, and affiliated companies, including PAVmed, and in some cases we have waived certain rights with respect thereto.
- Our historical financial information as a subsidiary of PAVmed may not be representative of our results as an independent public company.
- Our ability to operate our business effectively may suffer if the management services agreement with PAVmed is insufficient to meet our needs or if, upon the termination of the management services agreement, 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.
- In order to preserve the ability for PAVmed to distribute its shares of our common stock on a tax-free basis for U.S. federal income tax purposes, we may be prevented from pursuing opportunities to raise capital, to effectuate acquisitions or to provide equity incentives to our employees, which could hurt our ability to grow.
- Third parties may seek to hold us responsible for liabilities of PAVmed, which could result in a decrease in our income.
- Any disputes that arise between us and PAVmed with respect to our past and ongoing relationships could harm our business operations.
- PAVmed's ability to control our board of directors and company may make it difficult for us to recruit high-quality independent directors and employees.

*Risks Associated with Ownership of Our Common Stock*

- We may issue shares of our capital stock or debt securities in the future which could reduce the equity interest of our stockholders and might cause a change in control of our ownership.
- An active trading market may not develop for our common stock, and you may not be able to sell your shares at or above the initial public offering price.
- 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 purchasers of our common stock could incur substantial losses.
- We do not intend to pay any dividends on our common stock at this time.
- We will incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new 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.
- Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.
- 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 is the sole and exclusive forum for certain stockholder litigation matters, which limits our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.

*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.

*Our business may be adversely affected by health epidemics and or pandemics, including the COVID-19 pandemic.*

In 2019, an outbreak of a novel strain of a coronavirus occurred, which spread on a global basis to other countries, including the U.S. On March 11, 2020, the World Health Organization declared a pandemic resulting from the coronavirus, with such pandemic commonly referred to as the “COVID-19 pandemic” after the related illness. The COVID-19 pandemic is ongoing, and we continue to monitor the ongoing impact of the COVID-19 pandemic on the United States national economy, the global economy, and our business.

The COVID-19 pandemic may have an adverse impact on our operations, supply chains, and distribution systems and/or those of our contractors, and may increase our expenses, including because of preventive and precautionary measures being taken, restrictions on travel, quarantine policies, and social distancing. Such adverse impacts may include, for example, the inability of our employees and/or those of our contractors to perform their work or curtail their services provided to us. We expect the significance of the COVID-19 pandemic, including the extent of its effect on our consolidated financial condition and consolidated operational results and cash flows, to be dictated by the success of U.S. and global efforts to mitigate and/or to contain the spread of the coronavirus, as well as the impact of those efforts.

The spread of the coronavirus also has disrupted the United States’ healthcare and healthcare regulatory systems which could divert healthcare resources away from, or materially delay FDA approval with respect to our products. In addition, our clinical trials have been, and may be further, affected by the COVID-19 pandemic, as site initiation and patient enrollment may be delayed, for example, due to prioritization of hospital resources toward the virus and/or illness response, as well as travel restrictions imposed by governments, the inability to access clinical test sites for initiation and monitoring, and the inability of our investigators to perform EGDs required by our clinical trials. Furthermore, the COVID-19 pandemic may have an adverse impact on the economies and financial markets of many countries, including the U.S., resulting in an economic downturn that could adversely affect demand for our products and services and/or our product candidates.

Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 pandemic (or any similar health epidemic) is highly uncertain and subject to change, and therefore, its impact on our consolidated financial condition, consolidated results of operations, and/or consolidated cash flows, the adverse impact could be material.

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*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 screening 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 Capsulomics LLC have published limited data on methylation biomarkers for BE. Of note, both groups used the EsophaCap “sponge-on-a-string” cell collection device.

Other manufactures have developed noninvasive esophageal cell collection devices most notably “sponge-on-a-string” devices which may compete with EsoCheck. Two such devices, Cytosponge, previously marketed by in the U.S. by Medtronic Inc. (NYSE: MDT), and EsophaCap, manufactured by CapNostics, LLC and utilized almost exclusively for clinical research, are spherical mesh sponges encapsulated in soluble gelatin that dissolve in the stomach. The expanded sponge brushes the lining of the esophagus as it is withdrawn and 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. These or other 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 screening 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 Aeonose, 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 differences in the oral bacterial microbiome, obtain 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.

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*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 prospectus, 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 the License Agreement, 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, including by failing to use our commercially best efforts to achieve the milestones prescribed by 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.

Furthermore, the License Agreement imposes significant obligations on us. We will be required to pay CWRU a minimum yearly royalty commencing the year after the first commercial sale of a product utilizing the EsoGuard or EsoCheck technology, with the minimum amount rising based on prior years' net sales of the product. The License Agreement also is subject to certain regulatory and commercialization milestones, with a payment due from us to CWRU upon the achievement of certain of the milestones. The remaining milestone is the submission of a PMA application to FDA for a product using the licensed technology. Accordingly, we could be obligated to pay royalties or other amounts to CWRU even though we have generated no or limited revenue. Such payments could materially and adversely affect our profitability and could limit our investment in 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 intend to 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 expect to be dependent on third-party manufacturers since we do not expect to directly manufacture our products in the foreseeable future.***

We do not expect to directly manufacture our products and expect to rely on third parties to do so for us for the foreseeable future. If our manufacturing 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, which may delay distribution of our products, clinical development or submission of products for regulatory clearance or 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 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 if our manufacturers are unable to manufacture our products

at one or more of their facilities. As a result, the sale and marketing of our products could be delayed or we could be forced to develop our own manufacturing capacity, which could require substantial additional funds and personnel and compliance with extensive regulations.

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***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 commercialize our products and conduct any clinical trials required for additional regulatory clearances or approvals 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 our products in order to meet customer demand and to complete the clinical trials required for certain regulatory clearance or approval pathways.

We have no direct experience in large-scale product manufacturing, nor do we currently have the internal resources or facilities to manufacture most of our products on a commercial scale. Accordingly, we expect to rely on third party manufacturers. We cannot guarantee that our third-party manufacturers will be able to establish or increase production and processing capacity in a timely or cost-effective manner, or at all. Our third-party manufacturers may encounter delays or other difficulties in establishing or in increasing production or processing capacity at any time that could result in delays in the commercialization of our products, in the distribution of our products, in the clinical trials for our products or in the submissions for additional regulatory clearances or approvals for our products. Any such delays could have an adverse effect on our ability to obtain regulatory clearance or approval for, commercialize and secure sales of our products.

***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. Further, our CLIA-certified laboratory is partially managed through a laboratory management services agreement with our previous laboratory partner who may terminate its contract with us which may interrupt our ability to perform our tests and potentially materially harm our business.***

Our EsoGuard test is performed in a single commercial clinical laboratory facility located in Lake Forest, California. Our commercial clinical laboratory is partially managed by RDx under a laboratory management services agreement, under which RDx may terminate on short notice for any or no reason. This may interrupt our ability to perform our tests until we are able to transition to fully staff our laboratory with qualified personnel which may take substantial resources and time to fully operate our own laboratory. This may materially harm our business for a substantial period of time.

Our CLIA-certified commercial clinical laboratory facility, without purchasing additional lab equipment applicable to our test, is expected to have an annual capacity of approximately 100,000 tests per year. If demand for the EsoGuard test outstrips this capacity, and the laboratory fails to add additional equipment and staff, or complete, or timely complete, an expansion of its available laboratory facilities, it may significantly delay EsoGuard processing times and limit the volume of EsoGuard tests it 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.

We cannot guarantee our CLIA-certified commercial clinical laboratory will be able to maintain or increase processing capacity in a timely or cost-effective manner, or at all. Our CLIA-certified commercial clinical laboratory may encounter delays or other difficulties in maintaining or in increasing processing capacity at any time that could result in delays in the commercialization of our products, in the distribution of our products, in the clinical trials for our products or in the submissions for additional regulatory clearances or approvals for our products. Any such delays could have an adverse effect on our ability to obtain regulatory clearance or approval for, commercialize and secure sales of our products.

If the present, or any future, laboratory facilities we utilize 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.

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***We may remain dependent on the sales and marketing efforts of third parties if we are unable to or choose not to develop an extensive sales and marketing staff and other resources.***

We expect to continue to depend, at least in part, on the efforts of third parties (including independent sales representatives and, potentially in the future, distributors) to carry out the sales and marketing of our products. We anticipate that each third party will control the amount and timing of resources generally devoted to these activities. However, these third parties may not be able to generate demand for our products. In addition, there is a risk that these third parties will develop products competitive to ours, which would likely decrease their incentive to vigorously promote and sell our products. Various market factors may force us to expend substantially more time and resources to develop an effective internal sales infrastructure on a larger scale, requiring more capital and much sooner than we might have anticipated or budgeted. However, it may not be economical for us to market our own products, or we may be unable to effectively market our products. Therefore, our business could be harmed if we fail to enter into arrangements with third parties for the sales and marketing of our products or otherwise fail to establish sufficient marketing capabilities.

***Our 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, including unemployment benefits offered in response to the COVID-19 pandemic, 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, caused by COVID-19 or as a result of general macroeconomic factors, 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 mitigation 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 heavily rely upon certain suppliers, including suppliers that are the sole source of certain products. The loss or interruption of supply from our suppliers could have a disruptive effect on our business.***

We purchase certain supplies from third-party suppliers and manufacturers. In some cases, due to the unique attributes of products that are incorporated into our tests, we may maintain either a single-source supplier relationship or a very limited set of supplier relationships. Certain of our third-party suppliers may possess exclusive intellectual

property or otherwise may be the only party with the rights or expertise to provide us critical supplies. These third parties are independent entities subject to their own unique operational, regulatory compliance, and financial risks that are outside our control. These third parties may not be willing to enter or renew long-term supply arrangements with us or continue to supply us at all. Additionally, they may not perform their obligations in a timely and cost-effective manner and they may be unwilling to increase production capacity commensurate with demand for our tests or future products or services. Our relationships with suppliers may also be negatively affected by general supply chain material shortages worldwide, as suppliers struggle to keep pace with demand and manage their own supply chains.

We may become dependent on additional single- or limited-source suppliers, or become increasingly dependent on existing suppliers, as we expand and develop our product and service pipeline. The loss of a critical supplier, the failure to perform by a critical supplier, the deterioration of our relationship with a critical supplier or any unilateral modification to the contractual terms under which we are supplied materials could have a disruptive effect on our business, and could adversely affect our results of operations for an extended period of time, particularly if we are required to validate an alternative supplier.

***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 and 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, or 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.

Developing new or improved diagnostic tests and other medical products and services is a speculative and risky endeavor. Candidate products and services that may initially show promise may fail to achieve the desired results in larger clinical studies or may not achieve acceptable levels of clinical accuracy. Any test we develop will need to demonstrate a high level of accuracy in clinical studies. If in a clinical study a candidate product or service fails to identify even a small number of cases, the sensitivity rate may be materially and adversely affected, and we may have to abandon the candidate product or service.

We may need to explore a number of different designs, methods or technologies, alter our candidate products or services, and repeat clinical studies before we identify a potentially successful candidate. We may need to acquire, whether through purchase, license or otherwise, technologies owned by third parties, and we may not be able to acquire such technologies on commercially reasonable terms or at all. Product development is expensive, may take years to complete and can have uncertain outcomes. Failure can occur at any stage of the development. If, after development, a candidate product or service appears successful, we may, depending on the nature of the product or service, still need to obtain FDA and other regulatory clearances or approvals before we can market it. FDA's clearance or approval pathways are likely to involve significant time, as well as additional research, development and clinical study expenditures. There can be no guarantee that FDA would clear or approve any future product or service we may develop. Even if FDA clears or approves a new product or service we develop, we would need to commit substantial resources to commercialize, sell and market it before it could be profitable, and the product or service may never be commercially viable. Additionally, development of any product or service may be disrupted or made less viable by the development of competing products or services.

Commitments to develop new products must be made well in advance of any resulting sales, and technologies and standards may change during development, potentially rendering our products outdated or uncompetitive before their introduction. Our ability to develop products to meet evolving industry requirements and at prices acceptable to our customers will be significant factors in determining our competitiveness. We may expend considerable funds and other resources on the development of our products without any guarantee that these products will be successful. If we attempt to bring, but are not successful in bringing, one or more products to market, whether because we fail to address marketplace demand, fail to develop viable products or otherwise, our results of operations could be seriously harmed.

If we determine that any of our current or future development programs is unlikely to succeed, we may abandon it without any return on our investment into the program. We may need to raise significant additional capital to bring any new products or services to market, which may not be available on acceptable terms, if at all.

***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.

***We are party to agreements pursuant to which we may be required to make payments to certain of our affiliates, which may reduce our cash flow and profits.***

We are party to agreements pursuant to which we may be required to make payments to certain of our affiliates. For instance, under the License Agreement, we are required to make royalty and other payments to CWRU, which presently owns more than 5% of our outstanding common stock. In addition, we are required to make payments to PAVmed, our majority shareholder, under the MSA. While we believe that the agreements reflect arms'-length negotiations, we cannot assure you that such services are not available at lower cost from third parties. Any payments made to affiliates will reduce our cash flow and profits.

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

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

***Our business may suffer if we are unable to manage our growth.***

If we fail to effectively manage our growth, our ability to execute our business strategy could be impaired. The anticipated rapid growth of our business may place a strain on our management, operations and financial systems. We may need to improve existing systems and controls or implement new systems and controls in response to anticipated growth.

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***We may conduct business internationally, in which case our business, financial condition and results of operations could be adversely affected by the political and economic conditions of countries other than the U.S.***

Our business, financial condition and results of operations could be adversely affected by the political and economic conditions of countries other than the U.S. in which we conduct business. These factors include:

- differences in clinical practices, needs, products, modalities and preferences;
- differences in legal and regulatory requirements and approvals, permits and licenses for our products, and difficulties in complying with unclear product regulations in various jurisdictions, including the changing regulation in Europe with regard to medical device and IVD regulations;
- complexities associated with managing multiple payer reimbursement regimes, public payers or patient self-pay systems, and the complexity of compliance with local standard contractual requirements to access public customers and payers;
- logistics and regulations associated with shipping tissue samples or complying with local regulations concerning the analysis of tissue, including infrastructure conditions and transportation delays;
- limits in our ability to access or penetrate international markets if we are not able to process tests locally;
- variability in sterilization requirements for medical devices;
- challenges in implementing educational programs required by our approach to doing business;
- competition from local and regional product offerings;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our tests, and exposure to foreign currency exchange rate fluctuations;
- foreign exchange controls that might prevent us from repatriating cash earned in certain countries;
- import or export licensing requirements or restrictions imposed by governments;
- potentially burdensome taxation and adverse changes in foreign tax;
- adverse changes in laws and governmental policies, especially those affecting healthcare, trade and investment;
- varying practices of the regulatory, tax, judicial and administrative bodies in the jurisdictions where we operate.
- the threat that our operations or property could be subject to nationalization and expropriation;
  
- political and economic instability, including the threat of war, terrorist attacks, epidemic or civil unrest;
- pandemics, such as the coronavirus, the Ebola virus, the enterovirus and the avian flu, which may adversely affect our workforce as well as our local suppliers and customers;
- challenges associated with cultural differences, languages and distance;
- differing labor standards and employment laws;
- differing levels of protection of intellectual property;
- differing data protection laws and restrictions or prohibitions of transmitting personal data, including patient data, from foreign jurisdictions to our centralized laboratories in the U.S.; and
- regulatory and compliance risks that relate to maintaining accurate information and control over the activities of our salesforce and distributors that may fall within the purview of the U.S. F.C.P.A., its books and records provisions or its anti-bribery provisions, or similar anti-bribery or anti-corruption laws or regulations, such as the U.K. Anti-bribery Act and the U.K. Criminal Finances Act.

***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 have entered into, and may in the future enter into transactions to acquire other businesses, products, services or technologies. While we recently completed several small acquisitions, 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. In addition, an insufficient amount of time has passed to evaluate whether the acquisitions we completed were cost effective and otherwise beneficial to our business. The acquisitions we have completed and 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 examples, 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.

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***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**

***Our ability to market EsoGuard, or any other IVD product that we may develop, license, or acquire, as LDTs without FDA approval, is entirely dependent on FDA continuing to exercise enforcement discretion with regard to requiring premarket review of LDTs. If FDA ceases to exercise, or modifies how it exercises, this discretion through guidance documents, formal rulemaking, departmental directive, executive order or pursuant to legislation, we may be abruptly forced to halt commercialization of these diagnostic tests until we are able satisfy FDA's modified enforcement regime, or until we secure FDA approval for these IVD products.***

EsoGuard is currently being marketed as an LDT and has not received FDA approval to be marketed as an IVD. We would very likely also choose to market as LDTs, at least initially, any other IVD product without FDA approval that we may develop, license, or acquire.

FDA defines an LDT as “an IVD product that is intended for clinical use and designed, manufactured and used within a single laboratory.” Thus, LDTs are considered “devices”, specifically IVD devices, as defined by the FDCA. FDA has long maintained that it has clear regulatory authority over LDTs and could, therefore, require them to fully comply with the regulatory requirements governing device safety and effectiveness. FDA, however, has generally not enforced these regulatory requirements for LDTs

and has generally not required LDTs to undergo FDA premarket review of analytical validity and clinical validity, as other IVD products must. For over a decade, FDA has expressed the opinion that its enforcement discretion was based on the fact that, historically, most LDTs were low-risk, and that it has become concerned about insufficient regulatory oversight over increasingly high-risk LDTs. FDA has also exercised enforcement discretion of elements of its “single laboratory” definition of LDTs which by strict interpretation would require the LDT to have been “designed” at the “single laboratory” and not transferred from another research or commercial laboratory. FDA has demonstrated its position that it has regulatory authority over all IVD products, by choosing 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.

In July 2010, FDA announced its intent to reconsider its long-standing policy of enforcement discretion with respect to LDTs after identifying issues with several high-risk LDTs and hosted a public workshop to gather feedback from industry stakeholders. In October 2014, FDA published two draft guidance documents describing a proposed risk-based framework under which it might regulate LDTs. FDA’s draft framework proposed, among other things, premarket review for higher-risk LDTs, such as those that have the same intended use as FDA-approved or cleared diagnostics currently on the market. In November 2015, FDA issued a report citing evidence for the need for additional regulation of LDTs and stated FDA is continuing to work to finalize premarket review requirements for LDTs. However, in November 2016, FDA announced it would not issue a final guidance for LDTs. In January 2017, FDA issued a Discussion Paper on LDTs, which confirmed it would not finalize guidance on the regulation of LDTs to allow more time for public discussion and time for the congressional authorizing committees to develop a legislative solution. In March 2020, the bipartisan Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2020, which seeks to revamp the regulatory framework of diagnostic tests, including LDTs, was introduced in both chambers of the 116th Congress but was never brought to a vote. The VALID Act is expected to be reintroduced in 2021. In August 2020, HHS announced that, effective immediately, it was rescinding all guidance, compliance manuals, website statements, or other informal issuances concerning FDA premarket review of LDTs, and that FDA may not require premarket review of LDTs absent a formal notice-and-comment rulemaking process.

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The long-standing ambiguity of the regulatory status for LDTs makes it impossible for us to predict the future regulatory status of LDTs, and if or when it may be substantially modified through guidance documents, formal rulemaking, departmental directive, executive order or pursuant to legislation. For example, the current administration could abruptly rescind the August 2020 HHS directive of the prior administration, which could restore FDA regulatory authority over LDTs and herald a return to enforcement discretion. Similarly, passage of the VALID Act could usher a new era of full FDA oversight of LDTs. We cannot predict the potential effect of such shifts in LDT regulation on EsoGuard or any other LDT we may develop, license or acquire, or the potential impact of such shifts on our business, financial condition or results of operation.

Our business could also be materially affected if FDA regains enforcement discretion and modifies it, for example, to require that LDTs be truly “home brewed” at a single laboratory, since EsoGuard was designed and developed at the CWRU laboratory and transferred to our third-party CLIA-certified laboratory partner and then to our own CLIA-certified commercial clinical laboratory. It could also be materially affected if FDA is granted broader authority and a mandate to regulate LDTs, through pending legislation such as the VALID Act. If any of these were to occur, we may be required to change business plans regarding the development and commercialization of EsoGuard and any other LDTs we develop, license or acquire. They may significantly slow the time it would take us to bring LDTs to market, may materially increase the costs of developing, and decrease the profitability of providing, EsoGuard and any other LDTs we may develop, license or acquire, and may prevent us from commercializing certain products or services. We cannot provide any assurance that FDA clearance or approval will not be required in the future for EsoGuard or any other LDTs we develop, license or acquire, whether as a result of additional guidance or regulations issued by FDA, new enforcement policies adopted by FDA or new legislation adopted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated or guidance could be issued by FDA that may result in increased regulatory burdens for us to continue to offer diagnostic tests or to develop and introduce new tests. Moreover, if pre-market review is required by FDA or if we decide to voluntarily pursue FDA’s pre-market review for any of our IVD products, there can be no assurance that they will be approved, or timely approved, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our tests. If pre-market review is required, our business could be negatively impacted as a result of commercial delay that may be caused by any new requirements.

***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.***

Previously, our unrelated third-party CLIA-certified commercial clinical laboratory partner performed the EsoGuard test. In March 2022, we started to 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.

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***EsoGuard, or any other IVD product without FDA approval we may develop, license, or acquire and market as an LDT, 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, or any other IVD product that we develop, license or acquire, 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, or any other IVD product we may develop, license, or acquire, 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). Any other IVD product we may develop, license, or acquire, would likely also require PMA premarket approval to be marketed with EsoCheck as an IVD device. If we choose, or are required, as a result of changes in LDT regulation, to secure FDA approval of

EsoGuard, or any other IVD product we may develop, license or acquire, 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 or any new product or service that we develop. 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 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, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

***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. Likewise, if the results of our research and clinical studies and our sales and marketing activities relating to new products or services we may develop and seek to commercialize in the future do not convince FDA and other regulators, guidelines organizations, physicians and other healthcare providers, third-party payors and patients that such other products and services are safe and reliable, those tests may not receive or sustain necessary regulatory clearances or approvals and we may experience reluctance or refusal on the part of physicians to order, and third-party payors to pay for, those tests, 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. We also act as a sponsor of clinical trials in connection with the development of our tests, which are frequently conducted in collaboration with different parties. We seek to receive approval from an ethical review board, or institutional review board ("IRB") for projects that meet the definition of "human subjects research," which includes review and approval of processes for subject informed consent and authorization for use of personal information or waivers thereof. We could conduct clinical trials in a number of different countries. When we utilize clinical research contractor or partner with other third parties, 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.

***Our business and reputation will suffer if we are unable to establish and comply with, stringent quality standards to assure that the highest level of quality is observed in the performance of our tests.***

Inherent risks are involved in providing and marketing cancer tests and related services. Patients and healthcare providers rely on us to provide accurate clinical and diagnostic information that may be used to make critical healthcare decisions. As such, users of our tests may have a greater sensitivity to errors than users of some other types of products and services.

We must maintain top service standards and FDA-mandated and other quality controls. Past or future performance or accuracy defects, incomplete or improper process controls, excessively slow turnaround times, unanticipated uses of our tests or mishandling of samples or test results (whether by us, patients, healthcare providers, courier delivery services or others) can lead to adverse outcomes for patients and interruptions to our services. These events could lead to voluntary or legally mandated safety alerts relating to our tests or our laboratory facilities and could result in the removal of our products and services from the market or the suspension of our laboratories' operations. Insufficient quality controls and any resulting negative outcomes could result in significant costs and litigation, as well as negative publicity that could reduce demand for our tests and payers' willingness to cover our tests. Even if we maintain adequate controls and procedures, damaging and costly errors may occur.

***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 intend to operate patient service centers where prescribing physicians can send patients for EsoGuard testing, including undergoing specimen collection using EsoCheck. These patient service 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 patient service 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 patient service 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 patient service 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 patient service 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.

Our failure to comply with these regulations in the operation of these patient service 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 who respond to our direct-to-consumer (“DTC”) marketing activities seeking EsoGuard testing and, if clinically indicated, refer the patient to our patient service centers to undergo EsoCheck specimen collection for EsoGuard testing. Telemedicine, and its specific use in conjunction with DTC, 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 pillar of our growth strategy is to expand EsoGuard commercialization across multiple channels, including DTC marketing. Patients with chronic heartburn who respond to DTC advertising of our products or to consumer-oriented educational material we provide, or who otherwise become aware of the availability of a simple noninvasive test to screen for esophageal precancer may seek EsoGuard testing. We intend to facilitate access to EsoGuard testing for such patients by contracting with one or more third-party telemedicine companies who will provide physicians to evaluate such a patient via video communications, determine whether EsoGuard testing is clinically indicated based on the patient’s history and condition, and order an EsoGuard test by referring the patient to one of our patient service centers where the patient would undergo EsoCheck specimen collection for EsoGuard testing by our CLIA-certified commercial clinical laboratory. The EsoGuard test result would then be sent directly to the prescribing telemedicine physician who, based on the test result, would refer the patient to a gastroenterologist for further care.

The logistics required to manage the patient’s journey through such a DTC/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 DTC/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, and its specific use in conjunction with DTC, 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. For example, in recent years, the federal government has conducted several major investigations into the use of telemedicine to generate orders or prescriptions for laboratory tests, pharmaceuticals, durable medical equipment and other ancillary items and services that are billed to Medicare and other federal health care program (“FHCPs”). In such cases, the supplier that received the order or prescription and billed for the ancillary item or service would compensate the telemedicine provider (or management company) for the patient consultation because the actual telehealth service may not be a covered service or meet the coverage requirements under the Medicare or other FHCPs (due to lack of provider-patient relationship or audio-only modality). The Department of Justice has prosecuted providers on the legal theory that this is akin to a kickback or bribe in the form of remuneration paid to the telemedicine provider or management company for the order or prescription itself, whether the ancillary item or service was medically necessary.

The complexities of these regulations have required us to establish a costly and substantial regulatory and compliance infrastructure for the DTC/telemedicine program, including retaining multiple legal and regulatory consultants with specific expertise in this space and a special Quality & Compliance Committee of our board of directors to provide board-level oversight. Our contracts with our third-party telemedicine partners are also complex, as are the standard operating procedures that our quality management system requires all parties to meticulously follow. Despite these measures, 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 (“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 (“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 payer, including commercial insurers.

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

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. As currently drafted, 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. Because EKRA is a relatively new law, there is no agency guidance or court precedent to indicate how and to what extent it will be applied and enforced. 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.

Recently, the medical device industry has been under heightened scrutiny as the subject of government investigations and regulatory or legal enforcement actions involving manufacturers who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business, including arrangements with physician consultants. If 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.

***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 ("MoIDx") performs technical assessment of molecular diagnostic tests on behalf of itself and other MACs. We submitted EsoGuard payment and coverage dossiers to MoIDx in 2020. Although CMS granted EsoGuard final Medicare payment determination of \$1,938.01, effective January 1, 2021, we are awaiting Medicare local coverage determination from MoIDx, where the Covid-19 pandemic and change of administrations has resulted in a significant backlog of local coverage reviews. We have no information on when MoIDx will complete its technical assessment of our dossier, cannot predict whether or not it will grant EsoGuard local coverage determination and whether other MACs will utilize the MoIDx determination.

Commercial third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new healthcare products. As a result, there is uncertainty surrounding whether EsoGuard or EsoCheck, or any other product or service we develop, will be eligible for coverage by third-party payors or, if eligible for coverage, what the reimbursement rates will be. 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. For example, the Patient Protection and Affordable Care Act (the "PPACA") may be repealed or materially modified, in whole or in part, or replaced with an alternative legal framework governing healthcare matter. Such repeal, modification or replacement may eliminate or modify coverage mandates for preventive services, and any such elimination or modification may have an adverse effect on our business prospects.

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.

We may pursue a variety of strategies to increase commercial payor coverage and reimbursement of EsoGuard, used with EsoCheck, and any other product or service we may develop. In certain situations, where we believe payors are obligated to cover EsoGuard under federal and state laws that mandate coverage for certain esophageal precancer and cancer screening tests, we may sue to enforce coverage obligations or pursue similar tactics. Such litigation and tactics may be costly, may divert management attention from other responsibilities, may cause payors, including those not directly involved in any litigation, to resist contracting with us, and may ultimately prove unsuccessful.

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. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U.S.

***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.

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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 payer 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.***

In the U.S., there have been, and we expect there will continue to be, ongoing legislative and regulatory changes to the healthcare system which could affect our future revenue and profitability. Federal and state lawmakers regularly propose and, at times, enact legislation that could result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the PPACA was enacted in 2010. The PPACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs. The PPACA, among other things, also could result in the imposition of injunctions.

While the U.S. Supreme Court has repeatedly upheld the constitutionality of most elements of the PPACA, other legal challenges are still pending final adjudication in several jurisdictions. Although efforts in Congress to repeal the PPACA have repeatedly fallen short, there are a number of ongoing legislative initiatives to modify it. At this time, it remains unclear whether there will be any changes made to the PPACA. We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. Medicare reimbursement for all products and services, including ours, remains highly susceptible to threats of automatic reductions triggered by budgetary shortfalls. Such payments are subject to recovery of purported overpayment for several years. We cannot predict the initiatives that may be adopted in the future or their full impact. We cannot predict whether any additional legislative changes will affect our business.

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.

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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.

***We face uncertainty related to healthcare reform, pricing, coverage and reimbursement, which could reduce our revenue.***

Healthcare reform laws, including the PPACA and PAMA, are significantly affecting the U.S. healthcare and medical services industry. Recently passed legislation and possible future legal and regulatory changes, including potential repeal or modification of the PPACA, or approval of health plans that allow lower levels of coverage for preventive services, could substantially change the structure and finances of the health insurance system and the methodology for reimbursing medical services, drugs and devices, including our current and future products and services. Healthcare reforms, which may intend to reduce healthcare costs, may have the effect of discouraging third-party payors from covering certain kinds of medical products and services, particularly newly developed technologies, such as our EsoGuard test or EsoCheck device, or any other products or services we develop. We cannot predict whether future healthcare reform initiatives will be implemented at the federal or state level or the effect any such

future legislation or regulation will have on us. The taxes imposed by new legislation, cost reduction measures and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, which may adversely affect our business, financial condition and results of operations.

Because Medicare currently covers a significant portion of the patients in the current targeted screening population for EsoGuard, any reduction in the CMS reimbursement rate for EsoGuard would negatively affect our revenues and our business prospects. There can be no assurance under PAMA that adequate CMS reimbursement rates will initially be assigned or will continue to be assigned to our tests. Further, it is possible that Medicare or other federal payors that provide reimbursement for our tests in the future may later suspend, revoke or discontinue coverage at any time, may require co-payments from patients, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues.

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

All clinical trials have a substantial risk of failing to meet their safety or effectiveness endpoints. EsoCheck is our only product which has received FDA marketing clearance in the U.S. EsoGuard is currently marketed as an LDT without FDA approval as an IVD device. It is impossible to predict when or if EsoGuard, or any other products we are develop, license or acquire, including EsoGuard, used with EsoCheck, as a combined IVD product, will prove safe and effective and receive regulatory approval as an IVD device. Undesirable side effects caused by any products we are developing could cause us or regulatory authorities to interrupt, delay or halt any required clinical trials. They could also result in a more restrictive label or the delay or denial of regulatory clearance or approval by FDA or other comparable foreign regulatory authority.

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

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

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

***We intend to market our products in Europe, however major changes in the EU regulation of medical devices and IVDs may make it burdensome, costly and impossible to successfully do so, which could adversely impact our business.***

We recently 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, which refers to Medical Device Directive 93/42/EEC, has 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 for nearly three decades but is now obsolete and has been replaced by MDR, which 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, which refers to In-Vitro Diagnostic Medical Devices Directive (98/79/EC), 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 for over twenty years but will become obsolete and replaced in 2022 with 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. 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 certification mark. If we fail to secure UKCA mark certification for our products before CE Mark certification expires in the UK, we will no longer be able to commercialize our products there, which may adversely impact our business.

***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.

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***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.

***Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk of fraud, misconduct, or other illegal activity by our employees, independent contractors, consultants, commercial partners, and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the rules and regulations of the CMS, FDA, and other comparable foreign regulatory authorities; provide true, complete and accurate information to such regulatory authorities; comply with manufacturing and clinical laboratory standards; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. In particular, research, sales, marketing, education, and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices, as well as off-label product promotion. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of participant recruitment for clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Even if it is later determined after an action is instituted against us that we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions, and have to divert significant management resources from other matters.

**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.

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***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.

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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 attack could cause our management to conclude that our disclosure controls and procedures were not effective.

#### **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, 2021 and December 31, 2020, we had a net loss of \$28.1 million and \$8.3 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.

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

We intend to continue to make investments to support our business growth, and we may require additional funds to:

- continue our research and development including existing and new clinical trials;
- pursue additional regulatory clearances and approvals for our products;
- protect our intellectual property rights or defend, in litigation or otherwise, any claims that we infringe third-party patents or other intellectual property rights;
- fund our operations;
- 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.

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 circumstances such as the outbreak of COVID-19, influenza or other disease 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.

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#### **Risks Associated with Our Relationship with PAVmed Inc.**

***PAVmed owns a majority of our voting stock and thus may control certain actions requiring a stockholder vote.***

PAVmed owns approximately 75.8% as of December 31, 2021 and 74.6% as of March 29, 2022 of our issued common stock (with such percentage inclusive of shares of our common stock underlying granted but unvested restricted stock awards). Thus, we are a majority-owned subsidiary of PAVmed, and PAVmed has a controlling financial interest. Accordingly, for the foreseeable future, PAVmed will control us and our corporate affairs. So long as PAVmed continues to control more than 50% of the voting control of our common stock, PAVmed will be able to direct the election of all the members of our board of directors. In addition, as long as PAVmed continues to control more than 50% of our common stock, 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 voting control and its additional rights described above may discourage transactions involving a change of control of us, including transactions in which holders of our common stock might otherwise receive a premium for their shares over the then-current market price. PAVmed is not prohibited from selling a controlling interest in us to a third party and may do so without the approval of the other stockholders and without providing for a purchase of our other shares of common stock. Accordingly, shares of common stock held by our other stockholders may be worth less than they would be if PAVmed did not maintain voting control over us or have the additional rights described above.

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 acquirer 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.

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

Certain of our officers have fiduciary obligations to other companies and organizations engaged in medical device business activities, namely PAVmed. Accordingly, they may participate in transactions and have obligations that may be in conflict or competition with our business. In addition, some of our directors and executive officers own equity awards based on PAVmed's common stock, and some of our directors are executive officers and/or directors of PAVmed. Ownership of equity awards based on PAVmed's common stock by our directors and officers after this offering and the presence of executive officers or directors of PAVmed on our board of directors could create or appear to create conflicts of interest with respect to matters involving both us and PAVmed that could have different implications for PAVmed than they do for us.

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.

Furthermore, PAVmed, our majority shareholder, operates in the medical device industry. As a result, PAVmed may produce devices that compete directly or indirectly with our products. While PAVmed will not pursue any opportunity related to commercializing the EsoGuard diagnostic test or the EsoCheck cell collection device or developing and commercializing other products that use or enhance the same underlying technology, there can be no assurance that PAVmed will not engage in increased competition with us in the future. PAVmed could assert control over us in a manner which could impede our growth or our ability to enter new markets or otherwise adversely affect our business. PAVmed could utilize its control over us to cause us to take or refrain from taking certain actions, including with respect to entering into relationships with sales, marketing, distribution, technology and other partners, enforcing our intellectual property rights, and pursuing corporate opportunities or product development initiatives, which could adversely affect our competitive position, including our competitive position relative to that of PAVmed in markets where we may compete with them in the future. If any of these scenarios were to materialize, our market share could be reduced, which could have an adverse impact on our results of operations.

***Our historical financial information as a private subsidiary of PAVmed, during which time we were managed as part of PAVmed's overall business, may not be representative of our results as an independent public company.***

A substantial portion of our historical financial information reflects our operations as a private subsidiary of PAVmed, during which time we were managed as part of PAVmed's overall business. Accordingly, such historical financial information may not necessarily reflect what our financial position, results of operations or cash flows would have been had we been an independent public company during the historical periods presented or what they would have been if we were managed independently. The historical costs and expenses reflected in our combined financial statements include charges under the management services agreement for management, technical and administrative services provided by PAVmed, including centralized legal, accounting, tax, treasury, information technology and other corporate services and infrastructure costs. We will continue to incur these charges until such time as our Board of Directors determines to terminate the management services agreement or amend the scope of services to be provided thereby. We and PAVmed believe these charges are reasonable reflections of the utilization levels of these services in support of our business. The historical financial information, however, is not necessarily indicative of our future results of operations, financial position, cash flows or costs and expenses. We have not made adjustments to reflect the changes that will occur in our cost structure, funding and operations as a result of our separation from PAVmed, such as increased costs associated with being a publicly traded, stand-alone company. We also have not made adjustments to reflect the many significant changes that will occur in our cost structure, funding and operations

once our Board of Directors determines that we should be managed independently and terminates the management services agreement or amends the scope of the services to be provided thereby, including changes in our employee base, potential increased costs associated with reduced economies of scale, increased marketing expenses and increased administrative expenses. For additional information, see Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our historical combined financial statements included elsewhere herein and the notes thereto.

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***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.***

As a private subsidiary of PAVmed, we have historically relied on the financial resources and the services provided by PAVmed pursuant to the MSA to operate our business. The MSA covers a variety of matters and provides for our use of PAVmed’s office space and personnel for management, technical and administrative services. See Item 1, “Business.”

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.

***In order to preserve the ability for PAVmed to distribute its shares of our common stock on a tax-free basis for U.S. federal income tax purposes, we may be prevented from pursuing opportunities to raise capital, to effectuate acquisitions or to provide equity incentives to our employees, which could hurt our ability to grow.***

Beneficial ownership of at least 80% of the total voting power and 80% of each class of non-voting capital stock is required in order for PAVmed to effect a spin-off of our company that is tax-free for U.S. federal income tax purposes. PAVmed has advised us that it does not have any present intention or plans to undertake any spin-off. However, PAVmed may wish to preserve its ability to engage in a spin-off in the future. If PAVmed decides to retain its ability to effectuate a spin-off, it may use its controlling position to prevent us from raising capital, effectuating acquisitions or providing equity incentives to our employees. This could cause us to forgo capital raising or acquisition opportunities that would otherwise be available to us. As a result, we may be precluded from pursuing certain growth initiatives.

***Third parties may seek to hold us responsible for liabilities of PAVmed, which could result in a decrease in our income.***

Third parties may seek to hold us responsible for PAVmed’s liabilities. Likewise, our relationship with PAVmed, as a larger company and our majority shareholder, may make us more of a target for litigation than we otherwise would be on our own. If we are ultimately responsible for any such liabilities, it could have a material adverse effect on our business, financial condition and results of operations.

***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.

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***PAVmed’s ability to control our board of directors and company may make it difficult for us to recruit high-quality independent directors and employees.***

So long as PAVmed beneficially owns shares of our common stock representing at least a majority of the votes entitled to be cast by the holders of outstanding voting stock, PAVmed can effectively control and direct our board of directors and our company generally. Further, the interests of PAVmed and our other stockholders may diverge. Under these circumstances, persons who might otherwise accept our invitation to join our board of directors or become our employees may decline.

### **Risks Associated with Ownership of Our Common Stock**

***We may issue shares of our capital stock or debt securities in the future which could reduce the equity interest of our stockholders and might cause a change in control of our ownership.***

Our certificate of incorporation authorizes the issuance of up to 100,000,000 shares of common stock, par value \$.001 per share, and 20,000,000 shares of preferred stock, par value \$.001 per share. There are 62,567,464 authorized but unissued shares of our common stock available for issuance as of March 29, 2022 (inclusive of granted but unvested restricted stock awards granted as of each such date under the Lucid Diagnostics 2018 Long-Term Incentive Equity Plan).

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”). Furthermore, in February 2022, we entered into the asset purchase agreement with RDx, pursuant to which we acquired certain licenses and other related assets necessary to operate a CLIA-certified, CAP-accredited clinical laboratory, with \$3,000,000 of the purchase price payable in installments in cash or, at our election, in shares of our common stock valued at a price based on the current market price. 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 stock from time to time at the our request. Although we have no commitments to issue our securities (including pursuant to the committed equity facility with an affiliate of Cantor), we may issue a substantial number of additional shares of our common stock or preferred stock, or a combination of common and preferred stock, to raise additional funds or in connection with any strategic acquisition or as compensation to our officers, directors, employees and consultants. 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 reduce 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 issue debt securities, it could result in:

- default and foreclosure on our assets if our operating revenues were insufficient to pay our debt 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;
- 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.

***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 do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our common stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, 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 Global 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 purchasers 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 not be able to sell their common stock at or above the initial public offering 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 will incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

As a public company, we will incur significant legal, accounting and other expenses that we did 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. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits on coverage or incur substantial costs to maintain the same or similar coverage. The impact of these events 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, beginning as early as our annual report on Form 10-K for the fiscal year ended December 31, 2021. 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.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

***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.

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***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;
- 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; and
- our Board of Directors will be able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

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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 will provide, 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 2. Property**

Our corporate offices are located at One Grand Central Place, 60 East 42nd Street, Suite 4600, New York, NY 10165. The office rental agreement is currently on a month-to-month basis, and can be cancelled with two months written notice. We also have short-term office space rental agreement in Pennsylvania. We also have lease agreements for our Lucid Test Centers in various locations in Arizona, Colorado and Nevada that in the aggregate approximate 2,155 square feet. At this time, we consider the office space to be commensurate with our current operations. Notwithstanding, we may obtain additional office space in the future, as warranted by our business operations.

Effective with their respective lease commencement dates, subsequent to December 31, 2021, the Company has entered into additional lease agreements to expand its operations including a CLIA laboratory in Lake Forest, California with 21,019 square feet, and additional Lucid Testing Center's (LTC's) with an aggregate of approximately 2,000 square feet.

#### **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. Except as otherwise noted herein, the Company does not believe it is currently a party to any other pending legal proceedings. Notwithstanding, legal proceedings are subject to inherent uncertainties, and an unfavorable outcome could include monetary damages, and excessive verdicts can result from litigation, and as such, could result in a material adverse impact on the Company's business, financial position, results of operations, and /or cash flows. Additionally, although the Company has specific insurance for certain potential risks, the Company may in the future incur judgments or enter into settlements of claims which may have a material adverse impact on the Company's business, financial position, results of operations, and /or cash flows.

#### **Item 4. Mine Safety Disclosures**

Not applicable.

## **PART II**

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

##### **Market for Common Equity**

Our common stock is traded on the Nasdaq Capital Market under the symbol "LUCD".

##### **Holders**

As of March 29, 2022, there were 37,432,536 shares of our common stock issued (inclusive of shares of common stock underlying unvested restricted stock awards granted under the Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan). Our shares of common stock are held by an estimated 13 holders of record and we believe our shares of common stock are held by more than beneficial owners.

##### **Dividends**

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

##### **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, 2021.

On October 14, 2021, we completed our IPO of our common stock under an effective registration statement on Form S-1 (SEC File No. 333-259721). Cantor and Cennacord Genuity served as joint bookrunning managers of the IPO. In our IPO, we sold a total of 5.0 million shares of our common stock, inclusive of 571,428 shares sold to PAVmed, at a public offering price of \$14.00 per share, resulting in gross proceeds of \$70.0 million and net proceeds of 64.4, after deducting underwriting fees of \$4.9 million and approximately \$0.7 million of offering costs incurred by us. None of the fees and expenses of the IPO were paid to any of our directors, officers, 10% stockholders, or affiliates.

As of December 31, 2021, of the net proceeds of \$64.4 million, approximately \$10.7 million has been used, in a manner consistent with the use of proceeds set forth in the prospectus for our IPO, as follows: at total of approximately \$3.3 million of repayments of Due To: PAVmed Inc., inclusive of: Management Services Agreement fee (“MSA Fee”) of \$2.3 million; operating expenses paid by PAVmed Inc. on-behalf-of the Company of approximately \$0.3 million; and the payment of interest expense of the Senior Unsecured Promissory Note dated June 1, 2021; and approximately \$0.8 million for the purchase of equipment; and \$6.7 million of working capital expenditures. None of the proceeds have been paid to any of our directors, officers, 10% stockholders, or affiliates, other than as described above.

#### Item 6. [Reserved]

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

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

##### Overview

##### Operations Overview

We are a commercial-stage medical diagnostics technology company focused on the millions of patients with long-standing GERD who are at risk of developing esophageal precancer and cancer, specifically highly lethal EAC, which is expected to lead to approximately 16,000 U.S. deaths in 2021.

We believe that our lead products, the EsoGuard Esophageal DNA Test performed on samples collected with the EsoCheck Esophageal Cell Collection Device, constitute the first and only commercially available diagnostic test capable of serving as a widespread screening tool to prevent EAC deaths, through early detection of esophageal precancer in at-risk GERD patients.

- EsoGuard is a DNA test performed on surface esophageal cells collected with EsoCheck in a brief noninvasive office procedure which has been shown to be over 90% sensitive and specific at detecting Barrett’s Esophagus (“BE”), a precancerous condition of the esophagus and all conditions along the BE-EAC spectrum, including on samples collected with EsoCheck (Moinova, et al. Sci Transl Med. 2018 Jan 17;10(424): eaa05848).
- EsoCheck is an FDA 510(k) and CE Mark cleared noninvasive swallowable balloon capsule catheter capable of sampling surface esophageal cells in a less than five-minute office procedure. We believe its proprietary Collect+Protect™ technology makes it the only noninvasive esophageal cell collection device capable of anatomically targeted and protected sampling to prevent dilution and contamination during device withdrawal.

EsoGuard is commercialized in the U.S. as a laboratory developed test (“LDT”) previously performed previously at our unrelated third-party commercial clinical laboratory service partner ResearchDx Inc. (with a d/b/a “Pacific Dx”) (“RDx”), at their Clinical Laboratory Improvement Amendments (“CLIA”) certified commercial clinical laboratory, located in Irvine, CA. Starting March 2022, the EsoGuard LDT is performed at our CLIA-certified commercial clinical laboratory, located in Lake Forest, CA. Additionally, RDx also manufactures our EsoGuard Specimen Kits. EsoCheck is commercialized in the U.S. as a 510(k) cleared esophageal cell collection device currently manufactured for us by our contract manufacturing partner, Sage Product Development Inc., located in Foxborough, MA. We are in the process of transferring EsoCheck manufacturing to Coastline International Inc., a high-volume manufacturer headquartered in San Diego, CA with plants in Mexico. Both EsoGuard and EsoCheck recently completed the CE Mark certification process. EsoGuard, used with EsoCheck, was granted FDA Breakthrough Device designation and is the subject of two large, actively enrolling, international multicenter PMA clinical trials.

The EsoGuard PLA code 0114U secured final Medicare payment determination of \$1,938.01, effective January 1, 2021. The CLIA certified laboratory where the EsoGuard assay is performed has begun to submit claims and receive out-of-network private insurance payments. We are awaiting Medicare local coverage determination. We are also aggressively pursuing EsoGuard U.S. private payor payment and coverage as well as payment in Europe.

Our initial EsoGuard commercialization efforts have focused on gastroenterology (“GI”) physicians. EsoGuard testing has accelerated as pandemic-related healthcare facility limitations have eased. We have utilized a hybrid sales model of full-time sales management supervising senior independent sales representatives and supported by full-time clinical specialists. We are significantly expanding our full-time commercial team and currently employ a national director of sales, seven regional business managers, three clinical specialists and a sales operations manager. We are contracted with approximately fifty independent sales representatives and are actively recruiting full-time territory managers in each region to specifically call on either GI or primary care physicians.

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We are working to expand EsoGuard commercialization across multiple channels by targeting primary care physicians and consumers in addition to GI physicians. To assure sufficient testing capacity and geographic coverage, as part of this expansion, we are building our own network of Lucid Test Centers, staffed by Lucid-employed clinical personnel, where patients can undergo the EsoCheck procedure and have the sample sent for EsoGuard testing, starting with three test centers launched in the Phoenix metropolitan area and have recently announced we have expanded our test centers into Utah, Nevada, and Colorado. We also are establishing an EsoGuard Telemedicine Program, in partnership with UpScript, LLC, an independent third-party telemedicine provider, that can accommodate EsoGuard self-referrals from direct-to-consumer marketing.

We are a majority owned subsidiary of PAVmed. We are party to an amended and restated patent license agreement with CWRU, dated August 23, 2021 (“Amended CWRU License Agreement”), which provides for the exclusive worldwide license of the intellectual property rights for the proprietary technologies underlying EsoCheck and EsoGuard.

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

Previously, in December 2019, there was an outbreak of a novel strain of a coronavirus occurred, with such coronavirus designated by the United Nations (UN) World Health Organization (“WHO”) as the “Severe Acute Respiratory Syndrome Coronavirus 2” - or “SARS-CoV-2”. The SARS-CoV-2 spread on a global basis to other countries,

including the United States of America (“USA” “U.S.” or “United States”). On March 11, 2020, the WHO declared a pandemic resulting from SARS-CoV-2, with such pandemic commonly referred to by its resulting illness of “COVID-19” (“coronavirus disease-2019”), and is referred to herein as the “COVID-19 pandemic”. The COVID-19 pandemic is ongoing, and we continue to monitor the ongoing impact of the COVID-19 pandemic on the United States national economy, the global economy, and our business.

The COVID-19 pandemic may have an adverse impact on our operations, supply chains, and distribution systems and /or those of our contractors, and increase our expenses, including as a result of impacts associated with preventive and precautionary measures being taken, restrictions on travel, quarantine policies, and social distancing. Such adverse impact may include, for example, the inability of our employees and /or those of our contractors to perform their work or curtail their services provided to us.

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

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

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

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

Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 pandemic (or a similar health epidemic) is highly uncertain and subject to change, and therefore, its impact on our consolidated financial condition, consolidated results of operations, and /or consolidated cash flows, the adverse impact could be material.

## **Results of Operations**

### ***Overview***

#### ***Revenue***

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

#### ***Cost of revenue***

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

#### ***Sales and marketing expenses***

Sales and marketing expenses consist primarily of the portion of the MSA Fee allocated to sales and marketing expenses, which are principally employee related costs of PAVmed employees, as well as advertising and promotion expenses. We anticipate our sales and marketing expenses will increase in the future, as we anticipate an increase in payroll and related expenses related to the roll-out of our commercial sales and marketing operations as we execute on our business strategy.

#### ***General and administrative expenses***

General and administrative expenses consist primarily of professional fees, accounting and legal services, consultants and expenses associated with obtaining and maintaining patents within our intellectual property portfolio, 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, as we anticipate an increase in the MSA Fee allocated to general and administrative expense, related to continued expansion of our overall business operations. We also anticipate expenses related to being a public company, including professional services fees for legal, accounting, tax, audit, employees involved in third-party payor reimbursement contract negotiations and regulatory services associated with maintaining compliance as a public company, along with insurance premiums, investor relations, and other corporate expenses.

#### ***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:

- consulting costs charged to us by various external contract research organizations we contract with to conduct preclinical studies and engineering studies;
- costs associated with regulatory filings;
- patent license fees;
- cost of laboratory supplies and acquiring, developing, and manufacturing preclinical prototypes;
- product design engineering studies;
- fees associated with conducting clinical trials for our EsoGuard diagnostic assay; and
- MSA Fee allocated to research and development, as such MSA Fee are discussed below.

We plan to incur research and development expenses for the foreseeable future as we continue the development of our existing products as well as new innovations. Our research and development activities are focused principally on obtaining FDA approvals and developing product improvements or extending the utility of the lead products in our pipeline, including EsoCheck and EsoGuard.

## ***Interest Expense***

Interest expense recognized is with respect to a Senior Unsecured Promissory Note, dated June 1, 2021, with a face value principal of \$22.4 million, an annual interest rate of 7.875%, and a contractual maturity date of May 18, 2028, issued by us to PAVmed. The Senior Unsecured Promissory Note replaced the \$22.4 million aggregate outstanding and payable balance of the Due To: PAVmed Inc., as of June 1, 2021. The Senior Unsecured Promissory Note provided for the partial or full repayment of the face value principal and accrued but unpaid interest thereon by the issue of shares of our common stock, at the election of PAVmed Inc., at a conversion price of \$1.42 per share of Lucid Diagnostics Inc. common stock.

On October 13, 2021, we issued 15,803,200 shares of our common stock to PAVmed upon the election by PAVmed to convert the \$22.4 million face value principal under the terms of a Senior Unsecured Promissory Note, dated June 1, 2021.

See our accompanying consolidated financial statements *Note 6, Due To PAVmed Inc.*, for a discussion of the Senior Unsecured Promissory Note dated June 1, 2021 issued by us to PAVmed.

#### ***Authorized Shares Increase and Stock-Split - October 6, 2021***

Effective October 6, 2021, our board of directors: increased the authorized shares of common stock to 100.0 million shares; and declared a 1.411-to-1.0 common stock-split. The number of shares of our common stock and the stock options and restricted stock awards granted under the Lucid Diagnostics Inc. 2018 Equity Plan, and the corresponding stock option exercise price per share; the fair value per share of the stock options and restricted stock awards; and the Senior Unsecured Promissory Note conversion price per share, for all periods presented, as applicable, have been adjusted for such common stock split.

#### ***Management Services Agreement (MSA)***

We are a majority-owned subsidiary of PAVmed, which has a majority equity ownership interest and has financial control of Lucid Diagnostics.

Our daily operations are managed by personnel employed by PAVmed, for which we incur the MSA Fee, according to the provisions of the MSA with PAVmed. The MSA Fee is charged on a quarterly basis and is subject to periodic adjustment corresponding with changes in the number of PAVmed employees providing services to us, with the change in the MSA Fee approved by each of the Lucid Diagnostics and PAVmed's board of directors. The MSA does not have a termination date, but may be terminated by the Lucid Diagnostics board of directors.

The classification of the MSA Fee between cost-of-revenue, sales and marketing expense, general and administrative expense, and research and development expense is based on the PAVmed quarterly classification of employee salary expense. In this regard, PAVmed classifies employee salary expense as cost-of-revenue for employees engaged in service delivery under the EsoGuard Commercialization Agreement, and sales and marketing expenses for employees performing sales, marketing, and reimbursement activities and functions, general and administrative, and research and development except for those employees who are engaged in product and services engineering development and design and /or clinical trials activities, for which such employee salary is classified as research and development expense.

See our accompanying unaudited condensed financial statements *Note 5, Related Party Transactions - PAVmed Inc. - Management Services Agreement*, for a discussion of the MSA between Lucid Diagnostics and PAVmed.

#### ***Presentation of Dollar Amounts***

All dollar amounts in this Management's Discussion and Analysis of Financial Condition and Results of Operations are presented in whole dollars, if not otherwise indicated as being presented as dollars in millions, except for the number of shares and per share amounts.

#### ***Year ended December 31, 2021 versus December 31, 2020***

##### ***Revenue***

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

##### ***Cost of revenue***

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

##### ***Sales and marketing expenses***

In the year ended December 31, 2021, sales and marketing costs were approximately \$5.3 million, compared to \$1.3 million for the corresponding period in the prior year. The net increase of \$4.0 million was principally related to:

- approximately \$1.9 million increase in compensation related costs principally related to an increase in headcount;
- approximately \$1.2 million increase in outside professional services related to EsoCheck, EsoGuard and consulting and professional services fees.
- approximately \$0.9 million increase in the MSA fee allocation from PAVmed related to the growth and expansion of Lucid's business and the services incurred through PAVmed.

##### ***General and administrative expenses***

In the year ended December 31, 2021, general and administrative costs were approximately \$12.8 million, compared to \$1.5 million for the corresponding period in the prior year. The net increase of \$11.2 million was principally related to:

- approximately \$6.1 million increase in stock based compensation from RSA grants to Lucid and PAVmed employees and non-employees, and an increase in stock options granted corresponding with the increase in the number of employees;
- approximately \$4.5 million in consulting services related to patents, regulatory compliance, legal processes for contract review, transition of PR and IR firms, and public company expenses; and
- approximately \$0.6 million increase in the MSA fees, after allocation, from PAVmed related to the growth and expansion of our business and the services incurred through PAVmed.

##### ***Research and development expenses***

In the year ended December 31, 2021, research and development costs were approximately \$9.3 million, compared to \$5.4 million for the corresponding period in the prior

year. The net increase of \$3.9 million was principally related to:

- approximately \$3.2 million increase in development costs, particularly in clinical trial activities and outside professional and consulting fees with respect to EsoCheck, EsoCure and EsoGuard;
- approximately \$0.3 million increase in compensation related costs and related to expanded clinical and engineering staff; and
- approximately \$0.4 million increase in the MSA fee allocation from PAVmed related to the growth and expansion of Lucid's business and the services incurred through PAVmed.

See our consolidated financial statements as of and for the years ended December 31, 2021 and 2020 for each of *Note 5, Related Party Transactions - PAVmed Inc.*, for a discussion of the consulting fee expense and stock based compensation expense recognized with respect to the Physician Inventors consulting agreements and stock options and restricted awards; and the MSA between Lucid Diagnostics and PAVmed; and *Note 12, Stock-Based Compensation*, for information regarding each of the Lucid Diagnostics 2018 Equity Plan and the PAVmed Inc. 2014 Equity Plan.

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## Liquidity and Capital Resources

*Due To: PAVmed Inc. & Senior Unsecured Promissory Note Issued to PAVmed Inc.*

Since inception, prior to our IPO discussed below, our operations have been funded by PAVmed providing working capital cash advances and the payment by PAVmed of certain operating expenses on-our-behalf. Additionally, our daily operations are managed by personnel employed by PAVmed, for which we incur a MSA Fee expense according to the provisions of the MSA discussed above.

As of December 31, 2021, we had a Due To: PAVmed Inc. payment obligation liability of an aggregate of approximately \$1.6 million payable to reimburse for employee related costs and payments PAVmed Inc. made on behalf of Lucid Diagnostics. See our accompanying consolidated financial statements *Note 6, Due To PAVmed Inc.*

On October 18, 2021, we completed an initial public offering ("IPO") of our common stock under an effective registration statement on Form S-1 (SEC File No. 333-259721), wherein a total of 5.0 million shares of our common stock were issued, with such total shares inclusive of 571,428 shares issued to PAVmed, at an IPO price of \$14.00 per share, resulting gross proceeds of \$70.0 million, before underwriting fees of \$4.9 million, and approximately \$0.7 million of offering costs incurred by us.

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 expect to continue to experience recurring losses from operations and we will continue to fund our operations with debt and/or equity financing transactions. Notwithstanding, however, with the cash on-hand as of the date hereof, of which is inclusive of the cash proceeds resulting from the as a result of our IPO, we expect to be able to fund its future operations for one year from the date of the issue of our consolidated financial statements, as included herein in this Annual Report on Form 10-K for the year ended December 31, 2021.

*Lucid Diagnostics Inc. Committed Equity Facility – Subsequent to December 31, 2021*

Subsequent to December 31, 2021, 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 our shares of our common stock from time to time at our request. 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.

Upon the initial satisfaction of the conditions to Cantor's obligation to purchase shares under the facility, including that a registration statement registering the resale by Cantor of the Shares under the Securities Act is declared effective by the SEC and a final prospectus relating thereto is filed with the SEC, we will have the right, but not the obligation, from time to time at our sole discretion until the first day of the month next following the expiration of the 36-month period after the effective date of the registration statement, to direct Cantor to purchase shares in accordance with the terms of the facility, by delivering written notice to Cantor prior to the commencement of trading on any trading day, subject to certain maximum amounts. The purchase price of the shares will be 96% of the volume weighted average price of the shares of common stock during the trading date on which we have timely delivered written notice to Cantor directing it to purchase shares under the facility.

We will not sell, and Cantor will not purchase, any shares pursuant to the facility, if the aggregate number of shares of common stock issued pursuant to the facility would exceed 7,482,763 shares of common stock, unless we obtain approval of our stockholders for the sale of shares in excess of such amount. In addition, we will not sell, and Cantor will not purchase, any shares pursuant to the facility, which, when aggregated with all other shares of common stock then beneficially owned by Cantor and its affiliates, would result in the beneficial ownership by Cantor and its affiliates of more than 4.99% of our outstanding voting power or shares of common stock.

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

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## Critical Accounting Policies and Significant Judgments and Estimates

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

### Revenue Recognition

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

## Research and Development Expenses

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

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## 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 and the volatilities of similar entities within the medical device industry over the period commensurate with the expected term with respect to stock options granted to the board of directors and employees in the years ended December 31, 2021 and 2020;
- With respect to stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan, the expected stock price volatility was based on the historical stock price volatility of similar entities within the medical device industry over the period commensurate with the expected term with respect to stock options granted to employees in the year ended December 31, 2021; There were no stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan in the year ended December 31, 2020;
- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period commensurate with either the expected term or the remaining contractual term, as applicable, of the stock option; and,
- The expected dividend yield is based on annual dividends of \$0.00 as there have not been dividends paid to-date, and there is no plan to pay dividends for the foreseeable future.

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

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

## Leases

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

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

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## Income Taxes

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

Under ASC 740, a "more-likely-than-not" criterion is applied when assessing the estimated realization of deferred tax assets through their utilization to reduce future taxable income, or with respect to a deferred tax asset for tax credit carryforward, to reduce future tax expense. A valuation allowance is established, when necessary, to reduce deferred tax assets, net of deferred tax liabilities, when the assessment indicates it is more-likely-than-not, the full or partial amount of the net deferred tax asset will not be realized. As a result of the evaluation of the positive and negative evidence bearing upon the estimated realizability of net deferred tax assets, and based on a history of operating losses, it is more-likely-than-not the deferred tax assets will not be realized, and therefore a valuation allowance reserve equal to the full amount of the deferred tax assets, net of deferred tax liabilities, has been recognized as a charge to income tax expense as of December 31, 2021 and December 31, 2020.

The Company recognizes the benefit of an uncertain tax position it has taken or expects to take on its income tax return if such a position is more-likely-than-not to be sustained upon examination by the taxing authorities, with the tax benefit recognized being the largest amount having a greater than 50% likelihood of being realized upon ultimate settlement. As of December 31, 2021, the Company does not have any unrecognized tax benefits resulting from uncertain tax positions.

The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. There were no amounts accrued for penalties or interest as of December 31, 2021 and December 31, 2020 or recognized during the year ended December 31, 2021 and December 31, 2020. The Company is not aware of any issues under review to potentially result in significant payments, accruals, or material deviations from its position.

On October 14, 2021, Lucid Diagnostics Inc. 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 Inc. is included in the PAVmed Inc and Subsidiaries consolidated income tax returns through October 13, 2021, and effective October 14, 2021, Lucid Diagnostics Inc. will file its income tax returns on a stand-alone legal entity basis. The Lucid Diagnostics Inc. 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 Inc. is computed as if its income tax returns were filed by Lucid Diagnostics Inc. on a stand-alone legal entity basis. Notwithstanding the absence of a formal tax sharing agreement between PAVmed Inc. and Lucid Diagnostics Inc., the Lucid Diagnostics Inc. stand-alone legal entity current tax expense and /or tax refund, if any, would be settled with PAVmed Inc. (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 Inc. stand-alone legal entity assumed filing of separate income tax returns.

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#### *Recent Accounting Standards Updates Adopted*

In August 2020, the FASB issued ASU 2020-06, Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40), ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, by eliminating the beneficial conversion and cash conversion accounting models previously contained in ASC 470-20 that required separate accounting for embedded conversion features. ASU 2020-06 also simplified the assessment of a financial instrument settlement to determine whether a contract is an entity's own equity qualifies for equity classification by removing certain conditions from ASC 815-4-25. The ASU 2020-06 amendments are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company's adoption of the ASU 2020-06 guidance as of January 1, 2021 did not have an effect on the Company's consolidated financial statements.

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

#### **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.

#### **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.

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#### **ITEM 9A. CONTROLS AND PROCEDURES**

##### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021. Based on such evaluation, our principal executive officer and principal financial officer concluded our disclosure controls and procedures (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) were effective as of such date to provide reasonable assurance the information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

##### **Management's Report on Internal Control Over Financial Reporting**

This Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

##### **Changes to Internal Controls Over Financial Reporting**

There have been no change in internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the year ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

##### **Item 9B. Other Information**

None.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections**

Not applicable.

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**PART III****Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this Item 10 is incorporated by reference to our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

**Item 11. Executive Compensation**

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

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

The information required by this Item 12 is incorporated by reference to our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

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

The information required by this Item 13 is incorporated by reference to our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

**Item 14. Principal Accounting Fees and Services**

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

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**PART IV****Item 15. Exhibits and Financial Statement Schedules**

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

(1) The following financial statements:

[Report of Independent Registered Public Accounting Firm \(PCAOB ID #688\)](#)  
[Consolidated Balance Sheets](#)  
[Consolidated Statements of Operations](#)  
[Consolidated Statements of Changes in Equity \(Deficit\)](#)  
[Consolidated Statements of Cash Flows](#)  
[Notes to Consolidated Financial Statements](#)

(2) The financial statement schedules:

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

(3) The following exhibits:

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**Item 15. Exhibits and Financial Statement Schedules - continued**

(3) The following exhibits:

Exhibit No.	Description	Incorporation by Reference		
		Form	Exhibit No.	Date
2.1†	<a href="#">Asset Purchase Agreement, dated as of February 25, 2022, by and among LucidDx Labs Inc., Lucid Diagnostics Inc. and ResearchDx, Inc.</a>	8-K	2.1	3/3/22
3.1	<a href="#">Amended and Restated Certificate of Incorporation</a>	S-1/A	3.1	10/7/21
3.2	<a href="#">Amended and Restated Bylaws</a>	S-1/A	3.2	10/7/21
4.1	<a href="#">Description of Registrant's Securities</a>	*		
4.2	<a href="#">Common Stock Certificate</a>	S-1/A	4.1	10/7/21
10.1#	<a href="#">Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan.</a>	S-1/A	10.1	10/8/21
10.2†	<a href="#">Amended and Restated License Agreement, dated as of August 23, 2021, by and between Case Western Reserve University and Lucid Diagnostics Inc.+</a>	S-1/A	10.2	10/1/21
10.3	<a href="#">License Agreement, dated as of May 20, 2019, by and between PAVmed Inc. and Lucid Diagnostics Inc.+</a>	S-1/A	10.3	10/1/21
10.4.1	<a href="#">Management Services Agreement, dated as of May 12, 2018, by and between PAVmed Inc. and Lucid Diagnostics Inc.+</a>	S-1/A	10.4.1	10/7/21

10.4.2	<a href="#">Amendment to Management Services Agreement, dated as of March 1, 2019, by and between PAVmed Inc. and Lucid Diagnostics Inc.+</a>	S-1/A	10.4.2	10/7/21
10.4.3	<a href="#">Second Amendment to Management Services Agreement, dated as of June 5, 2019, by and between PAVmed Inc. and Lucid Diagnostics Inc.+</a>	S-1/A	10.4.3	10/7/21
10.4.4	<a href="#">Third Amendment to Management Services Agreement, dated as of July 20, 2020, by and between PAVmed Inc. and Lucid Diagnostics Inc.+</a>	S-1/A	10.4.4	10/7/21
10.4.5	<a href="#">Fourth Amendment to Management Services Agreement, dated as of February 1, 2021, by and between PAVmed Inc. and Lucid Diagnostics Inc.+</a>	S-1/A	10.4.5	10/7/21
10.5.1	<a href="#">Consulting Agreement, dated as of May 12, 2018, by and between Lucid Diagnostics Inc. and Sanford Markowitz, M.D.+</a>	S-1/A	10.5.1	10/7/21
10.5.2	<a href="#">Renewed Consulting Agreement, dated as of May 12, 2021, by and between Lucid Diagnostics Inc. and Sanford Markowitz, M.D.+</a>	S-1/A	10.5.2	10/7/21
10.6.1	<a href="#">Consulting Agreement, dated as of May 12, 2018, by and between Lucid Diagnostics Inc. and Amitabh Chak, M.D.+</a>	S-1/A	10.6.1	10/7/21
10.6.2	<a href="#">Renewed Consulting Agreement, dated as of May 12, 2021, by and between Lucid Diagnostics Inc. and Amitabh Chak, M.D.+</a>	S-1/A	10.6.2	10/7/21
10.7.1	<a href="#">Consulting Agreement, dated as of May 12, 2018, by and between Lucid Diagnostics Inc. and Joseph Willis, M.D.+</a>	S-1/A	10.7.1	10/7/21
10.7.2	<a href="#">Renewed Consulting Agreement, dated as of May 12, 2021, by and between Lucid Diagnostics Inc. and Joseph Willis, M.D.+</a>	S-1/A	10.7.2	10/7/21
10.8#	<a href="#">Form of Stock Option Agreement.</a>	S-1/A	10.8	10/8/21
10.9#	<a href="#">Form of Indemnification Agreement.</a>	S-1/A	10.9	10/8/21
10.10	<a href="#">Form of Lock-Up Agreement.+</a>	S-1/A	10.10	
10.11	<a href="#">Quality &amp; Manufacturing Master Services Agreement, dated as of September 1, 2021, by and between Coastline International, Inc. and Lucid Diagnostics Inc.+</a>	S-1/A	10.11	10/1/21
10.12#	<a href="#">Form of Restricted Stock Agreement.</a>	S-1/A	10.12#	10/8/21
10.13#	<a href="#">Employment Agreement with Lishan Aklog, M.D.</a>	8-K	10.1	1/20/22
10.14#	<a href="#">Employment Agreement with Dennis M. McGrath</a>	8-K	10.2	1/20/22
10.15#	<a href="#">Employment Agreement with Shaun O'Neil.</a>	8-K	10.1	3/23/22
10.16	<a href="#">Management Services Agreement, dated as of February 25, 2022, by and among LucidDx Labs Inc. and ResearchDx, Inc.</a>	8-K	10.1	3/3/22
10.17.1†	<a href="#">Common Stock Purchase Agreement, dated as of March 28, 2022, by and between CF Principal Investments LLC and Lucid Diagnostics Inc.</a>	8-K	10.1	4/1/22
10.17.2‡	<a href="#">Registration Rights Agreement, dated as of March 28, 2022, by and between CF Principal Investments LLC and Lucid Diagnostics Inc.</a>	8-K	10.2	4/1/22
10.18#	<a href="#">Lucid Diagnostics Inc. Employee Stock Purchase Plan</a>	S-8	10.1	3/15/22

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**Item 15. Exhibits and Financial Statement Schedules - continued**

(3) The following exhibits - continued:

Exhibit No.	Description	Incorporation by Reference		
		Form	Exhibit No.	Date
14.1	<a href="#">Code of Ethics</a>	*		
21.1	<a href="#">List of Subsidiaries</a>	*		
23.1	<a href="#">Consent of Marcum LLP</a>	*		
31.1	<a href="#">Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	*		
31.2	<a href="#">Certification of Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	*		
32.1	<a href="#">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</a>	*		
32.2	<a href="#">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.</a>	*		
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 supplementally a copy of any omitted exhibit or schedule upon request by the Securities and Exchange Commission.

**Item 16. Form 10-K Summary**

None

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**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.

April 5, 2022

By: /s/ Dennis M McGrath

Dennis M McGrath  
President and Chief Financial Officer  
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated. Each person whose signature appears below hereby authorizes both Lishan Aklog, M.D. and Dennis M. McGrath or either of them acting in the absence of the others, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and re-substitution for him or her and in his or her name,

place and stead, in any and all capacities to sign any and all amendments to this report, and to file the same, with all exhibits thereto and other documents in connection therewith, with the United States Securities and Exchange Commission.

Signature	Title	Date
<u>/s/ Lishan Aklog, M.D.</u> Lishan Aklog, M.D.	Chairman of the Board of Directors Chief Executive Officer (Principal Executive Officer)	April 5, 2022
<u>/s/ Dennis M. McGrath</u> Dennis M. McGrath	President Chief Financial Officer (Principal Financial and Accounting Officer)	April 5, 2022
<u>/s/ Stanley N. Lapidus</u> Stanley N. Lapidus	Vice Chairman Director	April 5, 2022
<u>/s/ Aster Angagaw</u> Aster Angagaw	Director	April 5, 2022
<u>/s/ James L. Cox, M.D.</u> James L. Cox, M.D.	Director	April 5, 2022
<u>/s/ Sanford Markowitz, M.D.</u> Sanford Markowitz, M.D.	Director	April 5, 2022
<u>/s/ Jacque J. Sokolov, M.D.</u> Jacque J. Sokolov, M.D.	Director	April 5, 2022
<u>/s/ Ronald M. Sparks</u> Ronald M. Sparks	Director	April 5, 2022

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

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<a href="#">Consolidated Statements of Operations for the years ended December 31, 2021 and 2020</a>	F-4
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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Shareholders 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 Subsidiary (the "Company") as of December 31, 2021 and 2020, 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, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

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

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

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that

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

/s/ Marcum LLP

Marcum LLP

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

New York, NY

April 5, 2022

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

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
<b>Assets:</b>		
Current assets:		
Cash	\$ 53,656	\$ 111
Accounts receivable	200	—
Prepaid expenses, deposits, and other current assets	3,447	1,329
Total current assets	<u>57,303</u>	<u>1,440</u>
Fixed assets, net	971	—
Other assets	725	755
Total assets	<u>\$ 58,999</u>	<u>\$ 2,195</u>
<b>Liabilities, Preferred Stock and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,490	\$ 2,058
Accrued expenses and other current liabilities	1,113	394
Due To: PAVmed Inc. - MSA Fee, operating expenses, and interest expense	1,657	13,261
Total liabilities	<u>4,260</u>	<u>15,713</u>
Commitments and contingencies (Note 11)		
Stockholders' Equity (Deficit):		
Preferred stock, \$0.001 par value, 20,000,000 shares authorized; no shares issued and outstanding as of December 31, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value, 100,000,000 shares authorized; 34,917,907 and 14,114,707 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	35	14
Additional paid-in capital	96,608	294
Accumulated deficit	(41,904)	(13,826)
Total Stockholders' Equity (Deficit)	<u>54,739</u>	<u>(13,518)</u>
Total Liabilities and Stockholders' Equity (Deficit)	<u>\$ 58,999</u>	<u>\$ 2,195</u>

See accompanying notes to the financial statements.

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

	<u>Year Ended December 31,</u>	
	<u>2021</u>	<u>2020</u>
Revenue	\$ 500	\$ —
Cost of revenue	585	—
Gross profit (loss)	<u>(85)</u>	<u>—</u>
Operating expenses:		
Sales and marketing	5,260	1,305
General and administrative	12,778	1,532
Research and development	9,296	5,443
Total operating expenses	<u>27,334</u>	<u>8,280</u>
Loss from operations	(27,419)	(8,280)
Interest expense - Senior Unsecured Promissory Note	(659)	—
Loss before provision for income tax	<u>(28,078)</u>	<u>(8,280)</u>
Provision for income taxes	—	—
Net loss	<u>\$ (28,078)</u>	<u>\$ (8,280)</u>
Net loss per share - basic and diluted	<u>\$ (1.51)</u>	<u>\$ (0.59)</u>
Weighted average common shares outstanding, basic and diluted	<u>18,603,619</u>	<u>14,114,437</u>

See accompanying notes to the financial statements.

**LUCID DIAGNOSTICS INC.**  
**and SUBSIDIARY**  
(a majority-owned subsidiary of PAVmed Inc.)  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**  
**for the YEARS ENDED DECEMBER 31, 2021 and 2020**  
(in thousands except number of shares and per share data)

	<u>Common Stock</u>		<u>Additional Paid- In Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>			
<b>Balance as of December 31, 2019</b>	14,110,004	\$ 14	\$ 223	\$ (5,546)	\$ (5,309)
Exercise - stock options - Lucid Diagnostics Inc. 2018 Equity Plan	4,703	—	5	—	5
Stock-based compensation - Lucid Diagnostics Inc. 2018 Equity Plan	—	—	53	—	53
Stock-based compensation - PAVmed Inc. 2014 Equity Plan	—	—	13	—	13
Net Loss	—	—	—	(8,280)	(8,280)
<b>Balance as of December 31, 2020</b>	<u>14,114,707</u>	<u>\$ 14</u>	<u>\$ 294</u>	<u>\$ (13,826)</u>	<u>\$ (13,518)</u>
Issue of common stock - conversion of Senior Unsecured Promissory Note	15,803,200	16	22,384	—	22,400
Issuance of common stock - IPO, net of fees	5,000,000	5	64,331	—	64,336
Stock-based compensation - Lucid Diagnostics Inc. 2018 Equity Plan	—	—	9,134	—	9,134
Stock-based compensation - PAVmed Inc. 2014 Equity Plan	—	—	465	—	465
Net loss	—	—	—	(28,078)	(28,078)
<b>Balance as of December 31, 2021</b>	<u>34,917,907</u>	<u>\$ 35</u>	<u>\$ 96,608</u>	<u>\$ (41,904)</u>	<u>\$ 54,739</u>

See accompanying notes to the financial statements.

**LUCID DIAGNOSTICS INC.**  
**and SUBSIDIARY**  
(a majority-owned subsidiary of PAVmed Inc.)  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2021 and 2020**  
(in thousands except number of shares and per share data)

	<u>Year Ended December 31,</u>	
	<u>2021</u>	<u>2020</u>
<b>Cash flows from operating activities</b>		
Net loss	\$ (28,078)	\$ (8,280)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation expense	4	—
Stock-based compensation - Lucid Diagnostics Inc. 2018 Equity Plan	9,134	52
Stock-based compensation - PAVmed Inc. 2014 Equity Plan	465	13
Changes in operating assets and liabilities:		
Accounts receivable	(200)	—
Prepaid expenses and other current assets	(2,088)	(1,094)
Accounts payable	(665)	1,146
Accrued expenses and other current liabilities	926	171
Accrued CWRU License Agreement Fee	(223)	—
Due To: PAVmed Inc. - operating expenses paid on-behalf-of Lucid Diagnostics Inc.	984	683
Due To: PAVmed Inc. - Management Services Agreement Fee	1,350	1,680
Due To: PAVmed Inc. - Operating expenses	(314)	—
Due To: PAVmed Inc. - Employee Related Costs	1,037	—
Net cash flows used in operating activities	<u>(17,668)</u>	<u>(5,629)</u>
<b>Cash flows from investing activities</b>		
Purchase of equipment	(862)	—
Net cash flows used in investing activities	<u>(862)</u>	<u>—</u>
<b>Cash flows from financing activities</b>		
Proceeds – issue of common stock – initial public offering	70,000	—
Payment – offering costs – initial public offering	(5,664)	—
Proceeds – exercise of stock options	—	5
Proceeds – issue common stock – Employee Stock Purchase Plan	—	—
Proceeds – Due To: PAVmed Inc. - working capital cash advances	7,739	5,579
Net cash flows provided by financing activities	<u>72,075</u>	<u>5,584</u>
Net increase (decrease) in cash	53,545	(45)
Cash, beginning of period	111	156
Cash, end of period	<u>\$ 53,656</u>	<u>\$ 111</u>

**LUCID DIAGNOSTICS INC.**  
**and SUBSIDIARY**  
(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 — Summary Description of the Company**

The accompanying consolidated financial statements are those of Lucid Diagnostics Inc. (“Lucid Diagnostics” or “the Company”), which was incorporated in the State of Delaware on May 8, 2018. Lucid Diagnostics Inc. is a majority-owned subsidiary of PAVmed Inc., as discussed below.

The Company operates in one segment as a commercial-stage medical diagnostics technology company focused on the millions of patients with gastroesophageal reflux disease - “GERD” - which is also known as chronic heartburn, acid reflux or simply reflux, who are at risk for developing esophageal precancer and cancer, specifically highly lethal esophageal adenocarcinoma (EAC).

Lucid Diagnostics Inc. entered into a patent license agreement with Case Western Reserve University (“CWRU”), captioned the Amended and Restated License Agreement, dated August 23, 2021 (“Amended CWRU License Agreement”). The Amended CWRU License Agreement is a successor to and replaced in its entirety the previous CWRU License Agreement, dated May 12, 2018. The Amended CWRU License Agreement terminates upon the expiration of certain related patents, or on May 12, 2038 in countries where no such patents exist, or upon expiration of any exclusive marketing rights granted by the FDA or other U.S. government agency, whichever comes later.

The Amended CWRU License Agreement (as did the predecessor CWRU License Agreement) provides for the exclusive worldwide license of the intellectual property rights for the proprietary technologies of two distinct technology components - the “EsoCheck Cell Collection Device” referred to as “EsoCheck®”; and a panel of proprietary methylated DNA biomarkers, a laboratory developed test (“LDT”), referred to as “EsoGuard®”; and together are collectively referred to as the “EsoGuard Technology”. See Note 3, Patent License Agreement – Case Western Reserve University, for a discussion of the Amended CWRU License Agreement.

Since its inception, the Company has advanced the proprietary technologies underlying EsoGuard and EsoCheck from the academic research laboratory to commercial diagnostics tests and devices with scalable manufacturing capacity. The Company is presently focused on expanding commercialization across multiple sales channels, including: the communication and education of medical practitioners and clinicians of the EsoGuard LDT; and establishing “Lucid Diagnostics Test Centers” for the collection of cell samples using EsoCheck and delivery of the collected cell samples to ResearchDX Inc. (“RDx”), a CLIA certified commercial laboratory service provider, for the performance of the EsoGuard LDT. Additionally, the Company is conducting two concurrent clinical trials, including each of: the “EsoGuard screening study” (“ESOGUARD-BE-1”); and the “EsoGuard case control study” (“ESOGUARD-BE-2”), to support a United States Food and Drug Administration (“FDA”) pre-market approval (“PMA”) of the use of EsoGuard and EsoCheck as an in-vitro diagnostic medical device (“IVD”). Further, the Company is developing expanded clinical evidence to support recommendation of our products in professional society guidelines.

*Lucid Diagnostics Inc. Initial Public Offering - October 14, 2021*

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

**Note 1 — Summary Description of the Company - continued**

*Formation of Wholly-Owned Subsidiary LucidDx Labs Inc. - December 2021*

In December 2021, Lucid Diagnostics, Inc. formed a new wholly owned subsidiary, LucidDx Labs Inc., principally to construct and operate the Company’s new owned Commercial Lab Improvements Act (“CLIA”) certified, College of American Pathologists (“CAP”) accredited commercial clinical laboratory. The Company is in the process of completing the operational capacity of its commercial clinical laboratory.

*Asset Purchase Agreement - “RDx APA” - February 2022*

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

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

*Significant Accounting Policies*

**Basis of Presentation**

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”), and applicable rules and regulations of the United States Securities and Exchange Commission (“SEC”), and include the accounts of the Company and its wholly-owned subsidiary, LucidDx Labs Inc. All intercompany transactions and balances have been eliminated in consolidation. Lucid Diagnostics Inc. (“the Company”) is a majority-owned consolidated subsidiary of PAVmed Inc., which has a majority equity ownership interest and has financial control of Lucid Diagnostics Inc. 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.

Effective October 6, 2021, the Lucid Diagnostics Inc. board of directors: increased the authorized shares of common stock to 100.0 million shares; and declared a 1.411-to-1.0 common stock-split. All shares of common stock of the Company and per share amounts, for all periods presented, have been adjusted for the common stock-split, with such adjustment rounded-up to the next whole share in lieu of a fractional share, with no adjustment to the par value per share, inclusive of: the number of shares of common stock issued and outstanding (and the corresponding increase to common stock par value and decrease to additional paid in capital), along with the conversion price per share of the Senior Unsecured Promissory Note; basic and diluted weighted-average shares outstanding and the corresponding loss per share; and applicable notes to the financial statements, including: stock options granted, stock option exercise prices, and the number of restricted stock awards, and the respective fair value per share of the stock options and restricted stock awards, along with all other share and per share amounts for all periods presented as applicable.

#### 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. Other significant estimates include the provision or benefit for income taxes and the corresponding valuation allowance on deferred tax assets. Additionally, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. On an ongoing basis, the Company evaluates its estimates and assumptions. The Company bases its estimates on historical experience and on various other assumptions believed to be reasonable. Due to inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates.

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

##### *Significant Accounting Policies - continued*

#### Financial Condition

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

Since its inception to the date of the Company's IPO on October 14, 2021, the operations of Lucid Diagnostics Inc. have been funded by PAVmed Inc. providing working capital cash advances and the payment by PAVmed Inc. of certain operating expenses on-behalf-of Lucid Diagnostics Inc. Additionally, the daily operations of Lucid Diagnostics Inc. continue to be managed by personnel employed by PAVmed Inc., for which Lucid Diagnostics Inc. incurs expense according to the provisions of a Management Services Agreement between Lucid Diagnostics Inc. and PAVmed Inc. See Note 4, Related Party Transactions, for information with respect to the Management Services Agreement; and Note 6, *Due To PAVmed Inc.*, for further information with respect to amounts owed to PAVmed Inc. by Lucid Diagnostics Inc.

The Company is subject to all of the risks and uncertainties typically faced by medical device and diagnostic and medical device companies that devote substantially all of their efforts to the commercialization of their initial product and services and ongoing research and development activities and conducting clinical trials. The Company expects to continue to experience recurring losses from operations and will continue to fund its operations with debt and equity financing transactions. Notwithstanding, however, with the cash on-hand as of the date hereof and other debt and equity committed sources of capital with Lucid and its parent company, PAVmed, the Company expects to be able to fund its future operations for one year from the date of the issue of the Company's financial statements, as included herein in this Annual Report on Form 10-K for the period ended December 31, 2021.

#### 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.

#### 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.

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

##### *Significant Accounting Policies - continued*

#### Leases

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

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

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

The lease liability is measured at the lease commencement date with the discount rate generally based on the Company's incremental borrowing rate (to the extent the lease

implicit rate is not known nor determinable), with interest expense recognized using the interest method for financing leases.

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

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

### *Significant Accounting Policies - continued*

#### Revenue Recognition

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

#### 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. As of December 31, 2021 and December 31, 2020, there were no deferred offering costs.

#### Research and Development Expenses

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

#### Patent Costs and Purchased Patent License Rights

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

The Company has entered into agreements with third parties to acquire technologies for potential commercial development. Such agreements generally require an initial payment by the Company when the contract is executed. The purchase of patent license rights for use in research and development activities, including product development, are expensed as incurred and are classified as research and development expense. Additionally, the Company may be obligated to make future royalty payments in the event the Company commercializes the technology and achieves a certain sales volume. In accordance with 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.

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

### *Significant Accounting Policies - continued*

#### Stock-Based Compensation

Stock-based awards are made to members of the board of directors of the Company, the Company's employees and non-employees, under each of the Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan ("Lucid Diagnostics Inc. 2018 Equity Plan") and the PAVmed Inc. 2014 Long-Term Incentive Equity Plan ("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 and the volatilities of similar entities within the medical device industry over the period commensurate with the expected term with respect to stock options granted to the board of directors and employees in the years ended December 31, 2021 and 2020;

- With respect to stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan, the expected stock price volatility was based on the historical stock price volatility of similar entities within the medical device industry over the period commensurate with the expected term with respect to stock options granted to employees in the year ended December 31, 2021; There were no stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan in the year ended December 31, 2020;
- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period commensurate with either the expected term or the remaining contractual term, as applicable, of the stock option; and,
- The expected dividend yield is based on annual dividends of \$0.00 as there have not been dividends paid to-date, and there is no plan to pay dividends for the foreseeable future.

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

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.

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

### *Significant Accounting Policies - continued*

#### **Financial Instruments Fair Value Measurements**

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

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

As of December 31, 2021 and December 31, 2020, the carrying values of cash, and accounts payable, approximate their respective fair value due to the short-term nature of these financial instruments.

#### **Income Taxes**

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

Under ASC 740, a “more-likely-than-not” criterion is applied when assessing the estimated realization of deferred tax assets through their utilization to reduce future taxable income, or with respect to a deferred tax asset for tax credit carryforward, to reduce future tax expense. A valuation allowance is established, when necessary, to reduce deferred tax assets, net of deferred tax liabilities, when the assessment indicates it is more-likely-than-not, the full or partial amount of the net deferred tax asset will not be realized. As a result of the evaluation of the positive and negative evidence bearing upon the estimated realizability of net deferred tax assets, and based on a history of operating losses, it is more-likely-than-not the deferred tax assets will not be realized, and therefore a valuation allowance reserve equal to the full amount of the deferred tax assets, net of deferred tax liabilities, has been recognized as a charge to income tax expense as of December 31, 2021 and December 31, 2020.

The Company recognizes the benefit of an uncertain tax position it has taken or expects to take on its income tax return if such a position is more-likely-than-not to be sustained upon examination by the taxing authorities, with the tax benefit recognized being the largest amount having a greater than 50% likelihood of being realized upon ultimate settlement. As of December 31, 2021, the Company does not have any unrecognized tax benefits resulting from uncertain tax positions.

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

### *Significant Accounting Policies - continued*

The Company’s policy is to record interest and penalties related to income taxes as part of its income tax provision. There were no amounts accrued for penalties or interest as of December 31, 2021 and December 31, 2020 or recognized during the year ended December 31, 2021 and December 31, 2020. The Company is not aware of any issues under review to potentially result in significant payments, accruals, or material deviations from its position.

On October 14, 2021, Lucid Diagnostics Inc. 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 to below 80% after the IPO. Accordingly, Lucid Diagnostics Inc. is included in the PAVmed Inc and Subsidiaries consolidated income tax returns through October 13, 2021, and effective October 14, 2021, Lucid Diagnostics Inc. will file its income tax returns on a stand-alone legal entity basis. The Lucid Diagnostics Inc. 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 Inc. is computed as if its income tax returns were filed by Lucid Diagnostics Inc. on a stand-alone legal entity basis. Notwithstanding the absence of a formal tax sharing agreement between PAVmed Inc. and Lucid Diagnostics Inc., the Lucid Diagnostics Inc. stand-alone legal entity current tax expense and /or tax refund, if any, would be settled with PAVmed Inc. (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 Inc. stand-alone legal entity assumed filing of separate income tax returns.

## 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 stock options and unvested restricted stock awards granted under the Lucid Diagnostics Inc. 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.

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

### JOBS Act EGC Accounting Election

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

#### *Recent Accounting Standards Updates Adopted*

In August 2020, the FASB issued ASU 2020-06, Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815 – 40), (“ASU 2020-06”). ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, by eliminating the beneficial conversion and cash conversion accounting models previously contained in ASC 470-20 that required separate accounting for embedded conversion features. ASU 2020-06 also simplified the assessment of a financial instrument settlement to determine whether a contract is an entity’s own equity qualifies for equity classification by removing certain conditions from ASC 815-4-25. The ASU 2020-06 amendments are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company’s adoption of the ASU 2020-06 guidance as of January 1, 2021 did not have an effect on the Company’s consolidated financial statements.

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

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## Note 3 — Patent License Agreement – Case Western Reserve University

### *Overview*

Lucid Diagnostics Inc. entered into a patent license agreement with Case Western Reserve University (“CWRU”), captioned the Amended and Restated License Agreement and dated August 23, 2021 (“Amended CWRU License Agreement”). The Amended CWRU License Agreement is a successor to and replaced in its entirety the previous CWRU License Agreement, dated May 12, 2018, between Lucid Diagnostics Inc. and CWRU. The Amended CWRU License Agreement terminates upon the expiration of certain related patents, or on May 12, 2038 in countries where no such patents exist, or upon expiration of any exclusive marketing rights granted by the FDA or other U.S. government agency, whichever comes later.

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

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

### *Patent Fees Reimbursement*

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

### *Milestones*

The (predecessor) CWRU License Agreement contained milestones, including regulatory milestones with respect to the FDA 501(k) submission of EsoCheck and the FDA clearance of EsoCheck, respectively regulatory submissions and clearances; which were achieved in accordance with the requisite contractual due dates, for which a \$75 research and development expense was recognized and paid with respect to the achievement of the regulatory milestone related to FDA clearance of EsoCheck. The CWRU License Agreement was amended effective February 12, 2021, to: change the achievement date of commercialization milestone from November 2020 to August 2021; to eliminate the payment with respect to the commercialization milestone; and to add a non-refundable \$100 payment to CWRU in consideration for such changes to the commercialization milestone (“CWRU License Agreement Amendment Fee”), with such fee recognized as general and administrative expense as of December 31, 2020 and paid in February 2021. The regulatory milestone related to FDA PMA submission of a licensed product (“PMA Milestone”) is included in the Amended CWRU License Agreement, and is the sole remaining unachieved milestone, for which a \$200 milestone payment would be payable to CWRU upon its achievement.

### *Royalty Fee*

Under the Amended CWRU License Agreement, the Company is required to pay a royalty fee to CWRU with respect to the “Licensed Products” (as defined in the CWRU

License Agreement) of a percentage of “Net Sales”, as defined in the Amended CWRU License Agreement, as follows: 5.0% of Net Sales up to \$100.0 million per year; and 8.0% of Net Sales of \$100.0 million or greater per year, with such amounts subject-to a minimum annual royalty fee.

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

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

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

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

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

### Note 4 - Revenue from Contracts with Customers

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

#### *EsoGuard Commercialization Agreement*

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

On February 25, 2022, the EsoGuard Commercialization Agreement was terminated in conjunction with the execution of an Asset Purchase Agreement between LucidDx Labs Inc., a wholly-owned subsidiary of Lucid Diagnostics Inc., and RDx, as such agreement is further discussed above in Note 1, *Summary Description of the Company*.

#### *Revenue Recognized*

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

#### *Cost of Revenue*

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

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### Note 5 — Related Party Transactions

#### *Case Western Reserve University and Physician Inventors - CWRU License Agreement*

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

	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cost of Revenue</b>		
CWRU – Royalty Fee	\$ 25	\$ —
<b>General and Administrative Expense</b>		
CWRU – License Agreement - Amendment Fee - Milestone III	10	100
Stock-based compensation expense – Physician Inventors’ restricted stock awards	910	—
<b>Research and Development Expense</b>		
CWRU License Agreement - reimbursement of patent legal fees	195	250
EsoCheck devices provided to CWRU	—	15
Fees - Physician Inventors’ consulting agreements	29	83
Stock-based compensation expense – Physician Inventors’ stock options	169	23
<b>Total Related Party Expenses</b>	<b>\$ 1,338</b>	<b>\$ 471</b>

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

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

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

See Note 3, Patent License Agreement - Case Western Reserve University, for a discussion of: the Amended CWRU License Agreement; and the consulting agreements with the Physician Inventors; and Note 12, Stock-Based Compensation, for information regarding each of the Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan and the separate PAVmed Inc. 2014 Long-Term Incentive Equity Plan, including the stock-based equity awards granted to the Physician Inventors.

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#### Note 5 — Related Party Transactions - continued

##### PAVmed Inc. - Management Services Agreement

The daily operations of Lucid Diagnostics Inc. are managed by personnel employed by PAVmed Inc., for which Lucid Diagnostics Inc. incurs a service fee, referred to as the "MSA Fee", according to the provisions of a Management Services Agreement ("MSA") with PAVmed Inc. The MSA does not have a termination date, but may be terminated by the Lucid Diagnostics Inc. board of directors. The MSA Fee is charged on a quarterly basis and is subject to periodic adjustment corresponding with changes in the number of PAVmed Inc. employees providing services to Lucid Diagnostics Inc., with the change in the MSA Fee approved by each of the Lucid Diagnostics Inc. and PAVmed Inc. board of directors.

Lucid Diagnostics Inc. recognized MSA Fee expense of \$3,630 and \$1,680 in the years ended December 31, 2021 and 2020, respectively. The MSA Fee expense classification in the consolidated statement of operations for the periods noted is as follows:

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
Cost of Revenues	\$ 61	\$ —
Sales & Marketing	1,406	482
General & Administrative	1,255	659
Research & Development	908	539
Total MSA Fee	<u>\$ 3,630</u>	<u>\$ 1,680</u>

The classification of the MSA Fee as presented above is based on the PAVmed Inc. classification of employee salary expense. In this regard, PAVmed Inc. classifies employee salary expense as cost-of-revenue for employees engaged in service delivery under the EsoGuard Commercialization Agreement, and sales and marketing expenses for employees performing sales, marketing, and reimbursement activities and functions, general and administrative, and research and development except for those employees who are engaged in product and services engineering development and design and /or clinical trials activities, for which such employee salary is classified as research and development expense.

##### Other Related Party Transactions

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

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#### Note 6 — Due To PAVmed Inc.

The aggregate Due To: PAVmed Inc., inclusive of the Senior Unsecured Promissory Note, for the periods indicated is summarized as follows:

	Principal Senior Unsecured Promissory Note	Interest Unsecured Senior Promissory Note	Working Capital Cash Advances	PAVmed Inc. OBO Payments	ERC Payroll Benefits	MSA Fees	Total
Balance - December 31, 2020	\$ —	\$ —	\$ 8,200	\$ 2,361	\$ —	\$ 2,700	\$ 13,261
MSA fees	—	—	—	—	—	3,630	3,630
On Behalf Of (OBO) activities	—	—	7,739	984	—	—	8,723
ERC - Payroll & Benefits	—	—	—	—	1,037	—	1,037
Promissory Note Issuance	22,400	—	(15,939)	(2,411)	—	(4,050)	—
Conversion of Promissory Note to LUCD Common Stock	(22,400)	—	—	—	—	—	(22,400)
Interest on Promissory Note	—	659	—	—	—	—	659
Cash payments to PAVmed Inc.	—	(659)	—	(314)	—	(2,280)	(3,253)
Balance - December 31, 2021	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 620</u>	<u>\$ 1,037</u>	<u>\$ —</u>	<u>\$ 1,657</u>

	Principal Senior Unsecured Promissory Note	Interest Unsecured Senior Promissory Note	Working Capital Cash Advances	PAVmed Inc. OBO Payments	MSA Fees	Total
Balance as of December 31, 2019	\$ —	\$ —	\$ 2,622	\$ 1,679	\$ 1,020	\$ 5,321
Net Activity during 2020	—	—	5,578	682	1,680	7,940
Balance as of December 31, 2020	\$ —	\$ —	\$ 8,200	\$ 2,361	\$ 2,700	\$ 13,261

Lucid Diagnostics Inc. has principally financed its operations through working capital cash advances from PAVmed Inc. and the periodic payment of certain operating expenses by PAVmed Inc. on-behalf-of Lucid Diagnostics Inc. (the “PAVmed Inc. OBO Payments”). Additionally, the daily operations of Lucid Diagnostics Inc. are managed by personnel employed by PAVmed Inc., for which the Company incurs expense according to the provisions of a Management Services Agreement (MSA) between the Company and PAVmed Inc (the “MSA Fee”). See Note 5, *Related Party Transactions*, for further information regarding the MSA.

#### Senior Unsecured Promissory Note

On October 13, 2021, Lucid Diagnostics Inc. issued 15,803,200 shares of its common stock to PAVmed Inc. upon the election by PAVmed Inc. to convert the \$22.4 million face value principal under the terms of a Senior Unsecured Promissory Note, dated June 1, 2021. The Senior Unsecured Promissory Note was issued by Lucid Diagnostics Inc. to PAVmed Inc. with a face value principal of \$ 22.4 million, which replaced the aggregate outstanding and payable balance of the Due To: PAVmed Inc. as of June 1, 2021, had an annual interest rate of 7.875%, a contractual maturity date of May 18, 2028, and, at the election of PAVmed Inc., provided for the partial or full repayment of the face value principal and accrued but unpaid interest thereon by the issue of shares of Lucid Diagnostics Inc. common stock at a conversion price of \$1.42 per share of Lucid Diagnostics Inc. common stock.

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

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

	December 31, 2021	December 31, 2020
Advanced payments to service providers and suppliers	\$ 1,138	\$ 377
Prepaid insurance	1,578	0
Deposits	238	118
EsoCheck cell collection supplies	434	779
EsoGuard mailer supplies	59	55
Total prepaid expenses, deposits and other current assets	\$ 3,447	\$ 1,329

#### Non-Current Assets

The Company entered into an agreement with a clinical research organization (“CRO”) in connection with EsoGuard clinical trials (the “EsoGuard CRO Agreement”). The term of the EsoGuard CRO Agreement is from the September 2019 effective date to the conclusion of the respective clinical trials, but not to exceed 60 months from the effective date of the EsoGuard CRO Agreement. The CRO agreement may be cancelled with sixty days written notice, without an early termination fee. The Company incurred an on-account deposit of \$725 and \$755 as of December 31, 2021 and 2020, respectively, with the deposit classified as a non-current asset in the line item captioned “Other assets” on the accompanying consolidated balance sheets as of December 31, 2021 and 2020. See Note 11, *Commitment and Contingencies*, for a discussion of the EsoGuard CRO Agreement.

#### Note 8 — Fixed Assets

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

	Estimated Useful Life	December 31, 2021	December 31, 2020
Computer and office equipment	2-5 years	\$ 88	\$ —
Laboratory equipment	3-7 years	845	—
Furniture and fixtures	3-5 years	21	—
Leasehold improvements	(1)	1	—
Assets under construction	n/a	20	—
Total Fixed Assets		975	—
Less Accumulated Depreciation		(4)	—
Total Fixed Assets, net		\$ 971	\$ —

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

The assets under construction presented above are with respect to the establishment of a Company owned and operated CLIA-certified, CAP-accredited clinical laboratory.

Depreciation expense of \$4 for the year ended December 31, 2021 is included in general and administrative expenses in the accompanying consolidated statements of operations.

The total fixed assets is inclusive of \$98 of accounts payable and \$16 of accrued expenses and other current liabilities in the accompanying consolidated balance sheet as of December 31, 2021.

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#### Note 9 — Leases

As of December 31, 2021, the Company only had short-term leases for its Lucid Test Centers, resulting in rent expense of \$4 for the year ended December 31, 2021 (there was no such rent expense for the prior year ended December 31, 2020).

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

The total future lease payments of both the (existing) short-term leases as of December 31, 2021 and the (new) short-term leases with commencement dates subsequent to December 31, 2021, are \$75 in 2022 and \$9 in 2023, as of December 31, 2021.

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

2022	\$	912
2023		932
2024		883
2025		—
2026		—
Thereafter		—
<b>Total lease payments</b>		<b>2,727</b>

#### Note 10 — Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities for the periods indicated consist of the following:

	<b>December 31, 2021</b>	<b>December 31, 2020</b>
Compensation and Employee Benefits	\$ 557	\$ —
CWRU License Agreement fee	—	223
CWRU License Agreement Amendment fee	—	100
CWRU Amended License Agreement - Royalty fee	25	—
Operating expenses	531	49
EsoGuard mailer supplies	—	22
<b>Total accrued expenses and other current liabilities</b>	<b>\$ 1,113</b>	<b>\$ 394</b>

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

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

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#### Note 11 — Commitment and Contingencies

##### *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. Except as otherwise noted herein, the Company does not believe it is currently a party to any other pending legal proceedings. Notwithstanding, legal proceedings are subject to inherent uncertainties, and an unfavorable outcome could include monetary damages, and excessive verdicts can result from litigation, and as such, could result in a material adverse impact on the Company's business, financial position, results of operations, and /or cash flows. Additionally, although the Company has specific insurance for certain potential risks, the Company may in the future incur judgments or enter into settlements of claims which may have a material adverse impact on the Company's business, financial position, results of operations, and /or cash flows.

##### *Clinical Trials - Agreement with Clinical Research Organization*

The Company entered into an agreement with a clinical research organization ("CRO") in connection with EsoGuard clinical trials, referred to as the EsoGuard CRO Agreement. The CRO will assist the Company with conducting two concurrent clinical trials referred to as the "EsoGuard screening study" and the "EsoGuard case control study". The term of the EsoGuard CRO Agreement is from the September 2019 effective date to the conclusion of the respective clinical trials, but not to exceed 60 months from the effective date of the EsoGuard™ CRO Agreement. The CRO agreement may be cancelled with sixty days written notice, without an early termination fee.

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#### Note 12 — Stock-Based Compensation

##### *Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan*

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

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

##### *Lucid Diagnostics Inc. 2018 Equity Plan - Stock Options*

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

	Number of Stock Options	Weighted Average Exercise Price	Remaining Contractual Term (Years)
Outstanding stock options at December 31, 2019	1,403,945	\$ 0.61	9.0
Granted <sup>(1)</sup>	—	\$ —	
Exercised	(4,703)	\$ 1.06	
Forfeited	—	\$ —	
Outstanding stock options at December 31, 2020	1,399,242	\$ 0.61	8.0
Granted <sup>(1)</sup>	20,000	\$ 9.08	

Exercised	—	\$	—
Forfeited	—	\$	—
Outstanding stock options at December 31, 2021	1,419,242	\$	0.60
Vested and exercisable stock options at December 31, 2021	1,337,417	\$	0.61

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

Previously, in January 2020, 4,703 stock options issued under the Lucid Diagnostics Inc. 2018 Equity Plan were exercised for cash proceeds of \$999, resulting in the issue of the same number of shares of common stock of Lucid Diagnostics Inc.

The three Physician Inventors were each granted 141,100 stock options outside of the Lucid Diagnostics Inc. 2018 Equity Plan, with a grant date of May 12, 2018, an exercise price of \$0.35 per share of common stock of Lucid Diagnostics Inc., vesting ratably on a quarterly basis commencing June 30, 2018 and ending March 31, 2021, and a contractual period of ten years from the date of grant. See Note 5, *Related Party Transactions*, for a summary of the stock-based compensation expense recognized with respect to the stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan to the Physician Inventors.

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## Note 12 — Stock-Based Compensation - continued

### *Lucid Diagnostics Inc. 2018 Equity Plan – Restricted Stock Awards*

As of December 31, 2021, a total of 1,897,795 restricted stock awards were granted under the Lucid Diagnostics Inc. 2018 Equity Plan, summarized as follows:

On March 1, 2021, a total of 1,467,440 restricted stock awards were granted under the Lucid Diagnostics Inc. 2018 Equity Plan to employees of PAVmed Inc., a member of the board of directors of Lucid Diagnostics Inc. (who is also a member of the board of directors of PAVmed Inc.), and to each of the three physician inventors of the intellectual property licensed under the CWRU License Agreement, with such restricted stock awards having a single vesting date of March 1, 2023, and an aggregate grant date fair value of approximately \$18.9 million, measured as discussed below, with such aggregate estimated fair value recognized as stock-based compensation expense ratably on a straight-line basis over the vesting period, which is commensurate with the service period. The restricted stock awards are subject to forfeiture if the requisite service period is not completed. See Note 5, *Related Party Transactions*, for a summary of the stock-based compensation expense recognized with respect to the restricted stock awards granted under the Lucid Diagnostics Inc. 2018 Equity Plan to the Physician Inventors.

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

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

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

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

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

Subsequent to December 31, 2021, as of March 29, 2022, additional stock-based equity grants under the Lucid Diagnostics Inc. 2018 Equity Plan included each of 1.8 million stock options with a weighted average exercise price of approximately \$4.16 per share and the same vesting and contractual term as discussed above; and a total of 320,000 restricted stock awards with a weighted average grant date fair value of \$4.52 per share of Lucid Diagnostics Inc. common stock, with single vesting date of three years from date of grant.

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## Note 12 — Stock-Based Compensation - continued

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

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

The PWERM principally involved (i) the identification of scenarios and related probabilities; (ii) determine the equity value under each scenario; and (iii) determine the

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

#### PAVmed Inc. 2014 Equity Plan

The PAVmed Inc. 2014 Long-Term Incentive Equity Plan (the "PAVmed Inc. 2014 Equity Plan"), is separate and apart from the Lucid Diagnostics Inc. 2018 Equity Plan (as such equity plan is discussed above). The PAVmed Inc. 2014 Equity Plan is designed to enable PAVmed Inc. to offer employees, officers, directors, and consultants, as defined, an opportunity to acquire a proprietary interest in PAVmed Inc. The types of awards that may be granted under the PAVmed Inc. 2014 Equity Plan include stock options, stock appreciation rights, restricted stock awards, and other stock-based awards subject to limitations under applicable law. The PAVmed Inc. 2014 Equity Plan grants are subject to approval of the PAVmed Inc. board of directors compensation committee.

The three Physician Inventors were each granted 25,000 stock options under the PAVmed Inc. 2014 Equity Plan, with a grant date of May 12, 2018, an exercise price of \$1.59 per share of common stock of PAVmed Inc., vesting ratably on a quarterly basis commencing June 30, 2018 and ending March 31, 2021, and a contractual period often years from the date of grant. Additionally, the three Physician Inventors were each granted 50,000 stock options under the PAVmed Inc. 2014 Equity Plan, with a grant date of June 21, 2021, an exercise price of \$6.41 per share of common stock of PAVmed Inc., vesting ratably on a quarterly basis commencing June 30, 2021 and ending March 31, 2024, and a contractual period of ten years from the date of grant. See Note 5, *Related Party Transactions*, for a summary of the stock-based compensation expense recognized with respect to the stock options granted under the PAVmed Inc. 2014 Equity Plan to the Physician Inventors.

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#### Note 12 — Stock-Based Compensation - continued

##### Stock-Based Compensation Expense

The stock-based compensation expense recognized by the Company for both the Lucid Diagnostics Inc. 2018 Equity Plan and the PAVmed Inc. 2014 Equity Plan, for the periods indicated, was as follows:

	Year Ended December 31,	
	2021	2020
Lucid Diagnostics Inc 2018 Equity Plan – sales and marketing expenses	\$ 8	\$ —
Lucid Diagnostics Inc 2018 Equity Plan - general and administrative expense	9,073	—
Lucid Diagnostics Inc 2018 Equity Plan - research and development expenses	66	52
PAVmed Inc 2014 Equity Plan - sales and marketing expenses	202	—
PAVmed Inc 2014 Equity Plan - general and administrative expenses	38	—
PAVmed Inc 2014 Equity Plan - research and development expenses	212	13
Total stock-based compensation expense	\$ 9,599	\$ 65

The stock-based compensation expense, as presented above, is inclusive of: stock options and restricted stock awards granted under the Lucid Diagnostics Inc. 2018 Equity Plan to employees of PAVmed Inc., the Physician Inventors (as discussed above), and members of the board of directors of Lucid Diagnostics Inc., as well as the stock options granted under the PAVmed Inc. 2014 Equity Plan to the Physician Inventors (as discussed above).

As of December 31, 2021, 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 Inc. 2018 Equity Plan and the PAVmed Inc. 2014 Equity Plan, as discussed above, is as follows:

	Unrecognized Expense	Weighted Average Remaining Service Period (Years)
Lucid Diagnostics Inc. 2018 Equity Plan		
Stock Options	\$ 100	0.6
Restricted Stock Awards	\$ 16,000	1.3
PAVmed Inc. 2014 Equity Plan		
Stock Options	\$ 465	2.2
Restricted Stock Awards	\$ —	0.0

Stock-based compensation expense recognized with respect to stock options granted under the Lucid Diagnostics Inc. 2018 Equity Plan was based on a weighted average estimated fair value of such stock options of \$5.13 per share during the year ended December 31, 2021. There were no stock-based awards granted under the Lucid Diagnostics Inc. 2018 Equity Plan during the year ended December 31, 2020. The stock-based compensation was calculated using the following weighted average Black-Scholes valuation model assumptions:

	Year Ended December 31,	
	2021	2020
Expected term of stock options (in years)	5.7	0
Expected stock price volatility	70%	—%
Risk free interest rate	1.3%	—%
Expected dividend yield	—%	—%

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

The Lucid Diagnostics Inc. Employee Stock Purchase Plan ("Lucid Diagnostics Inc. ESPP"), adopted by the Company's board of directors effective November 9, 2021, provides eligible employees to purchase shares of Lucid Diagnostics Inc. common stock through payroll deductions during six month periods ending March 31 and September 30, wherein the purchase price per share of common stock is 85% of the lower quoted closing price per at either the beginning or end of each six month share purchase period. The Lucid Diagnostics Inc. ESPP has a total reservation of 500,000 shares of common stock of Lucid Diagnostics Inc. of which 500,000 shares are available-for-issue remaining as of December 31, 2021.

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#### Note 13 — Stockholders' Equity

## Preferred Stock

The Company is authorized to issue 20 million shares of its preferred stock, par value of \$0.001 per share, with such designation, rights, and preferences as may be determined from time-to-time by the Company's board of directors. There were no shares of preferred stock issued and outstanding as of December 31, 2021 and December 31, 2020.

## Lucid Diagnostics Inc. Common Stock

Effective October 6, 2021, the Lucid Diagnostics Inc. board of directors: increased the authorized shares of common stock of Lucid Diagnostics Inc. to 100.0 million shares, par value \$0.001; and declared a 1.411-to-1.0 common stock-split with respect to Lucid Diagnostics Inc. common stock, as discussed below.

There were 34,917,907 and 14,114,707 shares of common stock issued and outstanding as of December 31, 2021 and December 31, 2020, respectively. As of December 31, 2021, PAVmed Inc. holds 27,927,190 shares, representing a majority-interest equity ownership and has a controlling financial interest in Lucid Diagnostics Inc.

### Year Ended December 31, 2021

#### PAVmed Inc Conversion of the Senior Unsecured Promissory Note Principal - October 13, 2021

On October 13, 2021, 15,803,200 shares of common stock of Lucid Diagnostics Inc. were issued to PAVmed Inc. upon the election by PAVmed Inc. to convert the \$22.4 million face value principal of a Senior Unsecured Promissory Note, dated June 1, 2021, under the terms of such note, which was issued to PAVmed Inc. by Lucid Diagnostics Inc.

#### Lucid Diagnostics Inc. Initial Public Offering - October 14, 2021

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

### Year Ended December 31, 2020

During the year ended December 31, 2020, 4,703 shares of common stock of the Company were issued upon exercise of stock options for cash of approximately \$. See Note 12, *Stock-Based Compensation*, for a discussion of the Lucid Diagnostics Inc. 2018 Equity Plan.

#### Committed Equity Facility - March 28, 2022

Subsequent to December 31, 2021, on March 28, 2022, Lucid Diagnostics, Inc. entered into a committed equity facility with an affiliate of Cantor Fitzgerald ("Cantor"). Under the terms of the committed equity facility, Cantor has committed to purchase up to \$50 million of Lucid Diagnostics Inc. common stock from time to time at the request of 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.

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

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## Note 14 — Income Taxes

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

	Year Ended December 31,	
	2021	2020
Current		
Federal, State and Local	\$ —	\$ —
Deferred		
Federal	(4,862)	(1,447)
State and Local	(4,833)	(1,389)
	(9,695)	(2,836)
Less: Valuation allowance reserve	9,695	2,836
	\$ —	\$ —

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

	Year Ended December 31,	
	2021	2020
U.S. federal statutory rate	21.0%	21.0%
U.S. state and local income taxes, net of federal benefit	13.6%	13.6%
Permanent differences	—%	—%
Valuation allowance	(34.6)%	(34.6)%
Effective tax rate	—%	—%

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

Deferred Tax Assets	Year Ended December 31,	
	2021	2020

Net operating loss	\$	11,023	\$	4,687
Stock-based compensation expense		3,422		101
Accrued expenses		56		—
Research and development tax credit carryforwards		—		15
Deferred tax assets	\$	14,501	\$	4,803
<b>Deferred Tax Liabilities</b>				
Depreciation		(3)		—
Deferred Tax Liabilities	\$	(3)	\$	—
Deferred tax assets, net of deferred tax liabilities		14,498		4,803
Less: valuation allowance		(14,498)		(4,803)
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.

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#### Note 14 — Income Taxes - continued

As required by FASB ASC Topic 740, Income Taxes, (“ASC 740”), a “more-likely-than-not” criterion is applied when assessing the estimated realization of deferred tax assets through their utilization to reduce future taxable income, or with respect to a deferred tax asset for tax credit carryforward, to reduce future tax expense. A valuation allowance is established, when necessary, to reduce deferred tax assets, net of deferred tax liabilities, when the assessment indicates it is more-likely-than-not, the full or partial amount of the net deferred tax asset will not be realized. Accordingly, the Company evaluated the positive and negative evidence bearing upon the estimated realizability of the net deferred tax assets, and based on the Company’s history of operating losses, concluded it is more-likely-than-not the deferred tax assets will not be realized, and therefore recognized a valuation allowance reserve equal to the full amount of the deferred tax assets, net of deferred tax liabilities, as of December 31, 2021 and 2020.

Lucid Diagnostics Inc. has federal and state net operating loss (“NOL”) carryforwards, available to reduce future taxable income, if any, as of December 31, 2021 and 2020, as follows: federal NOL carryforward of approximately \$31.9 million and \$13.5 million, respectively, with such federal NOL carryforward not having a statutory expiration date; and state NOL carryforward of approximately \$31.9 million and \$13.5 million, respectively, with such state NOL carryforward having statutory expiration dates commencing in 2036. The Company has not yet conducted a formal analysis and the NOL carryforward may be subject to limitation under U.S. Internal Revenue Code (“IRC”) Section 382 (provided there was a greater than 50% ownership change, as computed under such IRC Section 382). The Company did not have research and development (“R&D”) tax credit carryforward as of December 31, 2021.

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

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

As discussed herein, on October 14, 2021, Lucid Diagnostics Inc. 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 Inc. is included in the PAVmed Inc and Subsidiaries consolidated income tax returns through October 13, 2021, and effective October 14, 2021, Lucid Diagnostics Inc. will file its income tax returns on a stand-alone legal entity basis. The Lucid Diagnostics Inc. 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 Inc. is computed as if its income tax returns were filed by Lucid Diagnostics Inc. on a stand-alone legal entity basis. Notwithstanding the absence of a formal tax sharing agreement between PAVmed Inc. and Lucid Diagnostics Inc., the Lucid Diagnostics Inc. stand-alone legal entity current tax expense and /or tax refund, if any, would be settled with PAVmed Inc. (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 Inc. stand-alone legal entity assumed filing of separate income tax returns.

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.

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#### Note 15 — Net Loss Per Share

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

	Year Ended December 31,	
	2021	2020
<b>Numerator</b>		
Net loss	\$ (28,078)	\$ (8,280)
<b>Denominator</b>		
Weighted average common shares outstanding, basic and diluted	18,603,619	14,114,437
<b>Loss per share</b>		
Net loss per share - basic and diluted	\$ (1.51)	\$ (0.59)

Basic weighted-average number of shares of common stock outstanding for the years ended December 31, 2021 and 2020 include the shares of the Company issued and outstanding during such periods, each on a weighted average basis. The basic weighted average number of shares common stock outstanding excludes common stock equivalent incremental shares, while diluted weighted average number of shares outstanding includes such incremental shares. However, as the Company was in a loss position for all periods presented, basic and diluted weighted average shares outstanding are the same, as the inclusion of the incremental shares would be anti-dilutive. The common stock equivalents excluded from the computation of diluted weighted average shares outstanding are as follows:

	Year Ended December 31,	
	2021	2020
Lucid Diagnostics Inc. 2018 Equity Plan:		
Stock options	995,942	975,942
Unvested restricted stock awards ("RSAs")	1,890,740	—
Stock options and unvested RSAs not granted under a plan	473,300	423,300
Total	<u>3,359,982</u>	<u>1,399,242</u>

**Note 15 - Subsequent Events**

*CapNostics, LLC*

On October 5, 2021, PAVmed Subsidiary Corporation, a wholly-owned subsidiary of PAVmed Inc., acquired all of the outstanding common stock of CapNostics, LLC ("CapNostics") for total (gross) purchase consideration of approximately \$2.1 million of cash, paid at the closing of the transaction. In March 2022, both the PAVmed and Lucid board of directors approved entering into a purchase and sale of the CapNostics, LLC assets from PAVmed to Lucid as well as transferring the consulting agreement with the previous principal owner of CapNostics, LLC. The transfer price is \$2.1 million for the assets.

*EsoCure*

EsoCure has been in development as an Esophageal Ablation Device by PAVmed, with the intent to allow a clinician to treat dysplastic BE before it can progress to EAC, a highly lethal esophageal cancer, and to do so without the need for complex and expensive capital equipment. In March 2022, both the PAVmed and Lucid board of directors have approved entering into an intercompany license between PAVmed and Lucid such that Lucid will be granted the rights to commercialize EsoCure for the treating dysplastic Barrett's Esophagus, including a royalty arrangement whereby Lucid will pay PAVmed a 5% royalty on all EsoCure sales up to \$100 million per calendar year, and 8% above that threshold. Lucid will be obligated to fund ongoing development costs and cumulative patent expenses. EsoCure will become part of an integrated suite of Lucid products addressing BE-EAC.

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

As of December 31, 2021, Lucid Diagnostics Inc. ("Lucid," the "Company" or "we," "us" or "our") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): common stock, \$0.001 par value per share. The common stock is listed on The Nasdaq Stock Market LLC.

In the discussion that follows, we have summarized selected provisions of our certificate of incorporation, bylaws and the Delaware General Corporation Law (the "DGCL") relating to our common stock. This summary is not complete. This summary is subject to the relevant provisions of the DGCL and is qualified in its entirety by reference to our amended and restated certificate of incorporation and our bylaws. Please read the provisions of our amended and restated certificate of incorporation and our bylaws as currently in effect for provisions that may be important to you.

**General**

The Company is authorized to issue 100,000,000 shares of common stock, par value \$.001, and 20,000,000 shares of preferred stock, par value \$.001. As of December 31, 2021, 34,917,907 shares of common stock are outstanding (inclusive of 1,940,740 shares underlying unvested restricted stock awards granted under the Lucid Diagnostics Inc. 2018 Long-Term Incentive Equity Plan as of such date), and no shares of our preferred stock are outstanding.

**Preferred Stock**

Our board of directors has the authority, without further action by our stockholders, to issue shares of preferred stock in one or more series and to fix the rights, preferences, privileges, and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, and sinking fund terms, any or all of which may be greater than the rights of common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Although we do not currently intend to issue any shares of preferred stock, we cannot assure you that we will not do so in the future.

**Common Stock**

Holders of our common stock are entitled to one vote for each share held of record on all matters to be voted on by stockholders. There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors. Subject to any preferential dividend rights of any outstanding shares of preferred stock, holders of common stock are entitled to receive dividends, if declared by our board of directors, out of funds that we may legally use to pay dividends. If we liquidate or dissolve, holders of common stock are entitled to share ratably in our assets once our debts and any liquidation preference owed to any then-outstanding preferred stockholders are paid. Our common stockholders have no conversion, preemptive or other subscription rights, and no liquidation preference, and there are no sinking fund or redemption provisions applicable to the common stock. All shares of common stock that are outstanding are fully-paid and non-assessable.

As of December 31, 2021, 1,419,242 shares of our common stock are issuable upon the exercise of outstanding stock options, including 995,942 shares issuable upon the exercise of stock options granted under our equity incentive plans, and 1,890,740 shares are reserved for issuance, but not subject to outstanding options or restricted stock awards, under our incentive equity plans. Furthermore, (i) in February 2022, we entered into an asset purchase agreement with ResearchDx, Inc. ("RDx"), pursuant which we acquired certain licenses and other related assets necessary to operate a CLIA-certified, CAP-accredited clinical laboratory, with \$3,000,000 of the purchase price payable in installments in cash or, at our election, in shares of our common stock valued at a price based on the current market price; and (ii) in March 2022, we entered into a committed equity facility with an affiliate of Cantor Fitzgerald ("Cantor"), pursuant to which Cantor has committed to purchase up to \$50 million in shares of our common stock from time to time at our request, at prices based on the current market price.

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(Exhibit 4.1)

Exhibit 4.1  
(continued)

**Dividends**

We have not paid any cash dividends on our shares of common stock to date. The payment of cash dividends 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 in the foreseeable future.

**Anti-Takeover Provisions**

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated by-laws contain provisions that could make it more difficult to acquire us by means of a tender offer or a proxy contest or otherwise, or to remove our incumbent officers and directors.

These provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated by-laws could have the effect of preventing changes in the composition of our board of directors and management. These provisions may also have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

*Delaware Anti-Takeover Statute*

We are subject to Section 203 of the DGCL, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who,

together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the Board of Directors. A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or by-laws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

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(Exhibit 4.1)

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Exhibit 4.1  
(continued)

#### *Undesignated Preferred Stock*

The ability of our board of directors, without action by the stockholders, to issue undesignated shares of preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

#### *Authorized Common Stock*

Our authorized but unissued shares of common stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital and corporate acquisitions. The existence of authorized but unissued shares of common stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

#### *Classified Board of Directors*

Our board of directors is divided into three classes. The number of directors in each class will be as nearly equal as possible. Directors elected to succeed those directors whose terms expire shall be elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election. The existence of a classified board may extend the time required to make any change in control of the board of directors when compared to a corporation with an unclassified board. It may take two annual meetings for our stockholders to effect a change in control of the board of directors, because in general less than a majority of the members of the board of directors will be elected at a given annual meeting. Because our board of directors is classified and our certificate of incorporation does not otherwise provide, under Delaware law, our directors may only be removed for cause.

#### *Vacancies on the Board*

Our amended and restated certificate of incorporation and our amended and restated by-laws provide that any vacancy occurring on the board of directors, including by reason of removal of a director, and any newly created directorship may be filled only by a majority of the remaining directors in office. This system of appointing directors may discourage a third party from making a tender offer or otherwise attempting to obtain control of our company, because it generally makes it more difficult for stockholders to replace a majority of the directors.

#### *Advance Notice Requirements for Stockholder Proposals and Director Nominations*

Our amended and restated by-laws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at any meeting of stockholders. Our amended and restated by-laws also will specify certain requirements regarding the form and content of a stockholder's notice. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our meetings of stockholders.

#### *No Cumulative Voting; Special Meeting of Stockholders*

Stockholders will not be permitted to cumulate their votes for the election of directors. Furthermore, special meetings of our stockholders may be called only by Chief Executive Officer, our President, our board of directors, or a majority of our stockholders.

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Exhibit 4.1  
(continued)

#### *Exclusive Forum Selection*

Our amended and restated certificate of incorporation requires, 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 provides 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.

Although we believe this provision benefits our company by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, a

court may determine that this provision is unenforceable, and to the extent it is enforceable, the provision may have the effect of discouraging lawsuits against our directors and officers and increasing the cost to stockholders of bringing such lawsuits.

**Listing of our Common Stock**

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol "LUCD."

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company located at 1 State Street, 30th Floor, New York, NY 10004.

**LUCID DIAGNOSTICS INC.**  
**CODE OF ETHICS**  
**(As Adopted as of October 14, 2021)**

**1. Introduction**

The Board of Directors (the “**Board**”) of Lucid Diagnostics Inc. (the “**Company**”) has adopted this code of ethics (this “**Code**”), which is applicable to all directors, officers, and employees (each a “**person**,” as used herein) of the Company, with the intent to:

- promote honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- promote the full, fair, accurate, timely, and understandable disclosure in reports and documents that the Company files with, or submits to, the Securities and Exchange Commission (the “**SEC**”), as well as in other public communications made by or on behalf of the Company;
- promote compliance with applicable governmental laws, rules, and regulations;
- deter wrongdoing; and
- require prompt internal reporting of breaches of, and accountability for adherence to, this Code.

This Code also is designed to ensure an appropriate and timely response to detected violations, establish appropriate disciplinary mechanisms and create procedures to prevent further offenses, including modification of this Code, when necessary.

This Code codifies the personal and professional ethical and legal standards of conduct required of Company employees, officers and directors, the procedures by which complaints of violations of those standards will be investigated and the disciplinary actions which may be taken to enforce this Code. **This Code is intended to supplement, but not to replace, our Employee Handbook and any other policies that we have established.**

This Code shall constitute the Company’s written “code of ethics” under Section 406 of the Sarbanes-Oxley Act of 2002, as amended, in compliance with the standards set forth in Item 406 of Regulation S-K promulgated by the SEC. This Code also shall be a “program that has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal conduct” as designated by the Federal Sentencing Guidelines for Organizations.

This Code may be amended only by resolution of the Board. In this Code, references to the “**Company**” include, in appropriate context, its subsidiaries.

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(Exhibit 14.1)

**Exhibit 14.1**  
(continue)

**2. Honest, Ethical and Fair Conduct**

Each person owes a duty to the Company to act with integrity. Integrity requires, among other things, being honest, fair, and candid. Deceit, dishonesty, and subordination of the Company’s interests to personal interests are inconsistent with integrity. Service to the Company should never be subordinated to personal gain or advantage.

Each person must:

- Act with integrity, including being honest and candid while still maintaining the confidentiality of the Company’s information where required or in the Company’s interests.
- Observe all applicable governmental laws, rules, and regulations within the United States and other jurisdictions in which the Company operates.
- Comply with the requirements of applicable accounting and auditing standards, as well as Company policies, in order to maintain a high standard of accuracy and completeness in the Company’s financial records and other business-related information and data.
- Adhere to a high standard of business ethics and not seek competitive advantage through unlawful or unethical business practices.
- Deal fairly with the Company’s customers, suppliers, competitors, and employees.
- Refrain from taking advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts, or any other unfair-dealing practice.

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(Exhibit 14.1)

**Exhibit 14.1**  
(continue)

- Maintain the confidentiality of information entrusted to them by the Company or by its customers, suppliers, or partners, except when disclosure is expressly authorized or is required or permitted by law. Confidential information includes all nonpublic information (regardless of its source) that might be of use to the Company’s competitors or harmful to the Company or its customers, suppliers or partners if disclosed.
- that are discovered through the use of corporate assets, (ii) using corporate assets, information, or position for personal gain, and (iii) competing with the Company.

- Board (or the appropriate committee of the Board). Anything that would be a conflict for a person subject to this Code also will be a conflict if it is related to a member of his or her family or a close relative. Examples of conflict of interest situations include, but are not limited to, the following:
  - any significant ownership interest in any supplier or customer;
  - any consulting or employment relationship with any customer, supplier, or competitor;
  - any outside business activity that detracts from a person's ability to devote appropriate time and attention to his or her responsibilities with the Company;
  - receipt or provision, directly or indirectly, of any payment, gift of more than nominal value, meal, entertainment or any form of preferential treatment from any vendor, customer, partner or competitor of the Company or any other individual or entity with which the Company has current or prospective business dealings. For example, no payments, direct or indirect, including gifts of more than nominal value, or any form of preferential treatment, may be solicited or accepted to obtain or retain the Company's business or to realize a certain price for the Company's products. Any such payments, gifts, meals, entertainment or other preferential treatment which would imply or incur an obligation must not be accepted or provided by any person, or any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law, significant other of any such person, or any person (other than a tenant or employee) sharing such person's household ("immediate family member"), in connection with transactions involving the Company. For example, acceptance of any such payment, gift, meal, entertainment or preferential treatment by an immediate family member of a person from one of the Company's suppliers could create a conflict of interest and result in a violation of this Code by such person. Notwithstanding the foregoing, to the extent consistent with other Company policies, inexpensive gifts and meals and entertainment that are not excessive and do not create an appearance of impropriety may be accepted in the normal course of business relations and, to the extent practical, may be reciprocated. Questions regarding whether a particular payment, gift, meal, entertainment or preferential treatment violates this policy are to be directed to the Chief Financial Officer;
  - being in the position of supervising, reviewing, or having any influence on the job evaluation, pay, or benefit of any immediate family member;
  - selling anything to the Company or buying anything from the Company, except on the same terms and conditions as comparable officers or directors are permitted to so purchase or sell;
  - any other financial transaction, arrangement, or relationship (including any indebtedness or guarantee of indebtedness) involving the Company; and
  - any other circumstance, event, relationship, or situation in which the personal interest of a person subject to this Code interferes – or even appears to interfere – with the interests of the Company as a whole.

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(Exhibit 14.1)

**Exhibit 14.1**  
(continue)

### 3. Disclosure

The Company strives to ensure that the contents of and the disclosures in the reports and documents that the Company files with the SEC and other public communications shall be full, fair, accurate, timely, and understandable in accordance with applicable disclosure standards, including standards of materiality, where appropriate. Each person must:

- not knowingly misrepresent, or cause others to misrepresent, facts about the Company to others, whether within or outside the Company, including to the Company's independent auditors, governmental regulators, self-regulating organizations, and other governmental officials, as appropriate; and
- in relation to his or her area of responsibility, properly review and critically analyze proposed disclosure for accuracy and completeness.

In addition to the foregoing, the Chief Executive Officer and Chief Financial Officer of the Company and each subsidiary of the Company (or persons performing similar functions), and each other person that typically is involved in the financial reporting of the Company must familiarize himself or herself with the disclosure requirements applicable to the Company as well as the business and financial operations of the Company.

Each person must promptly bring to the attention of the chairperson of the audit committee of the Board (the "Audit Committee"), or the chairperson of the Board if no Audit Committee exists, any information he or she may have concerning (a) significant deficiencies in the design or operation of internal and/or disclosure controls which could adversely affect the Company's ability to record, process, summarize, and report financial data or (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's financial reporting, disclosures, or internal controls.

### 4. Compliance

It is the Company's obligation and policy to comply with the letter and spirit of all applicable governmental laws, rules, and regulations. It is the personal responsibility of each person to, and each person must, adhere to the standards and restrictions imposed by those laws, rules, and regulations, including those relating to accounting and auditing matters.

### 5. Reporting and Accountability

The Audit Committee is responsible for applying this Code to specific situations in which questions are presented to it and has the authority to interpret this Code in any particular situation. Any person who becomes aware of any existing or potential breach of this Code is required to notify the chairperson of the Board or Audit Committee promptly. Failure to do so is itself a breach of this Code.

Specifically, each person must:

- Notify the chairperson promptly of any existing or potential violation of this Code.
- Not retaliate against any other person for reports of potential violations that are made in good faith.

The Company will follow the following procedures in investigating and enforcing this Code and in reporting on this Code:

- The Audit Committee will promptly take all appropriate action to diligently and expeditiously investigate any breaches reported to it.
- If the Audit Committee determines by majority decision that a breach has occurred, it will inform the Board.

- Upon being notified that a breach has occurred, the Board by majority decision will take or authorize such disciplinary or preventive action as it deems appropriate, after consultation with the Audit Committee and/or the Company's counsel, up to and including dismissal or, in the event of criminal or other serious violations of law, notification of the SEC or other appropriate law enforcement authorities.

No person following the above procedure shall, as a result of following such procedure, be subject by the Company or any officer or employee thereof to discharge, demotion, suspension, threat, harassment, or, in any manner, discrimination against such person in terms and conditions of employment.

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(Exhibit 14.1)

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**Exhibit 14.1**  
(continue)

## 6. Waivers and Amendments

Any waiver (defined below) or implicit waiver (defined below) from a provision of this Code for the principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions and any amendment (as defined below) to this Code is required to be disclosed in the Company's Annual Report on Form 10-K or in a Current Report on Form 8-K filed with the SEC or, as and to the extent required or permitted by SEC regulations, on the Company's website.

A "waiver" means the approval by the Board of a material departure from a provision of this Code. An "implicit waiver" means the Company's failure to take action within a reasonable period of time regarding a material departure from a provision of this Code that has been made known to an executive officer of the Company. An "amendment" means any amendment to this Code other than minor technical, administrative, or other non-substantive amendments hereto.

All persons should note that it is not the Company's intention to grant or to permit waivers from the requirements of this Code. The Company expects full compliance with this Code.

## 7. Financial Statements and Other Records

All of the Company's books, records, accounts and financial statements must be maintained in reasonable detail, must appropriately reflect the Company's transactions and must both conform to applicable legal requirements and to the Company's system of internal controls. Unrecorded or "off the books" funds or assets of the Company should not be maintained unless permitted by applicable law or regulation and shall be disclosed to the extent required by applicable law or regulation. Company records should always be retained or destroyed according to the Company's record retention policies. In accordance with those policies, in the event of litigation or governmental investigation, please consult the Board or the Company's internal or external legal counsel.

## 8. Improper Influence on Conduct of Audits

No director, officer, or employee, or any other person acting under the direction thereof, shall directly or indirectly take any action to coerce, manipulate, mislead or fraudulently influence the public or certified public accountant engaged in the performance of an audit or review of the financial statements of the Company or take any action that such person knows or should know that if successful could result in rendering the Company's financial statements materially misleading. Any person who believes such improper influence is being exerted should report such action to such person's supervisor, or if that is impractical under the circumstances, to any of our directors.

Types of conduct that could constitute improper influence include, but are not limited to, directly or indirectly:

- offering or paying bribes or other financial incentives, including future employment or contracts for non-audit services;
- providing an auditor with an inaccurate or misleading legal analysis;
- threatening to cancel or canceling existing non-audit or audit engagements if the auditor objects to the Company's accounting;
- seeking to have a partner removed from the audit engagement because the partner objects to the Company's accounting;
- blackmailing; and
- making physical threats.

Page 5 of 6  
(Exhibit 14.1)

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**Exhibit 14.1**  
(continue)

## 9. Anti-Corruption Laws

The Company complies with the anti-corruption laws of the countries in which it does business, including the U.S. Foreign Corrupt Practices Act. To the extent prohibited by applicable law, directors, officers, and employees will not directly or indirectly give anything of value to government officials, including employees of state-owned enterprises or foreign political candidates. These requirements apply both to Company employees and agents, such as third-party sales representatives, no matter where they are doing business. If you are authorized to engage agents, you are responsible for ensuring they are reputable and for obtaining a written agreement to uphold the Company's standards in this area.

## 10. Violations

All persons will be held accountable for adherence to this Code. Persons who violate the policies set forth in this Code will be subject to discipline. Disciplinary measures will vary, depending on the seriousness of the violation and the individual circumstances involved. Available disciplinary sanctions include suspension, termination, and referral to public law enforcement authorities for possible prosecution.

## 11. Other Policies and Procedures

Any other policy or procedure set out by the Company in writing or made generally known to employees, officers, or directors of the Company prior to the date hereof or hereafter are separate requirements and remain in full force and effect.

## 12. Inquiries

All inquiries and questions in relation to this Code or its applicability to particular people or situations should be addressed to the Company's Chief Financial Officer.

Page 6 of 6  
(Exhibit 14.1)

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**List of Subsidiaries of the Registrant**  
(Lucid Diagnostics Inc. DE - 82-5488042)

Subsidiary Legal Entity Name	State of Incorporation
LucidDx Labs Inc. (87-41661458) <i>- Wholly-Owned Subsidiary of Lucid Diagnostics Inc.</i>	Delaware Incorporated November 21, 2021

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Lucid Diagnostics Inc. on Forms S-8 [File No. 333-263566, File No. 333-261807] of our report dated April 5, 2022, with respect to our audits of the consolidated financial statements of Lucid Diagnostics Inc. as of December 31, 2021 and 2020, and for each of the two years in the period ended December 31, 2021, which report is included in this Annual Report on Form 10-K of Lucid Diagnostics Inc. for the year ended December 31, 2021.

/s/ Marcum llp

Marcum llp  
New York, NY  
April 5, 2022

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## CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER

I, Lishan Aklog, M.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Lucid Diagnostics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 5, 2022

By: /s/ Lishan Aklog, M.D.  
Lishan Aklog, M.D., Chief Executive Officer  
(Principal Executive Officer)

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## CERTIFICATION BY PRINCIPAL FINANCIAL OFFICER

I, Dennis M. McGrath, certify that:

1. I have reviewed this Annual Report on Form 10-K of Lucid Diagnostics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 5, 2022

By: /s/ Dennis M. McGrath

Dennis M. McGrath  
President & Chief Financial Officer  
(Principal Financial and Accounting Officer)

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**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Lucid Diagnostics Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lishan Aklog, M.D., Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 5, 2022

By: /s/ Lishan Aklog, M.D.  
Lishan Aklog, M.D.  
Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Lucid Diagnostics Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Dennis M. McGrath, President & Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 5, 2022

By: /s/ Dennis M. McGrath

Dennis M. McGrath  
President & Chief Financial Officer  
*(Principal Financial and Accounting Officer)*

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