

May 11, 2022



# Lucid Diagnostics Provides Business Update and Preliminary First Quarter 2022 Financial Results

*Conference call to be held today at 4:30 PM EDT*

NEW YORK--(BUSINESS WIRE)-- [Lucid Diagnostics Inc.](#) (Nasdaq: LUCD) (“Lucid”, the “Company”), a commercial-stage, cancer prevention medical diagnostics company, and majority-owned subsidiary of [PAVmed Inc.](#) (Nasdaq: PAVM, PAVMZ) (“PAVmed”), today provided a business update for the Company and presented preliminary financial results for the three months ended March 31, 2022.

## Conference Call and Webcast

A conference call and webcast for today’s business update and first quarter 2022 financial results will take place at 4:30 PM EDT. To access the conference call, listeners should dial 877-407-0789 toll-free in the U.S., and international listeners should dial 201-689-8562 and ask to join the “Lucid Diagnostics Business Update Conference Call”. The conference call will be available live via a webcast and for replay at the investor relations section of the Company’s website at <https://ir.luciddx.com>. Following the conclusion of the conference call, a replay will be available for one week and can be accessed by dialing 844-512-2921 toll-free in the U.S. or 412-317-6671, followed by the PIN number: 13729511.

## Business Update Highlights

“I am delighted to report that Lucid Diagnostics is making excellent progress on all fronts and that we continue to lay a solid foundation for our long-term growth strategy,” said [Lishan Aklog, M.D.](#), Lucid’s Chairman and Chief Executive Officer. “Our team continues to drive EsoGuard<sup>®</sup> commercialization, expand our sales infrastructure, execute the second stage of our Lucid Test Center rollout, transition to our own fully staffed laboratory, and work tirelessly to secure EsoGuard reimbursement. Our balance sheet remains strong, providing us with the necessary resources to execute this strategy.”

Highlights from the first quarter and recent weeks include:

- On April 4<sup>th</sup>, the [American College of Gastroenterology](#) (“ACG”) updated its [clinical guideline](#) for the diagnosis and management of esophageal precancer, endorsing, for the first time, nonendoscopic biomarker screening as an acceptable alternative to costly and invasive endoscopy to detect precancer and prevent highly lethal esophageal cancer. The updated guideline supports esophageal precancer screening utilizing Lucid’s EsoGuard<sup>®</sup> DNA Test on samples collected with its EsoCheck<sup>®</sup> Cell Collection Device, the only such nonendoscopic biomarker screening test available.

- Lucid processed 533 commercial EsoGuard tests in the first quarter of 2022, which represents a 76% increase sequentially from the fourth quarter of 2021 and a nearly 500% increase annually from the first quarter of 2021. The Company continued to expand its sales infrastructure consistent with its year-end goals.
- Lucid completed its first stage of its Lucid Test Center program covering metropolitan areas in seven states. The Company subsequently launched the second stage of the program and plans to open test centers in nine additional states this year. The Company hired an experienced Director of Clinical Services to oversee the expansion.
- LucidDx Labs Inc. (“LucidDx Labs”), a wholly owned subsidiary of Lucid, acquired the assets necessary to operate its own CLIA-certified, CAP-accredited clinical laboratory effective February 25, 2022. The Company hired an experienced VP of Laboratory Operations who will oversee an accelerated transition from the current management service agreement to the lab being fully staffed by Lucid employees. It also upgraded its revenue cycle management provider which for the first time will begin billing and processing claims directly on behalf of Lucid.
- LucidDx Labs entered into Lucid’s first commercial payer agreement—a participating provider agreement with MediNcrease Health Plans, LLC, a national, directly-contracted, multi-specialty PPO provider network with over 8 million lives covered through its clients and payers. The agreement provides for reimbursement rates at a percent of charges for services rendered, including the performance of the EsoGuard test.
- Medicare Administrative Contractor Palmetto GBA’s MoIDX Program published a proposed foundational Local Coverage Determination (“LCD”) for tests designed to detect upper gastrointestinal precancer and cancer, an important step in Lucid’s efforts to secure Medicare coverage for EsoGuard. As part of the public review process which extends to May 14, 2022, Lucid, along with multiple other stakeholders, will be submitting comments suggesting important modifications to the proposed LCD. The Company, along with other stakeholders, also participated in a substantive Open Meeting held by the MoIDX Program on May 10, 2022.

## **Preliminary Financial Results**

- For the three months ended March 31, 2022, EsoGuard related revenues were \$0.2 million. Operating expenses were approximately \$11.9 million, which include stock-based compensation expenses of \$3.8 million. GAAP net loss attributable to common stockholders was approximately \$12.3 million, or \$(0.35) per common share.
- As shown below and for the purpose of illustrating the effect of stock-based compensation and other non-cash expenses on the Company’s financial results, the Company’s preliminary non-GAAP adjusted loss for the three months ended March 31, 2022, was approximately \$8.2 million or \$(0.23) per common share.
- Lucid had cash and cash equivalents of \$47.9 million as of March 31, 2022, compared to \$53.7 as of December 31, 2021.
- On March 28, 2022, the Company entered into a Common Stock Purchase Agreement (the “Purchase Agreement”) with CF Principal Investments LLC (“Cantor”), an affiliate of Cantor Fitzgerald, relating to a committed equity facility (the “Facility”). Pursuant to the Purchase Agreement, the Company has the right to sell to Cantor up to \$50.0 million of its common shares (the “Shares”), subject to certain conditions and limitations set forth in the Purchase Agreement. 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 a price related to the current market price.

- Sales of the Shares to Cantor under the Purchase Agreement and the timing of any sales, will be determined by the Company from time to time at its sole discretion and will depend on a variety of factors, including, among other things, market conditions, the trading price of the Shares, and determinations by the Company regarding the use of proceeds of such Shares. Upon the satisfaction of the conditions to Cantor's obligation to purchase Shares, the Company will have the right, from time to time during the 36-month period after the commencement of the Facility, to direct Cantor to purchase up to a maximum number of Shares on any trading day. The purchase price of the Shares will be 96% of the volume-weighted average price of the Shares on such trading day.
- The unaudited financial results for the three months ended March 31, 2022, are expected to be filed with the SEC on Form 10-Q on May 16, 2022 and will then be available at [www.luciddx.com](http://www.luciddx.com) or [www.sec.gov](http://www.sec.gov).

### Lucid Non-GAAP Measures

- To supplement our unaudited financial results presented in accordance with U.S. generally accepted accounting principles (GAAP), management provides certain non-GAAP financial measures of the Company's financial results. These non-GAAP financial measures include net loss before interest, taxes, depreciation, and amortization (EBITDA), and non-GAAP adjusted loss, which further adjusts EBITDA for stock-based compensation expense and other non-cash income and expenses, if any. The foregoing non-GAAP financial measures of EBITDA and non-GAAP adjusted loss are not recognized terms under U.S. GAAP.
- Non-GAAP financial measures are presented with the intent of providing greater transparency to the information used by us in our financial performance analysis and operational decision-making. We believe these non-GAAP financial measures provide meaningful information to assist investors, shareholders, and other readers of our unaudited financial statements in making comparisons to our historical financial results and analyzing the underlying performance of our results of operations. These non-GAAP financial measures are not intended to be, and should not be, a substitute for, considered superior to, considered separately from or as an alternative to, the most directly comparable GAAP financial measures.
- Non-GAAP financial measures are provided to enhance readers' overall understanding of our current financial results and to provide further information for comparative purposes. Management believes the non-GAAP financial measures provide useful information to management and investors by isolating certain expenses, gains, and losses that may not be indicative of our core operating results and business outlook. Specifically, the non-GAAP financial measures include non-GAAP adjusted loss, and its presentation is intended to help the reader understand the effect of the loss on the issuance or modification of convertible securities, the periodic change in fair value of convertible securities, the loss on debt extinguishment, and the corresponding accounting for non-cash charges on financial performance. In addition, management believes non-GAAP financial measures enhance the comparability of results against prior periods.
- A reconciliation to the most directly comparable GAAP measure of all non-GAAP financial measures included in this press release for the three months ended March

31, 2022, and 2021 is as follows:

|  | For the three months ended<br>March 31, |           |
|--|---|-----------|
|  | 2022                                    | 2021      |
| <b>Revenue</b>   | \$ 189                                  | \$ -      |
| <b>Gross profit</b>  | (180)                                   | -         |
| <b>Operating expenses</b>                                    | 11,917                                  | 3,653     |
| <b>Other expense</b>   | 173                                     | -         |
| <b>Net loss</b>  | (12,270)                                | (3,653)   |
| <b>Net income (loss) per common share, basic and diluted</b> | \$ (0.35)                               | \$ (0.26) |
| Adjustments:   |   |           |
| Depreciation and amortization expense <sup>1</sup>           | 24                                      | 3         |
| Interest expense, net <sup>3</sup>                           | -                                       | -         |
| <b>EBITDA</b>  | (12,246)                                | (3,650)   |
| <b>Other non-cash or financing related expenses:</b>         |   |           |
| Stock-based compensation expense <sup>3</sup>                | 3,835                                   | 805       |
| Fair value adjustments <sup>2</sup>                          | 173                                     | -         |
| <b>Non-GAAP adjusted (loss)</b>                              | (8,238)                                 | (2,845)   |
| Basic and Diluted shares outstanding                         | 35,123                                  | 14,114    |
| Non-GAAP adjusted (loss) income per share                    | (\$0.23)                                | (\$0.20)  |

<sup>1</sup>Included in general and administrative expenses in the financial statements

<sup>2</sup>Included in other income and expenses

|   | For the three months ended<br>March 31, |       |
|---|---|-------|
|   | 2022                                    | 2021  |
| <b><sup>3</sup>Stock-based compensation ("SBC") expenses:</b> |   |       |
| <b>Sales and Marketing expense total</b>                      | 3,318                                   | 689   |
| Stock-based compensation expense                              | (440)                                   | -     |
| Net commercial operations expense excluding SBC               | 2,878                                   | 689   |
| <b>General and administrative expense total</b>               | 5,718                                   | 1,212 |
| Stock-based compensation expense                              | (3,269)                                 | (789) |
| Net general and administrative expense excluding SBC          | 2,449                                   | 423   |
| <b>Research and development expense total</b>                 | 2,881                                   | 1,752 |
| Stock-based compensation expense                              | (126)                                   | (16)  |
| Net research and development expense excluding SBC            | 2,755                                   | 1,736 |

|                                      |              |              |
|--------------------------------------|--------------|--------------|
| <b>Total operating expenses</b>      | 11,917       | 3,653        |
| Stock-based compensation expense     | (3,835)      | (805)        |
| Net operating expenses excluding SBC | <u>8,082</u> | <u>2,848</u> |

## About EsoGuard<sup>®</sup> and EsoCheck<sup>®</sup>

Millions of patients with GERD are at risk of developing esophageal precancer and a highly lethal form of esophageal cancer (“EAC”). Over 80% of EAC patients die within five years of diagnosis, making it the second most lethal cancer in the U.S. The mortality rate is high even in those diagnosed with early stage EAC. 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. All EAC is believed to arise from esophageal precancer, which occurs in approximately 5% to 15% of at-risk GERD patients. Early esophageal precancer can be monitored for progression to late esophageal precancer which can be cured with endoscopic esophageal ablation, reliably halting progression to cancer.

Esophageal precancer screening is already recommended by clinical practice guidelines in millions of GERD patients with multiple risk factors, including age over 50 years, male gender, White race, obesity, smoking history, and a family history of esophageal precancer or cancer. Unfortunately, fewer than 10% of those recommended for screening undergo traditional invasive endoscopic screening. 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 treatment.

The only missing element for a viable esophageal cancer prevention program has been the lack of a widespread screening tool that can detect esophageal precancer. Lucid believes EsoGuard<sup>®</sup>, performed on samples collected with EsoCheck<sup>®</sup>, is the missing element—the first and only commercially available test capable of serving as a widespread screening tool to prevent esophageal cancer deaths through the early detection of esophageal precancer in at-risk GERD patients. A recently updated American College of Gastroenterology clinical practice [guideline](#) endorses nonendoscopic biomarker tests as an acceptable alternative to costly and invasive endoscopy for esophageal precancer screening. EsoGuard is the only such test currently available in the United States.

EsoGuard is a bisulfite-converted NGS DNA assay performed on surface esophageal cells collected with EsoCheck which 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 cancer.

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

Collect+Protect™ technology makes EsoCheck the only noninvasive esophageal cell collection device capable of such anatomically targeted and protected sampling. The sample is sent by overnight express mail to Lucid's CLIA-certified, CAP-accredited laboratory, LucidDx Labs, for EsoGuard testing.

## **About Lucid Diagnostics**

Lucid Diagnostics Inc. (Nasdaq: LUCD) is a commercial-stage, cancer prevention medical diagnostics company, and subsidiary of PAVmed Inc. (Nasdaq: PAVM). Lucid is focused on the millions of patients with gastroesophageal disease (GERD), also known as chronic heartburn, who are at risk of developing esophageal precancer and cancer. Lucid's EsoGuard® Esophageal DNA Test, performed on samples collected in a brief, noninvasive office procedure with its EsoCheck® Esophageal Cell Collection Device, is the first and only commercially available diagnostic test capable of serving as a widespread screening tool to prevent cancer and cancer deaths through early detection of esophageal precancer in at-risk GERD patients. EsoGuard is commercialized in the U.S. as a Laboratory Developed Test (LDT). EsoCheck is commercialized in the U.S. as a 510(k)-cleared esophageal cell collection device. EsoGuard, used with EsoCheck, was granted FDA Breakthrough Device designation and is the subject of multiple ongoing clinical trials. Lucid is building a nationwide direct sales and marketing team targeting primary care physicians, specialists, and institutions, as well as a network of Lucid Test Centers where at-risk GERD patients can undergo the EsoCheck procedure for EsoGuard testing. For more information, please visit [www.luciddx.com](http://www.luciddx.com), follow Lucid on [Twitter](#), and connect with Lucid on [LinkedIn](#). For detailed information on EsoGuard, please visit [www.EsoGuard.com](http://www.EsoGuard.com) and follow us on [Twitter](#), [Facebook](#) and [Instagram](#).

## **Forward-Looking Statements**

This press release includes forward-looking statements. Forward-looking statements are any statements that are not historical facts. Such forward-looking statements, which are based upon the current beliefs and expectations of Lucid's management, are subject to risks and uncertainties, which could cause actual results to differ from the forward-looking statements. Risks and uncertainties that may cause such differences include, among other things, volatility in the price of Lucid's common stock; general economic and market conditions; the uncertainties inherent in research and development, including the cost and time required to advance Lucid's products to regulatory submission; whether regulatory authorities will be satisfied with the design of and results from Lucid's clinical and preclinical studies; whether and when Lucid's products are cleared by regulatory authorities; market acceptance of Lucid's products once cleared and commercialized; Lucid's ability to raise additional funding as needed; and other competitive developments. In addition, Lucid has been monitoring the COVID-19 pandemic and the pandemic's impact on Lucid's businesses. Lucid expects the significance of the COVID-19 pandemic, including the extent of its effect on its financial and operational results, to be dictated by, among other things, the success of efforts to contain the pandemic and the impact of such efforts on Lucid's businesses. These factors are difficult or impossible to predict accurately and many of them are beyond Lucid's control. In addition, new risks and uncertainties may arise from time to time and are difficult to predict. For a further list and description of these and other important risks and uncertainties that may affect Lucid's future operations, see Part I, Item 1A, "Risk Factors," in Lucid's most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission and

Lucid's Registration Statement No. 333-259721 filed with the Securities and Exchange Commission. Lucid disclaims any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in its expectations or in events, conditions, or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements.

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