

May 15, 2023



Lucid Diagnostics Provides Business Update and First Quarter Financial Results

EsoGuard[®] test volume increases 57 percent sequentially and 245 percent year-on-year

Conference call and webcast to be held tomorrow, May 16th at 8:30 AM EST

NEW YORK, May 15, 2023 /PRNewswire/ -- [Lucid Diagnostics Inc. \(Nasdaq: LUCD\)](#) ("Lucid" or 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 financial results for the three months ended March 31, 2023.



Conference Call and Webcast

The webcast will take place on Tuesday, May 16, 2023, at 8:30 AM and will be accessible in the investor relations section of the Company's website at luciddx.com. Alternatively, to access the conference call by telephone, U.S.-based callers should dial 877-870-4263 and international listeners should dial 412-317-0790. All listeners should provide the operator with the conference call name "Lucid Diagnostics Business Update" to join.

Business Update Highlights

"Lucid had a strong start in the first quarter of 2023, with robust sequential growth in EsoGuard testing volume," said [Lishan Aklog, M.D.](#), Lucid's Chairman and Chief Executive Officer. "We attribute this progress to our relentless focus on EsoGuard commercial expansion, including the growing popularity and utilization of our satellite Lucid Test Center (sLTC) program, a broad expansion of #CheckYourFoodTube Precancer Detection Events (#CYFT) and growing awareness of EsoGuard as a much-needed widespread screening tool that is highly effective in detecting esophageal precancer in a sizeable at-risk patient population."

Highlights from the first quarter and recent weeks:

- Lucid's CLIA-certified clinical laboratory performed 1,841 commercial EsoGuard[®] Esophageal DNA Tests in the 1Q23, which represents a 57 percent increase

sequentially from 4Q22 and a 245 percent annual increase from 1Q22.

- Satellite Lucid Test Center (sLTC) activity, whereby Lucid clinicians collect samples at physician offices or high-volume testing events, continues to increase rapidly, representing 51 percent of all samples collected in 1Q23, up from 31 percent in 4Q22.
- In January, Lucid launched its #CheckYourFoodTube Precancer Detection Event (#CYFT Event) program, bringing EsoGuard testing directly to at-risk patients at high-volume testing day events. Since the inaugural event, Lucid has held additional events across the country during the first quarter and recent weeks. These events have identified patients with suspected esophageal precancer based on a positive EsoGuard result, including some less than 40 years of age, who will undergo appropriate monitoring and treatment, as indicated by clinical practice guidelines, to prevent progression to esophageal cancer.
- Lucid and its collaborators presented compelling new data at the Digestive Disease Week[®] (DDW) 2023 conference. EsoGuard demonstrated excellent esophageal precancer and cancer detection performance, including in the most prevalent and challenging precancer subgroup—short segment non-dysplastic Barrett's Esophagus. In addition, EsoCheck cell collection achieved 98 percent technical success and high DNA yields in real-world study of 1,483 patients.
- In the first quarter and recent weeks, Medicare Administrative Contractors Palmetto GBA MolDX and Noridian Healthcare Solutions published foundational Future Effective Local Coverage Determinations ("LCD"), both titled "[*Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia*](#)".

Financial Results

- For the three months ended March 31, 2023, EsoGuard related revenues were \$0.4 million, compared to \$0.2 million as of March 31, 2022. Operating expenses were approximately \$14.8 million, including stock-based compensation expenses of \$3.2 million. GAAP net loss attributable to common stockholders was approximately \$16.2 million, or \$(0.40) per common share.
- As shown below and for the purpose of illustrating the effect of stock-based compensation and other non-cash income and expenses on the Company's financial results, the Company's preliminary non-GAAP adjusted loss for the three months ended March 31, 2023, was approximately \$9.8 million or \$(0.24) per common share.
- Lucid had cash and cash equivalents of \$39.5 million as of March 31, 2023, compared to \$22.5 million as of December 31, 2022.
- In March, the Company received \$13.6 million from the sale of non-voting Series A Convertible Preferred Stock, which may not be converted until September 2023 and not until March 2025 without surrendering the right to an annual dividend.
- Also in March, the Company entered into a securities purchase agreement for Series A Convertible Notes with an aggregated principal amount of \$11.1 million, which may not

be converted below the stated \$5.00 conversion price until September 2023. The proceeds of these offerings will extend the Company's cash runway into 2024, through near-term commercial milestones, including expanded reimbursement.

- The unaudited financial results for the three months ended March 31, 2023, were filed with the SEC on Form 10-Q on May 15, 2023, and are available at www.luciddx.com or 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, 2023, and 2022 are as follows:

For the three months ended
March 31,

<i>(in thousands except per-share amounts)</i>	<u>2023</u>	<u>2022</u>
Revenue	\$ 446	\$ 189
Operating expenses	14,763	12,460
Other (Income) expense	1,930	(1)
Net Loss	(16,247)	(12,270)
Net income (loss) per common share, basic and diluted	\$ (0.40)	\$ (0.35)
Adjustments:		
Depreciation and amortization expense ¹	612	24
Interest expense, net ²	(45)	(1)
EBITDA	(15,680)	(12,247)
Other non-cash or financing related expenses:		
Stock-based compensation expense ³	3,208	3,835
ResearchDx acquisition in stock ¹	713	—
Change in FV convertible debt ²	789	—
Offering costs convertible debt ²	1,186	—
Non-GAAP adjusted (loss)	(9,784)	(8,412)
Basic and Diluted shares outstanding	40,971	35,123
Non-GAAP adjusted (loss) income per share	\$(0.24)	\$(0.24)

¹ Included in general and administrative expenses in the financial statements.

² Included in other income and expenses.

³ Stock-based compensation ("SBC") expense included in operating expenses is detailed as follows in the table below by category within operating expenses for the non-GAAP Net operating expenses:

<i>(in thousands except per-share amounts)</i>	For the three months ended March 31,	
	<u>2023</u>	<u>2022</u>
Cost of revenues	1,338	369
Stock-based compensation expense ³	(19)	—
Net cost of revenues	<u>1,319</u>	<u>369</u>
Amortization of intangible assets	505	—

Sales and marketing	4,127	3,318
Stock-based compensation expense ³	(356)	(440)
Net sales and marketing	<u>3,771</u>	<u>2,878</u>
General and administrative	6,511	5,892
Depreciation expense	(107)	(24)
Stock-based compensation expense ³	(2,668)	(3,269)
Net general and administrative	<u>3,736</u>	<u>2,599</u>
Research and development	2,282	2,881
Stock-based compensation expense ³	(165)	(126)
Net research and development	<u>2,117</u>	<u>2,755</u>
Total operating expenses	14,763	12,460
Depreciation and amortization expense	(612)	(24)
Stock-based compensation expense ³	(3,208)	(3,835)
Net operating expenses	<u>10,943</u>	<u>8,601</u>

About EsoGuard and EsoCheck

Millions of patients with GERD are at risk of developing esophageal precancer and a highly lethal form of esophageal cancer ("EAC"). Over 80 percent 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 percent 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 percent to 15 percent 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 percent 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, performed on samples collected with EsoCheck, 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. An updated American College of Gastroenterology clinical practice [guideline](#) and an American Gastroenterological Association clinical practice [update](#) both endorse non-endoscopic 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 percent 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. is a commercial-stage, cancer prevention medical diagnostics company, and subsidiary of PAVmed Inc. Lucid is focused on the millions of patients with gastroesophageal reflux 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.

For more information, please visit luciddx.com and for more information about its parent company PAVmed, please visit pavmed.com.

Forward-Looking Statements

This press release includes forward-looking statements that involve risk and uncertainties. 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 Diagnostics' 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 Diagnostics' common stock; general economic and market conditions; the uncertainties inherent in research and development, including the cost and time required to advance Lucid Diagnostics' products to regulatory submission; whether regulatory authorities will be

satisfied with the design of and results from Lucid Diagnostics' clinical and preclinical studies; whether and when Lucid Diagnostics' products are cleared by regulatory authorities; market acceptance of Lucid Diagnostics' products once cleared and commercialized; Lucid Diagnostics' ability to raise additional funding as needed; and other competitive developments. In addition, Lucid Diagnostics continues to monitor the COVID-19 pandemic and the pandemic's impact on Lucid Diagnostics' businesses. These factors are difficult or impossible to predict accurately and many of them are beyond Lucid Diagnostics' 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 Diagnostics' future operations, see Part I, Item 1A, "Risk Factors," in Lucid Diagnostics' most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, as the same may be updated in Part II, Item 1A, "Risk Factors" in any Quarterly Report on Form 10-Q filed by Lucid Diagnostics after its most recent Annual Report. Lucid Diagnostics 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.

🔗 View original content to download multimedia <https://www.prnewswire.com/news-releases/lucid-diagnostics-provides-business-update-and-first-quarter-financial-results-301825236.html>

SOURCE Lucid Diagnostics