

Lucid Diagnostics Provides Business Update and First Quarter 2024 Financial Results

Quarterly EsoGuard® test volume increased 10 percent

Strengthened balance sheet following completion of \$29.8 million Series B Preferred Stock Offering

MolDX pre-submission meeting scheduled for July 17, 2024

Conference call and webcast to be held today, May 13th at 8:30 AM EDT

NEW YORK, May 13, 2024 /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, 2024.

Conference Call and Webcast

The webcast will take place on Monday, May 13, 2024, 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 1-800-836-8184 and international listeners should dial 1-646-357-8785. All listeners should provide the operator with the conference call name "Lucid Diagnostics Business Update" to join.

Following the conclusion of the conference call, a replay will be available for 30 days on the investor relations section of the Company's website at luciddx.com.

Business Update Highlights

"I am very pleased with the excellent progress Lucid has made on multiple fronts during the first quarter and recent weeks and look forward to exciting very near-term milestones for our business," said [Lishan Aklog, M.D.](#), Lucid's Chairman and Chief Executive Officer. "We strengthened our balance sheet closing an approximately \$30 million preferred stock financing to long-term investors that extends our runway well past these milestones. Our EsoGuard commercial execution continues to deliver results as we drive towards expanded private and public coverage, as well as direct contracting. We look forward to our MolDX pre-submission meeting scheduled for mid-July where we will have the opportunity to present our now robust clinical evidence base for EsoGuard as we seek coverage under its Local Coverage Determination (LCD). We believe we have line of sight to Medicare coverage."

Highlights from the first quarter and recent weeks.

- For the quarter, [EsoGuard®](#) revenue was \$1.0M, which was flat compared to 4Q23 and represents a 124 percent annual increase from 1Q23.
- Lucid's CLIA-certified clinical laboratory performed 2,420 commercial EsoGuard Esophageal DNA Tests in 1Q24, which represents a 10 percent increase sequentially from 4Q23 and a 31 percent annual increase from 1Q23.
- Continuous revenue cycle management improvements, including prior authorization appeals, physician advocacy, etc., while maintaining stable out-of-network allowed amounts averaging ~\$1,800.
- Strengthened balance sheet by completing [\\$29.8 million Series B Preferred Stock Offering](#).
- [Peer-reviewed publication](#) of positive data from landmark [National Cancer Institute](#) (NCI)-sponsored clinical validation study of EsoGuard esophageal precancer testing demonstrating unprecedented early cancer detection. The publication of data strengthens EsoGuard's clinical data supporting ongoing engagement to secure commercial and Medicare payor coverage.
- Secured July 17, 2024 MolDX pre-submission meeting to review data for technical assessment (TA) seeking EsoGuard coverage under its foundational Local Coverage Determination (LCD).
- Robust pipeline of direct contracting engagements with benefits brokers, third-party administrators, and self-insured entities.
- Actively executing on aggressive market access strategy focused on securing medical policy coverage with regional plans in biomarker legislation states and pilots with national plans.

Financial Results

- For the three months ended March 31, 2024, EsoGuard related revenues were \$1.0 million. Operating expenses were approximately \$11.8 million, which included stock-based compensation expenses of \$0.9 million. GAAP net loss attributable to common stockholders was approximately \$18.1 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 non-GAAP adjusted loss for the three months ended March 31, 2024 was approximately \$9.4 million or \$(0.21) per common share.
- Lucid had cash and cash equivalents of \$24.8 million as of March 31, 2024, compared to \$18.9 million as of December 31, 2023. Subsequent to March 31, 2024, the Company completed an issuance of Convertible Preferred Stock Series B-1 resulting in gross proceeds of approximately \$11.6 million.
- The unaudited financial results for the three months ended March 31, 2024, were filed with the SEC on Form 10-Q on May 13, 2024, and 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, 2024, and 2023 are as follows:

Condensed consolidated statements of operations (unaudited)

(in thousands except per-share amounts)	For the three months ended	
	March 31,	
	2024	2023
Revenue	\$ 1,001	\$ 446
Operating expenses	11,793	14,763
Other (Income) expense	(180)	1,930
Net Loss	(10,612)	(16,247)
Net income (loss) per common share, basic and diluted	\$ (0.40)	\$ (0.40)
Net loss attributable to common stockholders	(18,108)	(16,247)
Preferred Stock dividends and deemed dividends	7,496	—
Net income (loss) as reported	(10,612)	(16,247)
Adjustments:		
Depreciation and amortization expense ¹	501	612
Interest expense (income), net ²	(56)	(45)
EBITDA	(10,167)	(15,680)

Other non-cash or financing related expenses:

Stock-based compensation expense ³	933	3,208
ResearchDx acquisition paid in stock ¹	—	713
Change in FV convertible debt ²	(291)	789
Offering costs convertible debt ²	—	1,186
Debt extinguishments loss - Senior Secured Convertible Note ²	167	—
Non-GAAP adjusted (loss)	<u>\$ (9,358)</u>	<u>\$ (9,784)</u>
Basic and Diluted shares outstanding	45,014	40,971
Non-GAAP adjusted (loss) income per share	\$(0.21)	\$(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:

Reconciliation of GAAP Operating Expenses to Non-GAAP Net Operating Expenses

(in thousands except per-share amounts)	For the three months ended	
	March 31,	
	2024	2023
Cost of revenues	\$ 1,656	\$ 1,338
Stock-based compensation expense ³	(36)	(19)
Net cost of revenues	<u>1,620</u>	<u>1,319</u>
Amortization of intangible assets	372	505
Sales and marketing	4,194	4,127
Stock-based compensation expense ³	(350)	(356)
Net sales and marketing	<u>3,844</u>	<u>3,771</u>
General and administrative	4,070	6,900
Depreciation expense	(129)	(107)
RDx Settlement in Stock	—	(713)
Stock-based compensation expense ³	(330)	(2,668)
Net general and administrative	<u>3,611</u>	<u>3,412</u>
Research and development	1,501	1,893
Stock-based compensation expense ³	(217)	(165)
Net research and development	<u>1,284</u>	<u>1,728</u>
Total operating expenses	11,793	14,763
Depreciation and amortization expense	(501)	(612)
RDx Settlement in Stock	—	(713)
Stock-based compensation expense ³	(933)	(3,208)
Net operating expenses	<u>\$ 10,359</u>	<u>\$ 10,230</u>

About EsoGuard and EsoCheck

Millions of patients with gastroesophageal reflux disease (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 for the millions of GERD patients with multiple risk factors, including age over 50 years, male sex, 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 death could likely have been prevented if the at-risk GERD patient had been screened and then undergone surveillance and curative treatment at the precancer stage.

The only missing element for a viable esophageal cancer prevention program has been the lack of an easily-accessible, in-office screening tool that can detect esophageal precancer. Lucid believes EsoGuard, performed on samples collected non-endoscopically 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 (ACG) clinical practice [guideline](#) and an American Gastroenterological Association (AGA) 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 Next Generation Sequencing (NGS) based DNA methylation 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 initially 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 a CE Marked and FDA 510(k) cleared noninvasive swallowable balloon capsule catheter device capable of sampling surface esophageal cells in a less than three-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, NYS CLEP approved 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 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 – the first and only commercially available tools designed with the goal of preventing esophageal cancer and cancer deaths through widespread, early detection of esophageal precancer in at-risk 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. 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.

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<https://ir.luciddx.com/2024-05-13-Lucid-Diagnostics-Provides-Business-Update-and-First-Quarter-2024-Financial-Results>