Lucid Diagnostics Provides Business Update and Third Quarter 2024 Financial Results

EsoGuard® revenue up 20 percent sequentially

Clinical evidence package for Medicare coverage submission complete

Direct contracting initiative expanded to multiple programs to drive near-term revenue growth

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

NEW YORK, Nov. 13, 2024 /PRNewswire/ -- **Lucid Diagnostics Inc.** (Nasdaq: LUCD) ("Lucid" or the "Company") a commercial-stage, cancer prevention medical diagnostics company, and 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 September 30, 2024.

Conference Call and Webcast

The webcast will take place on Wednesday, November 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

"The third quarter and recent weeks have been a transformational period for Lucid, including two key milestones announced last week," said Lishan Aklog, M.D., Lucid's Chairman and Chief Executive Officer. "We are now fully armed with a complete body of outstanding clinical data to go along with a renewed commercial focus on programs designed to drive near-term revenue. Our team is ready to make our final push towards broad reimbursement, including our upcoming submission formally seeking Medicare coverage of EsoGuard. We are energized by the vast clinical and market opportunity before us as we seek to expand patient access to our groundbreaking technologies to detect esophageal precancer, and drive shareholder value."

Highlights from the third quarter and recent weeks :

- For the quarter, EsoGuard® Esophageal DNA Test revenue was $1.2M, which represents a 20 percent increase sequentially from 2Q24 and a 50 percent annual increase from 3Q23.
- Lucid's CLIA-certified clinical laboratory performed 2,787 commercial EsoGuard tests in 3Q24. Additionally, for the month of October, the lab performed a single-month record of more than 1,400 tests, contributing to the largest three-month total in the Company's history.
- ESOGUARD BE-1 clinical validation study accepted for peer-reviewed publication in the American Journal of Gastroenterology. This publication completes Lucid's clinical evidence package for submission to formally seek Medicare coverage.
- Company leveraging complete clinical evidence package to expand direct contracting initiative with multiple programs focused on driving near-term revenue growth, including a shift to fully-contracted #CYFT Precancer Testing Events, broadening employer markets activity, and a new foray into the concierge medicine sector.
- Met with CMS Medicare Administrative Contractor (MAC) Palmetto GBA's Molecular Diagnostics Program (MolDX) to discuss EsoGuard clinical evidence package for upcoming submission for Medicare coverage.
- Peer-reviewed publication of EsoGuard analytical validation study, demonstrating excellent analytical accuracy, repeatability, and reproducibility of the assay.
- Received Notice of Allowance for key patent underlying EsoGuard.

Financial Results

- For the three months ended September 30, 2024, EsoGuard related revenues were $1.2 million. Operating

expenses were approximately $12.9 million, which included stock-based compensation expenses of $1.2 million. GAAP net loss attributable to common stockholders was approximately $12.4 million or $(0.25) 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 September 30, 2024 was approximately $10.1 million or $(0.20) per common share.
- Lucid had cash and cash equivalents of $14.5 million as of September 30, 2024, compared to $18.9 million as of December 31, 2023. As of November 12, the Company has entered into subscription agreements with long-term accredited investors to purchase $21.75 million of five-year Senior Secured Convertible Notes. The Company gave notice to the existing convertible note holder that it is exercising its right to redeem the existing notes. Upon closing of the subscription agreements and completing the redemption of the existing notes, the company expects to increase its cash runway by approximately $13.2 million.
- The unaudited financial results for the three and nine months ended September 30, 2024, were filed with the SEC on Form 10-Q on November 12, 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 and nine months ended September 30, 2024, and 2023 are as follows:

Condensed consolidated statements of operations (unaudited)

(in thousands except per-share amounts)	For the three months ended September 30,		For the nine months ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenue	$ 1,172	$ 783	$ 3,149	$ 1,388
Operating expenses	12,866	11,911	36,826	38,417
Other (Income) expense	677	3,080	311	4,807
Net Loss	(12,371)	(14,208)	(33,988)	(41,836)
Net income (loss) per common share, basic and diluted	$ (0.25)	$ (0.34)	$ (0.87)	$ (1.01)
Net loss attributable to common stockholders	(12,371)	(14,208)	(41,484)	(41,836)
Preferred Stock dividends and deemed dividends	—	—	7,496	—

Net income (loss) as reported	(12,371)	(14,208)	(33,988)	(41,836)
Adjustments:				
Depreciation and amortization expense[1]	215	625	945	1,870
Interest expense, net[2]	(80)	33	(237)	75
EBITDA	(12,236)	(13,550)	(33,280)	(39,891)
Other non-cash or financing related expenses:				
Stock-based compensation expense[3]	1,228	1,252	3,363	5,859
ResearchDx acquisition paid in stock[1]	—	—	—	713
Operating expenses issued in stock[1]	135	—	248	23
Change in FV convertible debt[2]	322	3,021	(568)	3,520
Offering costs convertible debt[2]	—	—	—	1,186
Debt extinguishments loss - Senior Secured Convertible Note[2]	435	26	1,116	26
Non-GAAP adjusted (loss)	$ (10,116)	$ (9,251)	$ (29,121)	$ (28,564)
Basic and Diluted shares outstanding	50,374	41,863	47,876	41,559
Non-GAAP adjusted (loss) income per share	$(0.20)	$(0.22)	$(0.61)	$(0.69)

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 September 30,		For the nine months ended September 30,	
	2024	**2023**	**2024**	**2023**
Cost of revenues	$ 1,684	$ 1,634	$ 4,954	$ 4,522
Stock-based compensation expense[3]	(41)	(26)	(121)	(70)
Net cost of revenues	1,643	1,608	4,833	4,452
Amortization of intangible assets	105	505	582	1,516
Sales and marketing	4,056	3,837	12,459	11,996
Stock-based compensation expense[3]	(351)	(334)	(1,066)	(1,056)
Net sales and marketing	3,705	3,503	11,393	10,940
General and administrative	5,355	4,320	14,292	15,049
Depreciation expense	(110)	(120)	(363)	(354)
RDx Settlement in Stock	—	—	—	(713)
Operating expenses issued in stock	(135)	—	(248)	(23)
Stock-based compensation expense[3]	(700)	(728)	(1,640)	(4,239)
Net general and administrative	4,410	3,472	12,041	9,720
Research and development	1,666	1,615	4,539	5,334
Stock-based compensation expense[3]	(136)	(164)	(536)	(494)
Net research and development	1,530	1,451	4,003	4,840
Total operating expenses	12,866	11,911	36,826	38,417
Depreciation and amortization expense	(215)	(625)	(945)	(1,870)
RDx Settlement in Stock	—	—	—	(713)

Operating expenses issued in stock	(135)	—	(248)	(23)
Stock-based compensation expense[3]	(1,228)	(1,252)	(3,363)	(5,859)
Net operating expenses	$ 11,288	$ 10,034	$ 32,270	$ 29,952

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.

SOURCE Lucid Diagnostics

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