Lucid Diagnostics Provides Business Update and Third Quarter Financial Results

Quarterly EsoGuard® test volume and revenue increased 17 percent and 392 percent sequentially, respectively

Conference call and webcast to be held tomorrow, November 14th at 8:30 AM EST

NEW YORK, Nov. 13, 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 and nine months ended September 30, 2023.

Conference Call and Webcast

The webcast will take place on Tuesday, November 14, 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 1-833-816-1418 and international listeners should dial 412-317-0511. 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 can confidently say that Q3 was the most important quarter in Lucid's history," said Lishan Aklog, M.D., Lucid's Chairman and Chief Executive Officer. "We crossed several critical milestones necessary to translate test volume growth into revenue and revenue growth. The initial impact that we saw in the second quarter from the upgrade to our revenue cycle management infrastructure has been sustained, driving record revenues this past quarter. Key metrics, such as the percentage of allowed claims and the average allowed payment, have held up nicely during this period. A key driver supporting in-network payor coverage engagement, along with claims history, is a solid base of clinical utility data. We went from no clinical utility data in the second quarter to over 1,500 patients across three clinical utility studies with near-perfect results—two published and one pending peer review."

Highlights from the third quarter and recent weeks:

- Lucid's CLIA-certified clinical laboratory performed 2,575 commercial EsoGuard® Esophageal DNA Tests in 3Q23, which represents a 17 percent increase sequentially from 2Q23 and a 137 percent annual increase from 3Q22. Lucid personnel performed cell collection for 82 percent of tests in the quarter, reflecting a steady increase in Satellite Lucid Test Center activity. High-volume #CYFT testing events continue to strongly contribute to test volume growth. Gaining traction with strategic accounts at health systems and academic medical centers.
- For the quarter, EsoGuard revenue was $783K, which represents a 392 percent increase sequentially from 2Q23 and a 930 percent annual increase from 3Q22.
- Upgrade to revenue cycle management infrastructure showed sustained impact during the quarter. Allowed claims percentage and average allowed payment amount also held up well. Active pipeline of claims going through appeals with success based on medical necessity vs. guidelines.
- Substantial increase in clinical utility data to support in-network payor coverage engagement. Near-perfect clinical utility data (99-100 percent concordance) from three studies—CLUE, the PREVENT Registries, and the SAFD Study—totaling over 1,500 patients released during the quarter. Two manuscripts published in peer reviewed journals, and one pending peer review.
- Accelerating activity in Direct Contracting with employers to offer EsoGuard as a benefit. First contract signed and on-site testing has begun. New VP, Employer Markets with 30 plus years of experience in employer benefits sales starts this week.
- EsoGuard 2.0 with multiplexed triplicate consensus launched last week, improving already unprecedented cancer and precancer detection results. Analytical validation studies to be presented at this week's Association of Molecular Pathology Annual Meeting (AMP 2023). Upgrading NGS-sequencing platform to a higher-throughput NextSeq 1000 to accommodate increased EsoGuard testing volume. Updated assay and platform expected to significantly lower per-sample sequencing costs.

Financial Results

- For the three months ended September 30, 2023, EsoGuard related revenues were $0.8 million. Operating expenses were approximately $11.9 million, including stock-based compensation expenses of $1.3 million. GAAP net loss was approximately $14.2 million, or $(0.34) 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 September 30, 2023, was approximately $9.3 million or $(0.22) per common share.
- Lucid had cash and cash equivalents of $24.1 million as of September 30, 2023, compared to $32.6 million as of June 30, 2023.

- The unaudited financial results for the three months ended September 30, 2023, will be filed with the SEC on Form 10-Q on November 14, 2023, 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, 2023, and 2022 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,	
	2023	**2022**	**2023**	**2022**
Revenue	$ 783	$ 76	$ 1,388	$ 265
Operating expenses	11,911	14,453	38,417	41,541
Other (Income) expense	3,080	(28)	4,807	(33)
Net Loss	(14,208)	(14,349)	(41,836)	(41,243)
Net income (loss) per common share, basic and diluted	$ (0.34)	$ (0.39)	$ (1.01)	$ (1.15)
Adjustments:				
Depreciation and amortization expense[1]	625	593	1,870	1,321
Interest expense, net[2]	33	(28)	75	(33)
EBITDA	(13,550)	(13,784)	(39,891)	(39,955)
Other non-cash or financing related expenses:				
Stock-based compensation expense[3]	1,252	3,571	5,859	11,251
ResearchDx acquisition paid in stock[1]	—	—	713	—
Change in FV convertible debt[2]	3,021	—	3,520	—
Offering costs convertible debt[2]	—	—	1,186	—
Debt extinguishments loss - Senior Secured Convertible Note[2]	26	—	26	—
Non-GAAP adjusted (loss)	$ (9,251)	$ (10,213)	$ (28,587)	$ (28,704)
Basic and Diluted shares outstanding	41,863	36,406	41,559	35,768
Non-GAAP adjusted (loss) income per share	$(0.22)	$(0.28)	$(0.69)	$(0.80)

[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,	
	2023	**2022**	**2023**	**2022**

Cost of revenues	$ 1,634	$ 1,626	$ 4,522	$ 1,996
Stock-based compensation expense[3]	(26)	(9)	(70)	(9)
Net cost of revenues	1,608	1,617	4,452	1,987
Amortization of intangible assets	505	505	1,516	1,144
Sales and marketing	3,837	3,930	11,996	11,121
Stock-based compensation expense[3]	(334)	(414)	(1,056)	(1,230)
Net sales and marketing	3,503	3,516	10,940	9,891
General and administrative	4,320	5,688	15,049	18,465
Depreciation expense	(120)	(88)	(354)	(177)
Stock-based compensation expense[3]	(728)	(3,068)	(4,239)	(9,728)
Net general and administrative	3,472	2,532	10,456	8,560
Research and development	1,615	2,704	5,334	8,815
Stock-based compensation expense[3]	(164)	(80)	(494)	(284)
Net research and development	1,451	2,624	4,840	8,531
Total operating expenses	11,911	14,453	38,417	41,541
Depreciation and amortization expense	(625)	(593)	(1,870)	(1,321)
Stock-based compensation expense[3]	(1,252)	(3,571)	(5,859)	(11,251)
Net operating expenses	$ 10,034	$ 10,289	$ 30,688	$ 28,969

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 - 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. 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.

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