Lucid Diagnostics Provides Business Update and Second Quarter Financial Results

Quarterly EsoGuard® test volume increased 20 percent sequentially and 159 percent annually

Revenue cycle management upgrade completed with immediate positive impact to claims processing and payments

Unprecedented cancer and precancer detection results from an NCI-funded EsoGuard study released

Conference call and webcast to be held tomorrow, August 15th at 8:30 AM EDT

NEW YORK, Aug. 14, 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 six months ended June 30, 2023.

Conference Call and Webcast

The webcast will take place on Tuesday, August 15, 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

"Lucid closed out a strong first half of 2023, with yet another quarter of double-digit EsoGuard test volume growth and major accomplishments on multiple strategic fronts, which we believe will drive substantial value in the coming quarters" said Lishan Aklog, M.D., Lucid's Chairman and Chief Executive Officer. "Commercial execution underpinning the sustained test volume growth remained very strong, driven by steadily increasing per-seller productivity as well as expanding utilization of our satellite Lucid Test Center program and high-volume #CheckYourFoodTube testing events. The launch of our first mobile test unit and the execution of our first direct contract with an employer to offer EsoGuard testing as an employee benefit, reflect our relentless commitment to expanding EsoGuard access across all available channels."

"Key accomplishments critical to translating this commercial success into future revenue growth include: the recently completed upgrade to our revenue cycle management infrastructure; reaching target enrollment in our prospective clinical utility studies which, together with the pending posting and submission of the results of those studies, will support payor coverage; and the release of unprecedented cancer and precancer detection results from an NCI-funded EsoGuard study. I am particularly encouraged by the immediate positive impact that the revenue cycle management upgrade has had on EsoGuard claims processing and payments," Dr. Aklog added.

Highlights from the second quarter and recent weeks:

- Lucid's CLIA-certified clinical laboratory performed 2,202 commercial EsoGuard® Esophageal DNA Tests in 2Q23, which represents a 20 percent increase sequentially from 1Q23 and a 159 percent annual increase from 2Q22. Satellite Lucid Test Center activity, including #CYFT high-volume testing events, increased 51 percent and now represents over half of all testing activity.
- Lucid upgraded its revenue cycle management provider to the market leader, completing the transition to an upgraded claims submission, adjudication, and payment collection process in late June. Claims submission and adjudication was paused during the transition starting in early May. An immediate positive impact on claims processing, allowances and collections was noted for the month of July.
- Lucid achieved its target end-of-quarter enrollment in its two prospective clinical utility studies. The Lucid Registry and multi-center CLUE studies have enrolled over 500 patients. Data on these cohorts is being analyzed and results will be posted on a preprint server later this month in advance of peer review. Clinical utility data, along with claims history, remains the key gating item in engaging payors on EsoGuard coverage.
- Lucid executed its first employer contract under its direct contracting strategic initiative. A Texas-based automotive group will now offer EsoGuard testing by Lucid as an employee benefit across twelve locations. Further details will be forthcoming.
- The NCI-funded BETRNet consortium, consisting of the leading academic medical centers in the field, released unprecedented cancer and precancer detection results of its highly anticipated case-control study of 242 patients comparing EsoGuard to upper endoscopy. EsoGuard detected 100 percent of esophageal cancers and over 80 percent of precancers, with an estimated negative predictive value of 99 percent—unprecedented results for such a molecular diagnostic test. Further details and analysis of these results will be forthcoming.

Financial Results

- For the three months ended June 30, 2023, EsoGuard related revenues were $0.2 million. Operating expenses were approximately $11.7 million, including stock-based compensation expenses of $1.4 million. GAAP net loss was approximately $11.4 million, or $(0.27) 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

June 30, 2023, was approximately $9.6 million or $(0.23) per common share.
- Lucid had cash and cash equivalents of $32.6 million as of June 30, 2023, compared to $39.5 million as of March 31, 2023.
- The unaudited financial results for the three months ended June 30, 2023, were filed with the SEC on Form 10-Q on August 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 six months ended June 30, 2023, and 2022 are as follows:

Condensed consolidated statements of operations (unaudited)

(in thousands except per-share amounts)	For the three months ended June 30,		For the six months ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenue	$ 159	$ —	$ 605	$ 189
Operating expenses	11,743	14,628	26,505	27,088
Other (Income) expense	(203)	(4)	1,728	(5)
Net Loss	(11,381)	(14,624)	(27,628)	(26,894)
Net income (loss) per common share, basic and diluted	$ (0.27)	$ (0.41)	$ (0.67)	$ (0.76)
Adjustments:				
Depreciation and amortization expense[1]	633	704	1,245	728
Interest expense, net[2]	87	(4)	43	(5)
EBITDA	(10,661)	(13,924)	(26,340)	(26,171)
Other non-cash or financing related expenses:				
Stock-based compensation expense[3]	1,399	3,844	4,607	7,679
ResearchDx acquisition paid in stock[1]	—	—	713	—
Change in FV convertible debt[2]	(290)	—	499	—
Offering costs convertible debt[2]	—	—	1,186	—
Non-GAAP adjusted (loss)	(9,552)	(10,080)	(19,335)	(18,492)
Basic and Diluted shares outstanding	41,834	35,760	41,405	35,444
Non-GAAP adjusted (loss) income per share	$(0.23)	$(0.28)	$(0.47)	$(0.52)

[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 June 30,		For the six months ended June 30,	
	2023	**2022**	**2023**	**2022**
Cost of revenues	1,549	—	2,887	369
Stock-based compensation expense[3]	(25)	—	(44)	—
Net cost of revenues	1,524	—	2,843	369

Amortization of intangible assets	505	639	1,010	639
Sales and marketing	4,032	3,873	8,159	7,191
Stock-based compensation expense[3]	(367)	(376)	(723)	(816)
Net sales and marketing	3,665	3,497	7,436	6,375
General and administrative	3,830	6,676	10,340	12,568
Depreciation expense	(128)	(65)	(235)	(89)
Stock-based compensation expense[3]	(844)	(3,390)	(3,512)	(6,659)
Net general and administrative	2,858	3,221	6,593	5,820
Research and development	1,827	3,440	4,109	6,321
Stock-based compensation expense[3]	(163)	(78)	(328)	(204)
Net research and development	1,664	3,362	3,781	6,117
Total operating expenses	11,743	14,628	26,505	27,088
Depreciation and amortization expense	(633)	(704)	(1,245)	(728)
Stock-based compensation expense[3]	(1,399)	(3,844)	(4,607)	(7,679)
Net operating expenses	9,711	10,080	20,653	18,681

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-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. EsoGuard is 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. 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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