Lucid Diagnostics Provides Business Update and Preliminary Fourth Quarter and Full Year 2023 Financial Results

Quarterly EsoGuard® revenue increased 33 percent sequentially

Expanding EsoGuard clinical validity and clinical utility data poised to drive medical policy coverage, including line of sight to Medicare coverage

Conference call and webcast to be held tomorrow, March 26th at 8:30 AM ET

NEW YORK, March 25, 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 year ended December 31, 2023.

Conference Call and Webcast

The webcast will take place on March 26, 2024, at 8:30 AM, and 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

"We are very pleased with the excellent progress Lucid has made on multiple fronts in the fourth quarter and recent weeks," said Lishan Aklog, M.D., Lucid's Chairman and Chief Executive Officer. "We saw solid revenue growth on stable test volume and our revenue cycle management processes are yielding improving allowances and stable pricing. Our #CYFT program targeting firefighters and other groups is thriving and we have a robust pipeline of scheduled high-volume testing events. Most importantly, we have rapidly built our clinical validity and clinical utility evidence base to drive positive medical policy coverage, including what now we believe is line of sight to Medicare coverage. Equipped with sufficient data, we have for the first time engaged with medical directors at major commercial payors to request positive coverage. Our direct contracting initiative is also accelerating and we are excited about the near-term prospects of delivering contracts, testing and revenue."

Highlights from the fourth quarter and recent weeks include:

- 4Q23 EsoGuard revenue was $1.04M, which represents a 33 percent increase sequentially from 3Q23 and an 829 percent annual increase from 4Q22.
- Lucid's CLIA-certified clinical laboratory performed 2,201 commercial EsoGuard® Esophageal DNA Tests in 4Q23.
- High-volume #CYFT health fair testing events continue to gain traction with a robust roster of events scheduled through July.
- Lucid initiated EsoGuard testing at over a dozen strategic accounts at health systems and academic medical centers with several dozen more engagements in process.
- Since upgrading to a new revenue cycle management provider in mid-June, Lucid has submitted claims to commercial and governmental payors representing approximately $20 million in pro forma revenue. The vast majority of these claims have been adjudicated with nearly half resulting in an allowable amount of approximately $1,800 per test, on average.
- EsoGuard's clinical validity and clinical utility data evidence base has expanded significantly in the fourth quarter and recent months. Lucid now has publicly-released data from three clinical validity studies demonstrating excellent EsoGuard sensitivity and negative predictive value, including unprecedented performance of a molecular diagnostic test in detecting precancer. In addition, three published clinical utility studies have documented near-perfect concordance between EsoGuard results and physician referral for upper gastrointestinal endoscopy. These data provide a strong foundation of critical evidence needed to support broad EsoGuard medical policy coverage. Lucid expects to leverage this data in its upcoming re-engagement with the MolDX program to secure Medicare coverage under the final and effective foundational Local Coverage Determination.
- Held several meetings in recent months with medical directors of major commercial payors to discuss clinical validity and utility data and formally request positive medical policy determinations for EsoGuard. The Company also participated in a Blue Cross Blue Shield Association of America webinar with dozens of medical directors in attendance, during which Nicholas Shaheen, M.D., M.P.H., a leading esophageal precancer expert and lead author of the American College of Gastroenterology's guidelines, advocated for coverage of non-endoscopic biomarker testing consistent with the ACG guidelines. Lucid also expects recent expansion of legislation requiring coverage of certain biomarker tests, now effective in fourteen states, will help drive medical policy coverage.
- Established that EsoGuard testing can be offered as a covered benefit within health and wellness programs as a means

to drive contractually-guaranteed revenues. Lucid has built a robust pipeline of direct contracting counterparties, including benefits brokers, third-party administrators, and self-insured entities. The Company expects to drive direct contract testing events with meaningful revenues in the coming quarters. The Company is adding resources to the direct contracting team to accelerate this initiative

Financial Results

- For the three months ended December 31, 2023, EsoGuard related revenues were $1.0 million, while for the year ended December 31, 2023, revenues were $2.4 million. Fourth quarter and full year 2023 operating expenses were approximately $12.5 million and $50.9 million, respectively, including stock-based compensation expenses of $1.0 million and $6.8 million, respectively. GAAP net loss for the fourth quarter and full year 2023 were approximately $10.8 million and $52.7 million, or $(0.26) and $(1.26) 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 fourth quarter and full year 2023, were approximately $9.9 million and $38.4 million or $(0.23) and $(0.92) per common share.
- Lucid had cash and cash equivalents of $18.9 million as of December 31, 2023, compared to $22.5 million as of December 31, 2022. Subsequent to December 31, 2023, the Company completed an issuance of Convertible Preferred Series B resulting in gross proceeds of approximately $18.1 million.
- The audited financial results for the year ended December 31, 2023, were filed with the SEC on Form 10-K on March 25, 2024, and available at www.luciddx.com or www.sec.gov.

Lucid Non-GAAP Measures

- To supplement our audited 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 audited 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 and year ended December 31, 2023, and 2022 are as follows:

Condensed consolidated statements of operations (unaudited)

(in thousands except per-share amounts)	For the three months ended December 31,		For the year ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenue	$ 1,040	$ 112	$ 2,428	$ 377
Operating expenses	12,493	15,086	50,910	56,628
Other (Income) expense	(624)	(47)	4,184	(80)
Net Loss	(10,829)	(14,927)	(52,666)	(56,171)
Net income (loss) per common share, basic and diluted	$ (0.26)	$ (0.40)	$ (1.26)	$ (1.55)
Adjustments:				
Depreciation and amortization expense[1]	629	615	2,499	1,936
Interest expense, net[2]	(84)	(47)	(8)	(80)
EBITDA	(10,284)	(14,359)	(50,175)	(54,315)
Other non-cash or financing related expenses:				
Stock-based compensation expense[3]	964	3,740	6,822	14,991
ResearchDx acquisition paid in stock[1]	—	—	713	—
Change in FV convertible debt[2]	(540)	—	2,980	—

Offering costs convertible debt[2]	—	—	1,186	—
Debt extinguishments loss - Senior Secured Convertible Note[2]	—	—	26	—
Non-GAAP adjusted (loss)	$ (9,860)	$ (10,619)	$ (38,448)	$ (39,324)
Basic and Diluted shares outstanding	42,330	37,373	41,756	36,172
Non-GAAP adjusted (loss) income per share	$(0.23)	$(0.28)	$(0.92)	$(1.09)

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 December 31,		For the year ended December 31,	
	2023	**2022**	**2023**	**2022**
Cost of revenues	$ 1,458	$ 1,618	$ 5,979	$ 3,614
Stock-based compensation expense[3]	(30)	(6)	(100)	(16)
Net cost of revenues	1,428	1,612	5,879	3,598
Amortization of intangible assets	505	505	2,021	1,649
Sales and marketing	4,408	5,012	16,404	16,134
Stock-based compensation expense[3]	(355)	(393)	(1,411)	(1,622)
Net sales and marketing	4,053	4,619	14,993	14,512
General and administrative	4,204	5,509	19,254	23,974
Depreciation expense	(124)	(110)	(478)	(287)
RDx Settlement in Stock	—	—	(713)	—
Stock-based compensation expense[3]	(390)	(3,227)	(4,628)	(12,953)
Net general and administrative	3,690	2,172	13,435	10,734
Research and development	1,918	2,442	7,252	11,257
Stock-based compensation expense[3]	(189)	(114)	(683)	(400)
Net research and development	1,729	2,328	6,569	10,857
Total operating expenses	12,493	15,086	50,910	56,628
Depreciation and amortization expense	(629)	(615)	(2,499)	(1,936)
RDx Settlement in Stock	—	—	(713)	—
Stock-based compensation expense[3]	(964)	(3,740)	(6,822)	(14,991)
Net operating expenses	$ 10,900	$ 10,731	$ 40,876	$ 39,701

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 medical diagnostics company focused on cancer prevention, and subsidiary of PAVmed Inc. (Nasdaq: PAVM). 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 for at-risk patients to mitigate the risks of cancer and cancer deaths through early detection of esophageal precancer.

For more information, please visit www.luciddx.com and for more information about its parent company PAVmed, please visit www.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's 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's common stock; general economic and market conditions; the uncertainties inherent in research and development, including the cost and time required to advance Lucid's products to regulatory submission; whether regulatory authorities will be satisfied with the design of and results from Lucid's clinical and preclinical studies; whether and when Lucid's products are cleared by regulatory authorities; market acceptance of Lucid's products once cleared and commercialized; Lucid's ability to raise additional funding as needed; and other competitive developments. In addition, Lucid continues to monitor the COVID-19 pandemic and the pandemic's impact on Lucid's businesses. These factors are difficult or impossible to predict accurately and many of them are beyond Lucid's 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's future operations, see Part I, Item 1A, "Risk Factors," in Lucid's 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 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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