

November 14, 2022



# Lucid Diagnostics Provides Business Update and Third Quarter 2022 Financial Results

***EsoGuard test volume increased 28% sequentially and 436% annually***

***Conference call and webcast to be held today at 4:30 PM EDT***

NEW YORK--(BUSINESS WIRE)-- [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, 2022.

## **Conference Call and Webcast**

A conference call and webcast for today’s business update and third quarter 2022 financial results will take place at 4:30 PM EDT. To access the conference call, listeners should dial 877-407-0789 toll-free in the U.S., and international listeners should dial 201-689-8562 and ask to join the “Lucid Diagnostics Business Update Conference Call”. The [webcast](#) presentation and conference call will be available live and for replay at the investor relations section of the Company’s website at <https://ir.luciddx.com>. Following the conclusion of the conference call, a replay will be available for one week and can be accessed by dialing 844-512-2921 toll-free in the U.S. or 412-317-6671, followed by the PIN number: 13732743.

## **Business Update Highlights**

“With recent transformational milestones behind us, the Lucid team is now intensely focused on executing on our long-term growth strategy and delivered solid results for the past quarter,” said [Lishan Aklog, M.D.](#), Lucid’s Chairman and Chief Executive Officer. “I am particularly proud that the team is delivering these results well under budget for the quarter and year, as we continue to keep a close eye on cash preservation to protect our long-term position. Testing volume continues to grow at a steady clip, consistent with the ‘mid-throttle’ strategy we have implemented until reimbursement becomes more predictable. I am also gratified that the claims submission process, which we launched mid-quarter, is starting to bear fruit in terms of payments and recognized revenue.”

Highlights from the third quarter and recent weeks include:

- LucidDx Labs Inc. (“LucidDx Labs”), Lucid’s wholly owned CLIA-certified, CAP-accredited clinical laboratory, performed 1,088 commercial EsoGuard<sup>®</sup> Esophageal DNA Tests in the third quarter of 2022, which represents a 28% increase sequentially from the second quarter of 2022 and a 436% annual increase from the third quarter of

2021.

- Lucid continued the steady expansion of its sales team to 37 professionals, particularly sales representatives who call on primary care physicians, and is progressing well towards its near-term target of 58 sales professionals early in the new year.
- Lucid now operates 13 Lucid Test Centers (LTC) in 11 states, including one recently opened in the Chicago metropolitan area. Test centers in three new cities are targeted to launch by the end of the year. Satellite LTC activity is rapidly increasing, representing 22% of patients tested in the third quarter.
- LucidDx Labs' is now operating independently and has rapidly enhanced key quality and efficiency metrics, including reducing average EsoGuard test turn-around time to less than one week.
- In August, LucidDx Labs began submitting claims for tests performed since the February transfer of the CLIA laboratory operations, which were held until its new revenue cycle management partner was in place. LucidDx Labs began receiving some payments for claims during the quarter.
- Lucid commenced production of its EsoCheck® Esophageal Cell Collection Devices ("EsoCheck") at Coastline International, Inc., a high-volume manufacturer headquartered in San Diego, CA with plants in Mexico, which is expected to decrease per-unit manufacturing costs by 60% and provide scalable manufacturing capacity to accommodate accelerating growth in EsoGuard testing volume.

## Financial Results

- For the three months ended September 30, 2022, EsoGuard related revenues were \$0.1 million. Operating expenses were approximately \$14.4 million, including stock-based compensation expenses of \$3.6 million. GAAP net loss attributable to common stockholders was approximately \$14.3 million, or \$(0.39) 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, 2022, was approximately \$10.2 million or \$(0.28) per common share.
- Lucid had cash and cash equivalents of \$26.9 million as of September 30, 2022, compared to \$53.7 million as of December 31, 2021.
- In March 2022, Lucid entered into a committed equity facility with an affiliate of Cantor Fitzgerald ("Cantor"). Under the terms of the facility, Cantor has committed to purchase up to \$50 million of Lucid common stock from time to time upon the request of Lucid. Through September 30, 2022, 680,263 Lucid shares were issued under this facility for total proceeds of \$1.8 million.
- The unaudited financial results for the three months ended September 30, 2022, were filed with the SEC on Form 10-Q on November 14, 2022, and will be available at [www.luciddx.com](http://www.luciddx.com) or [www.sec.gov](http://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 and nine months ended September 30, 2022, and 2021 are as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
<b>Revenue</b>	\$ 76	\$ 200	\$ 265	\$ 200
<b>Operating expenses</b>	14,425	6,710	41,508	16,378
<b>Other (Income) expense</b>	-	447	-	594
<b>Net loss</b>	(14,349)	(6,957)	(41,243)	(16,772)
<b>Net income (loss) per common share, basic and diluted</b>	\$ (0.39)	\$ (0.49)	\$ (1.15)	\$ (1.19)
Adjustments:				
Depreciation and amortization expense <sup>1</sup>	593	-	1,321	3
Interest expense, net	-	447	-	147
<b>EBITDA</b>	(13,756)	(6,510)	(39,922)	(16,622)

**Other non-cash or financing related expenses:**

Stock-based compensation expense <sup>2</sup>	3,572	2,772	11,251	6,156
<b>Non-GAAP adjusted (loss)</b>	<b>\$ (10,184)</b>	<b>\$ (3,738)</b>	<b>\$ (28,671)</b>	<b>\$ (10,466)</b>
Basic and Diluted shares outstanding	36,406	14,115	35,768	14,115
Non-GAAP adjusted (loss) income per share	(\$0.28)	(\$0.26)	(\$0.80)	(\$0.74)

	For the three months ended		For the nine months ended	
	September 30,		September 30,	
	2022	2021	2022	2021
<b>Non-GAAP Operating Expenses</b>				
<b>Cost of revenue</b>	1,626	144	1,996	144
Stock-based compensation expense <sup>2</sup> (SBC)	(9)	-	(9)	-
Net cost of revenue	\$ 1,617	\$ 144	\$ 1,987	\$ 144
<b>Amortization of acquired intangible assets<sup>1</sup></b>	505	-	1,144	-
<b>Sales and marketing expense total</b>	3,930	918	11,121	2,627
Stock-based compensation expense <sup>2</sup>	(414)	-	(1,230)	-
Net sales and marketing expense	\$ 3,516	\$ 918	\$ 9,891	\$ 2,627
<b>General and administrative expense total</b>	5,660	3,458	18,223	7,793
Depreciation and amortization expense <sup>1</sup>	(88)	-	(177)	(3)
Stock-based compensation expense <sup>2</sup>	(3,069)	(2,695)	(9,728)	(5,988)
Net general and administrative expense	\$ 2,503	\$ 763	\$ 8,318	\$ 1,802
<b>Research and development expense total</b>	2,704	2,190	9,024	5,814
Stock-based compensation expense <sup>2</sup>	(80)	(77)	(284)	(168)
Net research and development expense	\$ 2,624	\$ 2,113	\$ 8,740	\$ 5,646
<b>Total operating expenses</b>	14,425	6,710	41,508	16,378
Depreciation and amortization <sup>1</sup>	(593)	-	(1,321)	(3)
Stock-based compensation expense <sup>2</sup>	(3,572)	(2,772)	(11,251)	(6,156)
Net Non-GAAP operating expenses	\$ 10,260	\$ 3,938	\$ 28,936	\$ 10,219

## About EsoGuard<sup>®</sup> and EsoCheck<sup>®</sup>

Millions of patients with GERD are at risk of developing esophageal precancer and a highly lethal form of esophageal cancer (“EAC”). Over 80% 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% 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% 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% 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 nonendoscopic 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% 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. (Nasdaq: LUCD) is a commercial-stage, cancer prevention medical diagnostics company, and majority-owned subsidiary of PAVmed Inc. (Nasdaq: PAVM). Lucid is focused on the millions of patients with gastroesophageal disease (GERD), also known as chronic heartburn, who are at risk of developing esophageal precancer and cancer. Lucid's EsoGuard<sup>®</sup> Esophageal DNA Test, performed on samples collected in a brief, noninvasive office procedure with its EsoCheck<sup>®</sup> Esophageal Cell Collection Device, is the first and only commercially available diagnostic test capable of serving as a widespread screening tool to prevent cancer and cancer deaths through early detection of esophageal precancer in at-risk GERD patients. EsoGuard is commercialized in the U.S. as a Laboratory Developed Test (LDT). EsoCheck is commercialized in the U.S. as a 510(k)-cleared esophageal cell collection device. EsoGuard, used with EsoCheck, was granted FDA Breakthrough Device designation and is the subject of multiple ongoing clinical trials. Lucid is building nationwide direct sales and marketing teams targeting primary care physicians, specialists, and institutions, as well as a network of Lucid Test Centers, where at-risk GERD patients can undergo the EsoCheck procedure for EsoGuard testing. For more information, please visit [www.luciddx.com](http://www.luciddx.com), follow Lucid on [Twitter](#), and connect with Lucid on [LinkedIn](#). For detailed information on EsoGuard, please visit [www.EsoGuard.com](http://www.EsoGuard.com) and follow us on [Twitter](#), [Facebook](#) and [Instagram](#).

## Forward-Looking Statements

This press release includes forward-looking statements that involve risks 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, 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 after its most recent Annual Report and Lucid's Registration Statement No. 333-259721 filed with the Securities and Exchange Commission. 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.

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