

March 13, 2023



# Lucid Diagnostics Provides Business Update and Fourth Quarter and Full Year 2022 Financial Results

In the news release, Lucid Diagnostics Provides Business Update and Fourth Quarter and Full Year 2022 Financial Results, issued 13-Mar-2023 by Lucid Diagnostics over PR Newswire, we are advised by the company that the information in the financial tables has been updated. The complete, corrected release follows:

4Q22 and projected 1Q23 EsoGuard<sup>®</sup> test volume increases 8 and 36 percent sequentially and 288 and 300 percent annually.

Company signs in-network agreement with largest secondary PPO, MultiPlan, expanding patient access to EsoGuard.

Company secures financing of \$24.6 million through separate offerings of preferred stock and debt, convertible after September 2023.

Conference call and webcast to be held tomorrow, March 14<sup>th</sup> at 8:30 AM EST

NEW YORK, March 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 year ended December 31, 2022.



## Conference Call and Webcast

The webcast will take place on March 14, 2023, at 8:30 AM and be accessible in the investor relations section of the Company's website at [luciddx.com](http://luciddx.com). Alternatively, to access the conference call by telephone, U.S.-based callers should dial 877-550-1858 and international listeners should dial 1-848-488-9160. All listeners should provide the operator with the conference call name "Lucid Diagnostics Business Update Conference Call" to join.

## Business Update Highlights

"We continue to make significant strides in our efforts to expand EsoGuard testing volume and secure in-network commercial payor access for EsoGuard," said [Lishan Aklog, M.D.](#), Lucid's Chairman and Chief Executive Officer. "Testing volume growth has been particularly strong this quarter and we expect that growth to continue with ongoing expansion of our satellite Lucid Test Center (sLTC) program and high-volume testing events. We also are making steady progress with commercial payor engagements and expect that effort to accelerate as we continue to generate claims histories with major plans and collect data demonstrating clinical utility of EsoGuard testing."

"Our in-network agreement to participate in Multiplan's networks, comprising approximately 60 million consumers, represents a significant milestone in our efforts to broaden patient access to EsoGuard testing. Our recent financings, along with our ongoing cash preservation efforts, have strengthened our balance sheet and extended our cash runway well into 2024, through key value inflection milestones. We will continue to focus on commercial execution and market access expansion to drive long-term shareholder value," Dr. Aklog added.

Highlights from the 4Q22 and recent weeks include:

- Lucid's CLIA-certified clinical laboratory performed 1,174 commercial EsoGuard<sup>®</sup> Esophageal DNA Tests in the 4Q22, which represents an 8 percent increase sequentially from the 3Q22 and a 288 percent annual increase from the 4Q21. The Company projects approximately 1600 commercial EsoGuard tests in 1Q23, which represents a 36 percent increase sequentially from 4Q22 and a 300 percent annual increase from 1Q22.
- Satellite Lucid Test Center (sLTC) activity, whereby Lucid clinicians collect samples at physician offices, continues to increase rapidly, representing 31 percent of samples collected in 4Q22, up from 22 percent in 3Q22.
- Lucid signed an in-network agreement with MultiPlan<sup>®</sup>, the largest secondary Preferred Provider Organization (PPO), expanding EsoGuard's access to Multiplan's estimated 60 million consumers through its relationship with more than 700 healthcare payors and 1.2 million healthcare providers.
- Commercial payor engagement is accelerating, with a total of 13 in-network EsoGuard contracts, averaging more than \$2000 per test and all in-network PPO contracts priced at or above the Medicare payment rate of \$1938. Key drivers of future in-network commercial payor contracting—generating claims history with individual payors and collecting retrospective and prospective clinical utility data—are also progressing well.
- Lucid launched an aggressive Direct Contracting Strategic Initiative (DCSI) to engage directly with large Administrative Services Only (ASO) self-insured employers, unions and other entities, seeking to replicate the successes of other cancer screening diagnostic companies that have deployed similar strategies.
- Lucid launched its #CheckYourFoodTube Precancer Detection Event (#CYFT Event) program, bringing EsoGuard testing directly to at-risk patients at high-volume testing day events. The first #CYFT Event, held in partnership with the San Antonio Fire

Department, tested 391 firefighters over two weekends. The Company set new performance records during this inaugural event, reflecting enhanced operating efficiencies, including approximately:

- 100 individuals undergoing esophageal cell collection procedures per day;
- 50 cell collection procedures performed per nurse practitioner per day; and
- 200 EsoGuard tests processed by the laboratory in a single day.

The near-term pipeline for future #CYFT Events is robust.

- Lucid received Food and Drug Administration (FDA) 510(k) clearance to market its EsoCheck<sup>®</sup> Cell Collection Device without sterilization, which will significantly reduce the cost of goods, enhance gross margins, mitigate supply chain issues, and address potential environmental concerns with current sterilization techniques.
- Lucid secured financing of \$24.6 million through separate offerings of preferred stock and debt. Recently, the Company received \$13.6 million from the sale of shares of non-voting Series A Convertible Preferred Stock, which may not be converted until September 2023 and not until March 2025 without surrendering the right to an annual dividend. Also, on March 13, 2023 the Company entered into a securities purchase agreement for Series A Convertible Notes with an aggregated principal amount of \$11.1 million, which may not be converted until September 2023. Further details of these transactions are available on Form 8-K notices filed with the Securities and Exchange Commission. The proceeds of these offerings will extend the Company's cash runway well into 2024, through near-term commercial milestones, including expanded market access.
- Lucid management confirms that the entirety of its cash and cash-equivalent instruments are held at JP Morgan, and that it does not hold any cash at Silicon Valley Bank (SVB) or any other financial institution whose deposits have been reported to be at risk.

## Financial Results

- For 4Q22, EsoGuard related revenues were \$0.1 million while for the year ended December 31, 2021, revenues were \$0.3 million. Fourth-quarter and full-year 2022 operating expenses were approximately \$24.6 million and \$91.3 million, respectively, which include stock-based compensation expenses of \$4.9 million and \$19.5 million, respectively. GAAP net loss attributable to shareholders for the fourth quarter and full-year 2022 were approximately \$14.9 million and \$56.2 million, or \$(0.47) and \$(1.55) 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 year ended December 31, 2022, were approximately \$10.6 million and \$39.2 million or \$(0.33) and \$(1.08) per common share.

- Lucid had cash and cash equivalents of \$22.5 million as of December 31, 2022, compared with \$53.7 million as of December 31, 2021. Subsequent to December 31, 2022, the company completed an initial closing for the issuance of preferred securities resulting in net proceeds of approximately \$13.6 million and entered into a Securities Purchase Agreement to issues Secured Convertible Debt in the principal amount of \$11.1 million.

### 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 December 31, 2022, and 2021 are as follows:

	For the three months ended December 31,		For the years ended December 31,	
	2022	2021	2022	2021
<b>Revenue</b>	\$ 112	\$ 300	\$ 377	\$ 500
<b>Operating expenses</b>	15,040	11,541	56,548	27,919
<b>Other (Income) expense</b>	-	65	-	659
<b>Net loss</b>	(14,928)	(11,306)	(56,171)	(28,078)
<b>Net income (loss) per common share, basic and diluted</b>	\$ (0.47)	\$ (0.32)	\$ (1.55)	\$ (1.51)
Adjustments:				
Depreciation and amortization expense <sup>1</sup>	615	1	1,936	4
Interest expense, net	-	512	-	659
<b>EBITDA</b>	(14,313)	(10,793)	(54,235)	(27,415)
<b>Other non-cash or financing related expenses:</b>				
Stock-based compensation expense <sup>2</sup>	3,740	3,443	14,991	9,599
<b>Non-GAAP adjusted (loss)</b>	<u>\$ (10,573)</u>	<u>\$ (7,350)</u>	<u>\$ (39,244)</u>	<u>\$ (17,816)</u>
Basic and Diluted shares outstanding	31,923	34,918	36,172	18,604
Non-GAAP adjusted (loss) income per share	(\$0.33)	(\$0.21)	(\$1.08)	(\$0.96)

<sup>1</sup> Included in general and administrative expenses in the financial statements.

<sup>2</sup> Included in other income and expenses.

Non-GAAP Operating Expenses	For the three months ended December 31,		For the years ended December 31,	
	2022	2021	2022	2021
<b>Cost of revenue</b>	1,618	441	3,614	585
Stock-based compensation expense	(7)	-	(16)	-
<b>Net cost of revenue</b>	<u>\$ 1,611</u>	<u>\$ 441</u>	<u>\$ 3,598</u>	<u>\$ 585</u>
<b>Amortization of acquired intangible assets</b>	<u>505</u>	<u>-</u>	<u>1,649</u>	<u>-</u>
<b>Sales and marketing expense total</b>	5,013	2,633	16,134	5,260
Stock-based compensation expense	(392)	(210)	(1,622)	(210)
<b>Net sales and marketing expense</b>	<u>\$ 4,621</u>	<u>\$ 2,423</u>	<u>\$ 14,512</u>	<u>\$ 5,050</u>
<b>General and administrative expense total</b>	5,462	4,985	23,685	12,778
Depreciation and amortization expense	(110)	(1)	(287)	(4)
Stock-based compensation expense	(3,225)	(3,123)	(12,953)	(9,111)
<b>Net general and administrative expense</b>	<u>\$ 2,127</u>	<u>\$ 1,861</u>	<u>\$ 10,445</u>	<u>\$ 3,663</u>
<b>Research and development expense total</b>	2,442	3,482	11,466	9,296
Stock-based compensation expense	(116)	(110)	(400)	(278)
<b>Net research and development expense</b>	<u>\$ 2,326</u>	<u>\$ 3,372</u>	<u>\$ 11,066</u>	<u>\$ 9,018</u>
<b>Total operating expenses</b>	15,040	11,541	56,548	27,919

Depreciation and amortization	(615)	(1)	(1,936)	(4)
Stock-based compensation expense	(3,740)	(3,443)	(14,991)	(9,599)
Net Non-GAAP operating expenses	<u>\$ 10,685</u>	<u>\$ 8,097</u>	<u>\$ 39,621</u>	<u>\$ 18,316</u>

## 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, 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.

For more information, please visit [luciddx.com](http://luciddx.com) and for more information about its parent company PAVmed, please visit [pavmed.com](http://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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