

August 15, 2022



# Lucid Diagnostics Provides Business Update and Preliminary Second Quarter 2022 Financial Results

*EsoGuard test volume increased 60% for quarter and over 300% annually*

*CLIA-Certified LucidDx Labs fully operational and billing as an independent entity*

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

NEW YORK--(BUSINESS WIRE)-- [Lucid Diagnostics Inc.](#) (Nasdaq: LUCD) (“Lucid”, 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 preliminary financial results for the three and six months ended June 30, 2022.

## Conference Call and Webcast

A conference call and webcast for today’s business update and second 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 conference call will be available live via a webcast 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: 13730496.

## Business Update Highlights

“The past quarter and recent weeks have been a transformational period for Lucid, during which we have achieved key milestones which represent the final bricks in the foundation upon which we are building this company and driving its long-term growth strategy,” said [Lishan Aklog, M.D.](#), Lucid’s Chairman and Chief Executive Officer. “We now have a consensus among the major specialty societies which explicitly support the use of our products to prevent esophageal cancer deaths through early detection of esophageal precancer, and further expand our addressable market. And, for the first time, we are truly, from an operational perspective, an independent full-service medical diagnostic company capable of fulfilling the clinical and economic potential of these products.”

Highlights from the second quarter and recent weeks include:

- LucidDx Labs Inc. (“LucidDx Labs”), Lucid’s wholly owned CLIA-certified, CAP-accredited clinical laboratory is fully staffed and operational. The laboratory processed 850 commercial EsoGuard tests in the second quarter of 2022, which represents a

60% increase sequentially from the first quarter of 2022 and an over 300% increase annually from the second quarter of 2021. The proportion of tests performed at Lucid Test Centers increased and now represents about two-thirds of overall testing volume.

- Lucid continued its steady expansion of its sales team, particularly sales representatives who call on primary care physicians, and is progressing well toward reaching its year-end target of 39 such sales representatives and a total of 58 sales professionals. In concert with this expansion, we continue to hone our highly structured and data-driven standard operating procedures for sales processes and sales training.
- Lucid commenced stage two of its Lucid Test Center program launching new Lucid Test Centers in four new metropolitan areas: Orange County, California, the Dallas-Fort Worth, Texas metropolitan area, Palm Beach County, Florida, and Columbus, Ohio.
- LucidDx Labs' new revenue cycle management (RCM) partner is now in place and has commenced submitting claims to commercial payers. It also entered into four new participating provider agreements, including preferred provider organizations [Prime Health Services](#), [Three Rivers Provider Network](#), and [Galaxy Health Network](#) (the "PPOs"), as well as [Alivio Health](#), a specialized diagnostic laboratory network, covering millions of lives.
- Lucid and over a dozen partner entities, including key opinion leaders, National Cancer Institute-funded investigators, professional medical societies, patient and industry advocacy groups, participated in the now completed public comment periods following publication of a proposed "foundational" Local Coverage Decision by Medicare Administrative Contractor ("MAC") Palmetto GBA's MoIDX program as well as Noridian Healthcare Solutions, the MAC with jurisdiction over LucidDx Labs.
- [The American Gastroenterological Association](#) ("AGA") updated its clinical practice guideline entitled "[AGA Clinical Practice Update on New Technology and Innovation for Surveillance](#)," the first such update since 2011, following in the footsteps of the American College of Gastroenterology ("ACG"), which published a similar update in April. Both leading specialty associations now support Lucid's EsoCheck<sup>®</sup> Cell Collection Device and EsoGuard<sup>®</sup> Esophageal DNA Test as an acceptable alternative to endoscopy. Both guidelines expand the target population and addressable market opportunity for these products by no longer hedging on screening women. The AGA further expands the target population by now, for the first time, including asymptomatic patients in their recommendations who otherwise present with the applicable risk factors.

## Preliminary Financial Results

- For the three months ended June 30, 2022, due to an extended transition period following the opening of our LucidDx Labs and the onboarding of a new revenue cycle management ("RCM") partner, initial submission of claims by our RCM provider did not occur until after June 30, 2022. Presently, recognized revenue for GAAP purposes is measured by actual collections during the period. Accordingly, there were no EsoGuard revenues recorded for the 850 tests performed for the three months ending June 30, 2022. Operating expenses were approximately \$14.6 million, which include stock-based compensation expenses of \$3.8 million. GAAP net loss attributable to common stockholders was approximately \$14.6 million, or \$(0.41) 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, 2022, was approximately \$10.1 million or \$(0.28) per common share.

- Lucid had cash and cash equivalents of \$32.7 million as of June 30, 2022, compared to \$53.7 million as of December 31, 2021.
- The unaudited financial results for the three months ended June 30, 2022, are expected to be filed with the SEC on Form 10-Q on August 15, 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 six months ended June 30, 2022, and 2021 is as follows:

	For the three months ended June 30,		For the six months ended June 30,	
	2022	2021	2022	2021
Revenue	\$ -	\$ -	\$ 189	\$ -
Gross profit	-	-	(180)	-
Operating expenses	14,624	6,016	26,714	9,669
Other (Income) expense	-	147	-	147

<b>Net loss</b>	(14,624)	(6,163)	(26,894)	(9,816)
<b>Net income (loss) per common share, basic and diluted</b>	<u>\$ (0.41)</u>	<u>\$ (0.44)</u>	<u>\$ (0.76)</u>	<u>\$ (0.70)</u>
Adjustments:				
Depreciation and amortization expense <sup>1</sup>	704	-	728	3
Interest expense, net <sup>3</sup>	-	147	-	147
<b>EBITDA</b>	<u>(13,920)</u>	<u>(6,016)</u>	<u>(26,166)</u>	<u>(9,666)</u>
<b>Other non-cash or financing related expenses:</b>				
Stock-based compensation expense <sup>3</sup>	3,843	2,580	7,679	3,384
<b>Non-GAAP adjusted (loss)</b>	<u>(10,077)</u>	<u>(3,436)</u>	<u>(18,487)</u>	<u>(6,282)</u>
Basic and Diluted shares outstanding	35,760	14,115	35,444	14,115
Non-GAAP adjusted (loss) income per share	(\$ 0.28)	(\$ 0.24)	(\$ 0.52)	(\$ 0.45)

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

	For the three months ended June 30,		For the six months ended June 30,	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
<b><sup>2</sup> Stock-based compensation ("SBC") expenses:</b>				
<b>Sales and Marketing expense total</b>	3,873	1,021	7,191	1,710
Stock-based compensation expense	(375)	-	(816)	-
Net commercial operations expense excluding SBC	<u>3,498</u>	<u>1,021</u>	<u>6,375</u>	<u>1,710</u>
<b>General and administrative expense total</b>	7,311	3,122	13,202	4,334
Stock-based compensation expense	(3,390)	(2,505)	(6,659)	(3,294)
Net general and administrative expense excluding SBC	<u>3,921</u>	<u>617</u>	<u>6,543</u>	<u>1,040</u>
<b>Research and development expense total</b>	3,440	1,873	6,321	3,625
Stock-based compensation expense	(78)	(75)	(204)	(90)
Net research and development expense excluding SBC	<u>3,362</u>	<u>1,798</u>	<u>6,117</u>	<u>3,535</u>
<b>Total operating expenses</b>	14,624	6,016	26,714	9,669
Stock-based compensation expense	(3,843)	(2,580)	(7,679)	(3,384)
Net operating expenses excluding SBC	<u>10,781</u>	<u>3,436</u>	<u>19,035</u>	<u>6,285</u>

## 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 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® 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. 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. 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 has been monitoring the COVID-19 pandemic and the pandemic's impact on Lucid's businesses. Lucid expects the significance of the COVID-19 pandemic, including the extent of its effect on its financial and operational results, to be dictated by, among other things, the success of efforts to contain the pandemic and the impact of such efforts 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 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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