

Lucid Diagnostics Provides Business Update and Preliminary Fourth Quarter and Full Year 2021 Financial Results

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 year ended December 2021.

Conference Call and Webcast

A conference call and webcast for today's business update and fourth quarter and year ended December 31, 2021, 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. or 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 www.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: 13727145.

Business Update Highlights

"I am happy to report that Lucid Diagnostics is firing on all cylinders," said [Lishan Aklog, M.D.](#), Lucid's Chairman and Chief Executive Officer. "Our rapidly growing team is making excellent progress on all fronts and is laying a solid foundation for us to continue driving our long-term growth strategy. This includes EsoGuard commercialization, the rollout of our Lucid Test Center network, expansion of our sales infrastructure and operations, our laboratory operations, and clinical trial work. Our strong balance sheet provides us with the resources to execute on this strategy."

- The Company reported solid EsoGuard commercialization progress with excellent traction and robust growth in EsoGuard testing volume. Lucid processed 303 commercial EsoGuard tests in the fourth quarter of 2021, which represents an approximately 50% increase sequentially from the third quarter and a nearly 200% increase annually from the fourth quarter of 2020. This growth has continued into the new year, both in referrals to Lucid Test Centers and tests performed at gastroenterology and foregut surgeon practices.
- The Lucid Test Center program has completed its first stage, having advanced from a pilot program in Phoenix, launched in the third quarter of 2021, to a regional Southwest and Pacific Northwest program also covering Denver, Salt Lake City, Las Vegas, Seattle, Portland, and Boise. The Company reported that its experience with the test centers over the past six months has validated the test center model as a key driver of EsoGuard testing volume by simplifying the engagement of its sales reps with primary care physicians. Lucid is now in the process of launching the next stage of its Lucid Test Center program, with accelerated expansion into larger states across the nation. It has hired an experienced Director of Clinical Services who will oversee this expansion. The Company is also continuing the pilot of its EsoGuard Telemedicine Program, operated in partnership with independent third-party telemedicine provider UpScript, which launched in December 2021. It has pursued a direct-to-consumer advertising program on a limited pilot basis in Phoenix.
- The Company reported significant expansion of its sales infrastructure and operations during the fourth quarter and recent months. The team, led by its national VP of sales, now consists of three area directors covering the East, Central and West respectively, six market development managers, ten sales representatives, and several sales operations staff. The company expects the overall sales team to double in size and the number of sales reps to triple by the end of the calendar year. The company also reported substantial progress in honing its data and analytics driven sales process and intensive sales training to drive commercial success.
- Last month the Company announced that LucidDx Labs, a wholly-owned subsidiary of Lucid, had acquired certain licenses and other related assets from its long time CLIA laboratory partner, Research Dx, which allowed it to operate own new CLIA-certified, CAP-accredited clinical laboratory in Lake Forest, CA. The Laboratory has completed the necessary assay validations to process clinical samples as a Laboratory Developed Test (LDT), completed a College of American Pathologists (CAP) audit, and begun performing

EsoGuard testing at the new facility.

- In conjunction with it taking over the laboratory and fully controlling the EsoGuard billings and collection process, the Company has been able to upgrade our revenue cycle management provider and simplify the billing and collections process it had to utilize as a partner of a third-party commercial laboratory. It is now in position to start submitting Medicare claims using the effective \$1938 Medicare payment rate. The Company continues to wait for Medicare Administrative Contractor Palmetto GBA's MoIDx program to issue a draft local coverage determination (LCD) following an encouraging Contractor Advisory Committee (CAC) meeting in the fall.
- The laboratory has been submitting claims to private payors and is encouraged that it has been receiving approximately \$1,150 per test representing approximately 60% out-of-network coverage. It reported that is reaching critical threshold of submitted and processed claims in certain locales which will allow it to begin having meaningful conversations with select private payors in these locales on in-network payment and coverage. It is expanding its market access team and collecting the critical clinical utility data to allow it to fully engage in these negotiations.
- In March 2022, both the PAVmed and Lucid board of directors approved entering into an intercompany license between PAVmed and Lucid such that Lucid will be granted the rights to commercialize EsoCure for the endoscopic treatment of late esophageal precancer (dysplastic Barrett's Esophagus), including a royalty arrangement whereby Lucid will pay PAVmed a 5% royalty on all EsoCure sales up to \$100 million per calendar year, and 8% above that threshold.
- In March 2022, both the PAVmed and Lucid board of directors approved entering into a purchase and sale of the CapNostics, LLC assets, including the EsophaCap® non-endoscopic sponge-based esophageal cell collection device, from PAVmed to Lucid as well as transferring the consulting agreement with the principal owner of CapNostics, LLC prior to the purchase by PAVmed on October 5, 2021.

Preliminary Financial Results

- For the fourth quarter of 2021, EsoGuard related revenues were \$0.3 million, while for the year ended December 31, 2021, revenues were \$0.5 million. Fourth-quarter and full-year 2021 operating expenses were approximately \$11.1 million and \$27.3 million, respectively, which include stock-based compensation expenses of \$3.2 million and \$9.6 million, respectively. GAAP net loss attributable to common stockholders for the fourth quarter and full-year 2021 were approximately \$11.3 million and \$28.1 million, or \$(0.32) and \$(1.51) 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 fourth quarter and year ended December 31, 2021, were approximately \$7.7 million and \$17.8 million or \$(0.22) and \$(0.96) per common share.
- Lucid had cash and cash equivalents of \$53.7 million as of December 31, 2021, compared to \$0.1 million as of December 31, 2020.
- On March 28, 2022, the Company entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with CF Principal Investments LLC ("Cantor"), an affiliate of Cantor Fitzgerald, relating to a committed equity facility (the "Facility"). Pursuant to the Purchase Agreement, the Company has the right to sell to Cantor up to \$50.0 million of its common shares (the "Shares"), subject to certain conditions and limitations set forth in the Purchase Agreement. While there are distinct differences, the Facility is structured similarly to a traditional at-the-market equity facility, insofar as it allows the Company to raise primary equity capital on a periodic basis at a price related to the current market price.
- Sales of the Shares to Cantor under the Purchase Agreement, and the timing of any sales, will be determined by the Company from time to time at its sole discretion and will depend on a variety of factors, including, among other things, market conditions, the trading price of the Shares and determinations by the Company regarding the use of proceeds of such Shares. Upon the satisfaction of the conditions to Cantor's obligation to purchase Shares, the Company will have the right, from time to time during the 36-month period after the commencement of the Facility, to direct Cantor to purchase up to a maximum number of Shares on any trading day. The purchase price of the Shares will be 96% of the volume-weighted average price of the Shares on such trading day.
- The unaudited financial results for the year ended December 31, 2021, will be filed with the SEC on Form 10-K in the coming days and will be 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 fourth quarter and year ended December 31, 2021, and 2020 is as follows

	For the three months ended December 31,		For the year ended December 31,	
	2021	2020	2021	2020
Revenue	\$ 300	\$ -	\$ 500	\$ -
Gross profit	(141)	-	(85)	-
Operating expenses	11,100	2,731	27,334	8,280
Interest expense	65	-	659	-
Net loss	(11,306)	(2,731)	(28,078)	(8,280)
Net income (loss) per common share, basic and diluted	\$ (0.32)	\$ (0.19)	\$ (1.51)	\$ (0.59)
Adjustments:				
Depreciation and amortization expense ¹	-	-	3	-
Interest expense, net ³	65	-	659	-
EBITDA	(11,241)	(2,731)	(27,416)	(8,280)
Other non-cash or financing related expenses:				
Stock-based compensation expense ³	3,542	16	9,599	65
Non-GAAP adjusted (loss)	(7,699)	(2,715)	(17,817)	(8,215)
Basic and Diluted shares outstanding	34,918	14,115	18,604	14,114
Non-GAAP adjusted (loss) income per share	\$ (0.22)	\$ (0.19)	\$ (0.96)	\$ (0.58)

¹ Included in general and administrative expenses in the financial statements

² Included in other income and expenses

	For the three months ended December 31,		For the year ended December 31,	
	2021	2020	2021	2020
³ Stock-based compensation ("SBC") expenses:				
Commercial operations expense total	978	335	5,260	1,305
Stock-based compensation expense	-	-	(210)	-
Net commercial operations expense excluding SBC	978	335	5,050	1,305
General and administrative expense total	3,398	471	12,778	1,532
Stock-based compensation expense	(3,123)	-	(9,111)	-

Net general and administrative expense excluding SBC	275	471	3,667	1,532
Research and development expense total	2,190	1,216	9,296	5,443
Stock-based compensation expense	(110)	(16)	(278)	(65)
Net research and development expense excluding SBC	2,080	1,200	9,018	5,378
Total operating expenses	6,566	2,022	27,334	8,280
Stock-based compensation expense	(3,233)	(16)	(9,599)	(65)
Net operating expenses excluding SBC	3,333	2,006	17,735	8,215

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% 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 and EsoCheck are the missing element and constitute 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.

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 third-party CLIA-certified laboratory partner 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 two large, actively enrolling, international multicenter clinical trials to support FDA PMA approval. Lucid is building nationwide direct sales and marketing team targeting primary care physicians, gastroenterologists, and consumers, 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, follow Lucid on [Twitter](#), and connect with Lucid on [LinkedIn](#). For detailed information on EsoGuard, please visit 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 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.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20220328005856/en/>

Investors

Adrian K. Miller

PAVmed Inc.

AKM@PAVmed.com

Media

Shani Lewis

LaVoieHealthScience

(609) 516-5761

PAVmed@lavoiehealthscience.com

Source: Lucid Diagnostics Inc.

Released March 28, 2022

<https://ir.pavmed.com/2022-03-28-Lucid-Diagnostics-Provides-Business-Update-and-Preliminary-Fourth-Quarter-and-Full-Year-2021-Financial-Results>