

May 17, 2021



# PAVmed Provides Business Update and First Quarter 2021 Financial Results

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

NEW YORK, May 17, 2021 (GLOBE NEWSWIRE) -- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ)** (the “Company” or “PAVmed”), a highly differentiated, multi-product, commercial-stage medical device company, today provided a business update for the Company and its major subsidiary, Lucid Diagnostics Inc. (“Lucid”), and discussed financial results for the three months ended March 31, 2021.

“I am delighted with the solid momentum we have experienced during the first quarter of 2021 and in subsequent weeks,” said Lishan Aklog, M.D., PAVmed’s Chairman and Chief Executive Officer. “We continue to expand our commercial infrastructure and drive EsoGuard commercialization, while advancing products across our portfolio. We have strengthened our balance sheet, with \$49 million in cash as of March 31, 2021, sufficient to fund our current operations into 2023, and no debt. We also continue to take important steps to support an expanded strategic vision to enhance shareholder value, including seeking to take Lucid public, adding deep commercial experience to our Board of Directors, and exploring exciting new opportunities to partner on groundbreaking innovations.”

## Conference Call and Webcast

A conference call and webcast for today’s business update and first quarter 2021 financial results will take place at 4:30 PM EDT. To access the conference call, listeners should dial (877) 407-3982 toll-free in the U.S. or (201) 493-6780, and ask to join the “PAVmed, Inc. Business Update Conference Call”. The conference call will be available live via webcast and for replay at the investor relations section of the Company’s website at [www.pavmed.com](http://www.pavmed.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: 13719121.

## Business Update Highlights

- Lucid significantly expanded its full-time commercial team to accelerate execution of a pillar of its growth strategy, commercializing its EsoGuard<sup>®</sup> Esophageal DNA Test across multiple channels. Hired four industry veterans into senior leadership roles – Director of Sales, VP of Market Access & Reimbursement, National Sales Training Manager and Strategic Accounts Manager.
- EsoGuard testing accelerated as pandemic-related healthcare facility limitations eased. Lucid processed 78 EsoGuard tests in Q1 and 96 in the first half of Q2. Clinicians have been trained, and EsoCheck<sup>®</sup> Cell Collection Devices and EsoGuard Specimen Kits are in stock, at approximately 180 U.S. accounts. Lucid began to submit EsoGuard

claims in Q1, once CMS payment became effective on January 1<sup>st</sup>, and has recently begun to receive out-of-network private insurance payments.

- Preparatory work completed on Lucid's pilot program to expand EsoGuard commercialization to primary care physicians and consumers. Lucid hired clinical personnel and leased medical office space to launch three Lucid Test Centers in Phoenix, Arizona. Centers expected to be ready to accept physician referrals for EsoGuard testing in the coming weeks, once necessary regulatory and compliance infrastructure finalized in consultation with Lucid Board's new Compliance & Quality Committee. Direct-to-consumer marketing to commence once contractual arrangements with telemedicine company finalized.
- Lucid announced intent to go public as a stand-alone medical diagnostics company, assuming market conditions remain favorable, with PAVmed retaining a controlling majority equity interest in Lucid. Seeks to raise own capital to drive growth strategy to expand EsoGuard commercialization as well as its base of clinical evidence to support inclusion in clinical guidelines. Lucid's Board determined that the best interests of shareholders are served by going public through an initial public offering ("IPO").
- Lucid's new full-time VP of Market Access and Reimbursement working with two consulting firms to assemble strongest possible data package to support securing contracts with private payors for EsoGuard coverage and payment. First meeting with medical directors of major insurers to be held later this week. Await notification of CMS local coverage determination, as Medicare Administrative Contractor works through a pandemic and transition-related backlog.
- Lucid passed final Stage 2 Audit of the quality management systems by EU-based Notified Body. Recently notified that review of EsoCheck Technical File complete and final summary report submitted. EsoCheck CE Mark approval under MDD, and completion of EsoGuard IVDD self-certification expected prior to the EU's May 26<sup>th</sup> transition to new MDR regulatory regime.
- Lucid is actively enrolling U.S. patients in two international multi-center clinical studies, ESOGUARD-BE-1 and ESOGUARD-BE-2, to support a PMA application for FDA IVD registration of EsoGuard on samples collected using EsoCheck. European sites expected to begin enrolling patients this summer. Completion of study enrollment and PMA application submission expected in 2022.
- Lucid contacted FDA to begin discussions pursuant to its FDA Breakthrough Device designation for EsoGuard on samples collected using EsoCheck. Will seek FDA input on an extension of ESOGUARD-BE-1 screening study, sufficiently powered for an expanded indication to detect dysplastic Barrett's Esophagus, to support inclusion in clinical guidelines.
- Lucid working to transfer EsoCheck manufacturing to Coastline International Inc., a high-volume manufacturer based in San Diego, CA with production facilities in Mexico, by the end of 2021, which will increase EsoCheck manufacturing capacity up to one million units per year.
- PAVmed hired full-time CarpX National Sales Manager with over a decade of

experience in orthopedic sales, including successful launch and commercialization of a minimally invasive carpal tunnel release device. Tasked with reorganizing the CarpX advisory panel to accelerate procedural volume consistent with the steady and deliberate initial commercialization plan, focused on optimizing the procedural steps and safety prior to broader commercialization effort later this year.

- PAVmed informed by its EU-based Notified Body that review of CarpX Technical File is complete. Await final summary report submission. CarpX CE Mark approval under MDD expected prior to the EU's May 26<sup>th</sup> transition to new MDR regulatory regime.
- PAVmed completed in-person site initiation visits for PortIO study at four medical centers in Colombia, South America. Awaiting IRB approval and expect to begin enrollment this summer. Completing additional long-term animal studies while awaiting FDA re-opening of non-COVID pre-submission processes to discuss protocol for U.S. PortIO IDE study.
- PAVmed initiated design freeze verification testing in preparation for final verification and validation testing of NextFlo Intravenous Infusion Set, to support FDA 510(k) submission with clearance targeted for first half of 2022. Discussions and technologic diligence engagement with large strategic partner to license NextFlo technology for disposable infusion pumps continue while PAVmed advances technology towards self-commercialization.
- PAVmed completed acute and survival animal study of EsoCure<sup>™</sup> Esophageal Ablation Device, demonstrating successful direct thermal balloon catheter ablation of esophageal lining through working channel of standard endoscope using its proprietary CalduS<sup>™</sup> Technology.
- PAVmed, in close collaboration with research, development and manufacturing partner, Canon USA, advancing DisappEAR resorbable silk pediatric ear tubes to support FDA 510(k) submission targeted for late 2021.
- PAVmed and subsidiary Solys Diagnostics terminated a third-party license agreement and decided to advance own proprietary non-invasive glucose monitoring technology. Expect prototype to be ready for testing in human volunteers and a diabetic animal model later this year.
- PAVmed raised approximately \$58 million in gross proceeds from common stock equity offerings in Q1, including an underwritten \$45 million common stock public offering led by Cantor Fitzgerald & Co. Used approximately \$15 million to retire all outstanding convertible debt.
- PAVmed appointed prominent UK-based global industry executive, Debbie White, to its Board of Directors. Ms. White providing valuable guidance on strategy, operations, finance, and international commercialization.
- Lucid appointed nationally recognized healthcare executive Dr. Jacque Sokolov to its Board of Directors. Dr. Sokolov established and serves as the inaugural Chair of the Board's new Compliance & Quality Committee.

## FINANCIAL RESULTS

For the three months ended March 31, 2021, research and development expenses were \$3.3 million and general and administrative expenses were \$4.8 million. GAAP net loss attributable to common stockholders was \$9.5 million, or \$(0.13) per common share. As shown below and for the purpose of illustrating the effect of derivative accounting and other non-cash income and expenses on the Company's financial results, the Company reported a non-GAAP adjusted loss for the three months ended March 31, 2021, of \$5.9 million or \$(0.08) per common share.

PAVmed had cash and cash equivalents of \$48.5 million as of March 31, 2021, compared with \$17.3 million as of December 31, 2020.

The unaudited financial results for the three months ended March 31, 2021, as reported to the SEC on Form 10-Q can be obtained at [www.pavmed.com](http://www.pavmed.com) or [www.sec.gov](http://www.sec.gov).

### 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, loss on the issuance or modification of convertible securities, the periodic change in fair value of convertible securities, and loss on debt extinguishment. 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 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 ended March 31, 2021, and 2020 is as follows:

(ooo's except per-share amounts)	For the three months ended March 31,	
	2021	2020
<b>Net income (loss) per common share, basic and diluted</b>	\$ (0.13)	\$ (0.33)
<b>Net loss attributable to common stockholders</b>	(9,506)	(14,545)
Preferred Stock dividends and deemed dividends	75	70
<b>Net income (loss) as reported</b>	(9,431)	(14,475)
Adjustments:		
Depreciation expense <sup>1</sup>	12	3
Interest expense, net <sup>3</sup>	-	52
<b>EBITDA</b>	(9,419)	(14,420)
<b>Other non-cash or financing related expenses:</b>		
Stock-based compensation expense <sup>2</sup>	1,436	344
Debt extinguishment <sup>3</sup>	3,715	1,188
Change in FV convertible debt <sup>3</sup>	(1,682)	8,008
Offering costs convertible debt <sup>3</sup>	-	410
<b>Non-GAAP adjusted (loss)</b>	(5,950)	(4,470)
Basic and Diluted shares outstanding	73,954	43,500
Non-GAAP adjusted (loss) income per share	(\$ 0.08)	(\$ 0.10)

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

<sup>2</sup> For the three months ended March 31, 2021 includes \$1,118 of stock based compensation expense reported as general and administrative expenses, \$202 as sales and marketing expenses, and \$116 reported as research and development expense. For the three months ended March 31, 2020 includes \$244 of stock based compensation expense reported as general and administrative expenses, \$33 as sales and marketing expenses, and \$67 reported as research and development expenses.

<sup>3</sup> Included in other income and expenses

## About PAVmed and Lucid

PAVmed Inc. is a highly differentiated, multi-product, commercial-stage medical technology company with a diversified product pipeline addressing unmet clinical needs encompassing a broad spectrum of clinical areas with attractive regulatory pathways and market opportunities. Its major subsidiary, Lucid Diagnostics Inc., markets the first and only commercial tools for widespread early detection of esophageal precancer and cancer – the EsoGuard<sup>®</sup> Esophageal DNA Test and EsoCheck<sup>®</sup> Esophageal Cell Collection Device. Its GI Health division also includes the complementary EsoCure<sup>™</sup> Esophageal Ablation Device with CalduS<sup>™</sup> Technology. Its Minimally Invasive Interventions markets its CarpX<sup>®</sup> Minimally Invasive Device for Carpal Tunnel Syndrome. Other divisions include Infusion Therapy (PortIO<sup>™</sup> Implantable Intraosseus Vascular Access Device and NextFlo<sup>™</sup> Intravenous Infusion Set), and Emerging Innovations (non-invasive laser-based glucose monitoring, pediatric ear tubes, and mechanical circulatory support). For more information, please visit [www.pavmed.com](http://www.pavmed.com), follow us on [Twitter](#), connect with us on [LinkedIn](#), and watch our videos on [YouTube](#). For more information on our majority owned subsidiary, Lucid Diagnostics Inc., 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 statements that are not historical facts. Such forward-looking statements, based upon the current beliefs and expectations of PAVmed'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, our ability to complete our strategic initiatives, volatility in the price of PAVmed's common stock, Series W Warrants and Series Z Warrants; general economic and market conditions; the uncertainties inherent in research and development, including the cost and time required advance PAVmed's products to regulatory submission; whether regulatory authorities will be satisfied with the design of and results from PAVmed's preclinical studies; whether and when PAVmed's products are cleared by regulatory authorities; the effectiveness of our marketing initiatives; the establishment of government and private payment insurance coverage; market acceptance of PAVmed's products once cleared and commercialized; our ability to raise additional funding and other competitive developments. PAVmed has not yet received clearance from the FDA or other regulatory body to market many of its products. The Company has been monitoring the COVID-19 pandemic and its impact on our business. The Company expects the significance of the COVID-19 pandemic, including the extent of its effect on the Company's financial and operational results, to be dictated by, among other things, the success of efforts to contain it and the impact of actions taken in response. New risks and uncertainties may arise from time to time and are difficult to predict. All of these factors are difficult or impossible to predict accurately and many of them are beyond PAVmed's control. For a further list and description of these and other important risks and uncertainties that may affect PAVmed's future operations, see Part I, Item 1A, "Risk Factors," in PAVmed'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 PAVmed after its most recent Annual Report. PAVmed 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.

### Contacts:

Investors

Mike Havrilla

Director of Investor Relations

(814) 241-4138

[JMH@PAVmed.com](mailto:JMH@PAVmed.com)

Media

Shaun O'Neil

Chief Commercial Officer

(518) 812-3087

[SMO@PAVmed.com](mailto:SMO@PAVmed.com)

Jim Heins / Katie Gallagher

LaVoieHealthScience

(646) 491-7042 / (617) 792-3937  
[PAVmed@lavoiehealthscience.com](mailto:PAVmed@lavoiehealthscience.com)



Source: PAVmed Inc.