

February 22, 2021



PAVmed Provides Business Update and Preliminary Fourth Quarter 2020 Financial Results

Announces majority-owned subsidiary Lucid Diagnostics intends to spin-off into a separate public company

Lucid Diagnostics to launch major new multi-channel commercialization initiative for its EsoGuard Esophageal DNA Test

Conference call to be held today at 8:30 AM EST

NEW YORK, Feb. 22, 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 subsidiaries, Lucid Diagnostics Inc. (“Lucid”) and Solys Diagnostics Inc. (“Solys”), discussed preliminary financial results for the three and 12 months ended December 31, 2020 and made two strategic announcements regarding Lucid and its EsoGuard[®] product.

“Following a strong fourth quarter of 2020 and start of 2021, including raising over \$30 million from institutional investors, we find ourselves in the strongest financial position in our history and with the confidence and determination necessary to rapidly and effectively advance and expand our mission,” said Lishan Aklog, M.D., PAVmed’s Chairman and Chief Executive Officer. “In addition to providing an update on all areas of our business, we are making two important announcements regarding Lucid and EsoGuard consistent with that sentiment.”

Conference Call and Webcast

A conference call and webcast on today’s Business Update and Preliminary Fourth Quarter Financial Results will take place at 8:30 AM EST. To access the conference call, U.S.-based listeners should dial (877) 407-3982 and international listeners should dial (201) 493-6780. All listeners should provide the operator with the conference call name “PAVmed, Inc. Business Update Conference Call” to join. Individuals interested in listening to the live conference call via webcast may do so by visiting the investor relations section of the Company’s website at www.pavmed.com.

Lucid Diagnostics Spin-Off

The Company announced that its majority-owned subsidiary Lucid Diagnostics intends to spin off into a separate public company if favorable market conditions continue to hold, either through an initial public offering (“IPO”) or a business combination with a healthcare special purpose acquisition corporation (“SPAC”). The Lucid board of directors determined that this long-contemplated step is necessary for Lucid to fulfill its long-term potential, unlock its

present value, and execute on a major new commercial initiative. The Company believes that a Lucid spin-off that accomplishes the foregoing would also be in the best interests of PAVmed and its shareholders. PAVmed will remain Lucid's largest shareholder following any spin-off transaction.

Multi-Channel EsoGuard Commercialization Initiative

The Company also announced that Lucid is launching a major new commercial initiative which seeks to accelerate EsoGuard commercialization by simultaneously targeting multiple sales and marketing channels and building Lucid's own network of EsoCheck[®] operators to assure sufficient testing capacity and geographic coverage to accommodate demand.

Lucid plans to retain and train a network of full-time nurses or other clinical personnel to serve as EsoCheck operators deployed at different types of venues, including leased space in physician practices, and potentially at free-standing EsoGuard testing centers in locales where testing volume and economics can support them. Lucid also intends to seek joint-ventures with laboratory testing companies as well as pharmacy mini-clinic networks to establish EsoGuard testing capacity at their facilities.

Once sufficient EsoGuard testing capacity and geographic coverage has been established in a specific locale, Lucid plans to initiate multiple new sales and marketing channels, while continuing to aggressively drive adoption by gastroenterologists. These new channels include direct-to-consumer marketing, as well as sales and marketing directly targeting primary care physicians.

A pilot program in one major metropolitan area is planned for the second quarter.

Business Update Highlights

- PAVmed raised \$30.4 million in gross proceeds from three common stock registered direct offerings with institutional investors in December and January, including a \$13.4 million priced at-the-market offering in early January.
- Lucid initiated claims submission and billing for its EsoGuard Esophageal DNA Test after CMS payment of \$1938.01 for EsoGuard CPT code 0114U became effective on January 1, 2021. Continues to await EsoGuard local coverage determination from Medicare Administrative Contractor, Palmetto GBA. Engaged two leading consulting firms to help secure private payor payment and coverage. Completed preliminary insurance plan medical director interviews.
- Lucid expanded full-time sales team from four to seven regional business managers overseeing, over 50 independent sales representatives. Recruiting a team of clinical specialists who will train clinicians and support existing accounts while freeing up other sales personnel to focus on opening new accounts.
- Lucid launched consumer marketing campaign introducing an animated EsoGuard "mascot" to educate consumers on the link between chronic heartburn and esophageal cancer and to create EsoGuard visibility and awareness as a foundation for future direct-to-consumer marketing.
- EsoGuard testing volume rebounded following winter slowdowns related to Covid-19 surge and facility limitations during period of mass workforce vaccination. Anticipate return to accelerating EsoGuard testing volume growth in the coming quarter.
- ESOGUARD BE-1 and 2 studies in support of future PMA submission and FDA IVD

registration now have 40 of 60 study sites active and have enrolled approximately 70 patients total at U.S. sites. European site initiation postponed until second quarter due to travel restrictions. Target completion date adjusted to early 2022 due to cumulative Covid-related enrollment slowdowns.

- Lucid introduced an improved EsoGuard preservative buffer and received special 510(k) clearance to market a more user-friendly and precise EsoCheck accessory.
- PAVmed and Lucid successfully completed all EU-notified-body audits. Expect EsoCheck CE Mark approval and completion of EsoGuard EU IVDD self-certification in second quarter. Limited commercial launch in select EU countries planned for later this year.
- First U.S. carpal tunnel syndrome patient underwent successful CarpX[®] minimally invasive carpal tunnel release and returned to work within one week of the procedure, significantly shorter than recovery times following conventional surgery. Continuing steady and deliberate commercialization plan with a small team of world-class hand surgeons focused on optimizing the procedural steps and safety prior to broader commercialization effort later this year. Expect CarpX CE Mark approval in second quarter. Evaluating potential European distributors for future European commercial launch.
- PAVmed completed in-person site initiation visits for PortIO study at four Colombia, South America medical centers. Awaiting IRB approval and expect to begin enrollment next quarter. Remain engaged with FDA regarding US PortIO IDE study.
- PAVmed advancing NextFlo Intravenous Infusion system through design-controlled development and testing with FDA submission targeted for the third quarter. Ongoing M&A discussions and technologic diligence engagement with large strategic partner to license the NextFlo technology for disposable infusion pumps.
- PAVmed executed manufacturing services agreement for DisappEAR resorbable silk pediatric ear tubes with Canon Inc.'s United States manufacturing and technology center in Virginia. Received Canon-produced prototypes for upcoming animal testing pursuant to previously executed research and development agreement.
- Solys advanced research and development work on licensed non-invasive glucose monitoring technology, producing data in human volunteers and a diabetic rat model consistent with milestone accuracy parameters. In addition, developed and advanced its own proprietary non-invasive glucose monitoring technology which is not subject to the license agreement. Determined that it would be in PAVmed's best interests to focus future efforts on its own proprietary technology, terminate the license agreement, and seek a mutually agreeable unwinding of the relationship, which is currently being negotiated.

PRELIMINARY FINANCIAL RESULTS

For the three months ended December 31, 2020, research and development expenses were \$3.6 million and general and administrative expenses were \$3.9 million. GAAP net loss attributable to common stockholders was \$8.8 million, or \$(0.17) per common share. As illustrated below and for the purpose of helping the reader understand 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 December 31, 2020 of \$6.4 million or \$(0.12) per common share.

PAVmed had cash and cash equivalents of \$17.3 million as of December 31, 2020,

compared with \$6.2 million as of December 31, 2019. Subsequently, in early January 2021, the Company closed on its \$13.4 million registered direct offering for the sale of 6.0 million shares of common stock at \$2.24 per share which was priced at-the-market under Nasdaq rules.

The audited financial results for the year ended December 31, 2020 on Form 10-K will be filed with the SEC in the coming days and will be available at www.pavmed.com or 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 and 12 months ended December 31, 2020 and 2019 is as follows:

For the three months ended December 31,	For the year ended December 31,
_____	_____

(ooo's except per-share amounts)	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Net income (loss) per common share, basic and diluted	\$ (0.17)	\$ (0.19)	\$ (0.73)	\$ (0.55)
Net loss attributable to common stockholders	(8,813)	(6,313)	(34,563)	(16,727)
Preferred Stock dividends and deemed dividends	73	69	287	270
Net income (loss) as reported	(8,740)	(6,244)	(34,276)	(16,457)
Adjustments:				
Depreciation expense ¹	7	4	23	14
Interest expense, net ³	-	33	52	33
EBITDA	(8,733)	(6,207)	(34,201)	(16,410)
Other non-cash or financing related expenses:				
Stock-based compensation expense ²	585	393	2,044	1,571
Debt extinguishment ³	1,897	1,165	6,497	666
Change in FV convertible debt ³	(194)	(482)	3,467	341
Offering costs convertible debt ³	-	1,250	2,520	-
Non-GAAP adjusted (loss)	(6,445)	(3,881)	(19,673)	(13,832)
Basic and Diluted shares outstanding	52,487	33,223	45,564	29,212
Non-GAAP adjusted (loss) income per share	(\$0.12)	(\$0.12)	(\$0.43)	(\$0.47)

¹ Included in general and administrative expenses in the financial statements

² For the three months ended December 31, 2020 includes \$450 of stock based compensation expense reported as general and administrative expenses and \$136 reported as research and development expense. For the three months ended December 31, 2019 includes \$310 of stock based compensation expense reported as general and administrative expenses and \$84 reported as research and development expense. For the year ended December 31, 2020 includes \$1,581 of stock based compensation expense reported as general and administrative expenses and \$462 reported as research and development expense. For the year ended December 31, 2019 includes \$1,162 of stock based compensation expense reported as general and administrative expenses and \$408 reported as research and development expense.

³ Included in other income and expenses

Conference Call and Webcast

As announced last week, the Company changed the time for today's conference call and

webcast to 8:30 AM EST to accommodate the schedule of Lucid's Strategic Advisor, medical diagnostics pioneer Stanley Lapidus. Mr. Lapidus will join PAVmed Chairman and Chief Executive Officer Lishan Aklog, M.D., and President and Chief Financial Officer Dennis McGrath on the call.

Mr. McGrath will provide a financial update on the Company. Dr. Aklog will provide a business update and discuss Lucid's growth strategy with Mr. Lapidus, who will provide his perspective on Lucid's EsoGuard commercial opportunity, based on his similar experiences bringing early cancer detection technologies to market, including as the founder and former Chairman and CEO of Exact Sciences.

To access the conference call, U.S.-based listeners should dial (877) 407-3982 and international listeners should dial (201) 493-6780. All listeners should provide the operator with the conference call name "PAVmed, Inc. Business Update Conference Call" to join. Individuals interested in listening to the live conference call via webcast may do so by visiting the investor relations section of the Company's website at 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 from within the U.S. or (412) 317-6671 from outside the U.S. To access the replay, all listeners should provide the following pin number: 13715663. The webcast will be available for replay on the investor relations section of the Company's website at www.pavmed.com.

About PAVmed

PAVmed Inc. is a highly differentiated, multi-product, commercial-stage medical device company employing a unique business model designed to advance innovative products to commercialization rapidly and with less capital than the typical medical device company. This proprietary model enables PAVmed to pursue an expanding pipeline strategy with a view to enhancing and accelerating value creation while seeking to further expand its pipeline through relationships with its network of clinician innovators at leading academic centers. PAVmed's diversified product pipeline addresses unmet clinical needs encompassing a broad spectrum of clinical areas with attractive regulatory pathways and market opportunities. Its four operating divisions include GI Health (EsoGuard[®] Esophageal DNA Test, EsoCheck[®] Esophageal Cell Collection Device, and EsoCure[™] Esophageal Ablation Device with Calvus[™] Technology), Minimally Invasive Interventions (CarpX[®] Minimally Invasive Device for Carpal Tunnel Syndrome), Infusion Therapy (PortIO[™] Implantable Intraosseous Vascular Access Device and NextFlo[™] Highly Accurate Disposable 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, 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, 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 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 IA, "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

Media

Shaun O'Neil

Chief Commercial Officer

(518) 812-3087

SMO@PAVmed.com

Katie Gallagher

LaVoieHealthScience

(617) 792-3937

PAVmed@lavoiehealthscience.com



Source: PAVmed Inc.