

May 21, 2020



# PAVmed Reports Preliminary First Quarter 2020 Financial Results and Provides Business Update

*Conference call to be held today at 4:30 p.m. Eastern time*

NEW YORK, May 21, 2020 (GLOBE NEWSWIRE) -- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ)** (the “Company” or “PAVmed”), a highly differentiated, multiproduct medical device company, today reported preliminary financial results for the three months ended March 31, 2020 and provided a business update.

“We have continued to aggressively advance our strategic plan during the first quarter and recent weeks, including securing marketing clearance for our CarpX™ device,” said Lishan Aklog, M.D., PAVmed’s Chairman and Chief Executive Officer. “Our team has successfully confronted the challenges of the Covid-19 pandemic with minimal short-term and no anticipated long-term disruptions to our activities. We are encouraged that medical facilities are beginning to re-open with elective procedures restarting and look forward to achieving important milestones and accelerating commercial activities in the coming months.”

## RECENT ACCOMPLISHMENTS

- The Company received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) for its CarpX™ minimally invasive carpal tunnel device.
- PAVmed successfully recruited and engaged a CarpX™ National Sales Manager with over 20 years of commercial experience in the orthopedic space.
- The Company’s majority-owned subsidiary Lucid Diagnostics (“Lucid”) enrolled its first three patients in its international multi-center IVD clinical trials (ESOGUARD-BE-1 and 2) comparing EsoGuard™/EsoCheck™ to endoscopy. These trials include over 60 sites in the U.S. and Europe. Nicholas J. Shaheen MD, MPH, Professor and Chief of the Division of Gastroenterology and Hepatology at UNC HealthCare, and lead author of the most recent American College of Gastroenterology (ACG) guidelines, serves as principal investigator of both trials.
- Lucid submitted its final insurance reimbursement payment dossier to Medicare contractor Palmetto GBA and its molecular diagnostics program Mol Dx.
- The Company successfully completed an acute animal study of a working prototype of its EsoCure™ Esophageal Ablation Device, a disposable single-use thermal balloon ablation catheter designed to use its patented Calduz Technology to treat dysplastic Barrett’s Esophagus (BE) before it can progress to highly lethal esophageal cancer and to do so without the need for complex and expensive capital equipment. The EsoCure balloon catheter inserted through the working channel of a standard endoscope

circumferentially ablated the esophageal lining consistently and cleanly with ablation times far less than existing radiofrequency and cryoablation devices.

- Both PAVmed and Lucid received firm dates for the stage 1 audit of their quality systems by the EU notified body, which will allow them to restart efforts to pursue EU CE Mark clearance of EsoCheck, EsoGuard, CarpX and PortIO™ after delays related to a regulatory backlog in Europe due to systematic changes.
- PAVmed's majority-owned subsidiary, Solys Diagnostics ("Solys"), completed initial bench-top testing of its NDIR laser based non-invasive blood glucose diagnostic device demonstrating a linear response across a wide range of glucose concentrations.
- The Company continued to expand and advance its extensive intellectual property portfolio, which now includes over 130 issued and pending, owned, assigned or licensed patents across PAVmed and its subsidiaries.

## **UPCOMING KEY ACTIVITIES AND MILESTONES**

- Commercially launch CarpX and assemble a world-class Medical Advisory Board of hand surgeons to provide critical procedural development and professional education support.
- Accelerate and expand EsoGuard and EsoCheck commercial activities, including existing virtual sales and professional education, as well as aggressive marketing until clinical procedures can resume from Covid-19 limitations.
- Accelerate enrollment in ESOGUARD-BE-1 and 2 trials and initiate two additional clinical trials involving EsoCheck when clinical activities resume.
- Launch clinical trial of EsoCheck in Eosinophilic Esophagitis at the University of Pennsylvania.
- Launch clinical trial of EsoCheck with BE progression markers at Fred Hutchinson Cancer Research Center in Seattle.
- Submit final coverage dossier to Medicare contractor Palmetto GBA and its molecular diagnostics program Mol Dx. Continue discussions to secure payment and coverage decision for EsoGuard's CPT code.
- Complete ongoing formal M&A process seeking to secure a strategic partner or to license or acquire the Company's NextFlo™ technology for one or more clinical applications while simultaneously advancing NextFlo toward an initial FDA 510(k) submission later in 2020.
- Complete additional ongoing partnership discussions involving EsoGuard, EsoCheck and DisappEAR.
- Submit response to FDA comments following successful pre-submission meeting with the FDA on PortIO™ focused on the design of a clinical safety study in support of a *de novo* application and the target population of its proposed label. Submit PortIO

Breakthrough Device application.

- Initiate a PortIO clinical safety study to support its FDA *de novo* application and long-term clinical study in Colombia, South America to demonstrate up to 60-day maintenance free implant durations in humans.
- Complete benchtop, human and animal testing seeking to achieve accuracy milestone based on established FDA and ISO 15197 standards for Solys Diagnostics' NDIR laser based non-invasive blood glucose diagnostic device. Initiate commercial development of inpatient device.

## **PRELIMINARY FINANCIAL RESULTS**

For the three months ended March 31, 2020, research and development expenses were approximately \$2.6 million and general and administrative expenses were approximately \$2.6 million. GAAP net loss attributable to common stockholders was approximately \$14.5 million, or \$(0.33) 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 March 31, 2020 of \$4.5 million, or \$(0.10) per common share.

PAVmed had cash and cash equivalents of \$8.7 million as of March 31, 2020, compared with \$6.2 million as of December 31, 2019. Subsequently, in late April 2020, the Company received approximately \$3.6 million in proceeds from a private placement with an institutional investor for the sale of a Senior Secured Convertible Note.

### **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, 2020 and 2019 is as follows:

(ooo's except per-share amounts)	Three Months Ended March 31,	
	2020	2019
<b>Net income (loss) per common share, basic and diluted</b>	\$ (0.33 )	\$ (0.13 )
<b>Net loss attributable to common stockholders</b>	(14,545 )	(3,600 )
Preferred Stock dividends and deemed dividends	70	65
<b>Net income (loss) as reported</b>	(14,475 )	(3,535 )
Adjustments:		
Depreciation expense <sup>1</sup>	4	3
Interest expense, net <sup>3</sup>	52	-
<b>EBITDA</b>	(14,419 )	(3,532 )
<b>Other non-cash or financing related expenses:</b>		
Stock-based compensation expense <sup>2</sup>	344	459
Debt extinguishment <sup>3</sup>	1,188	1
Change in FV convertible debt <sup>3</sup>	8,008	559
Offering costs convertible debt <sup>3</sup>	410	-
<b>Non-GAAP adjusted (loss)</b>	(4,469 )	(2,513 )
Basic and Diluted shares outstanding	43,500	27,149
Non-GAAP adjusted (loss) income per share	(\$0.10 )	(\$0.09 )

1 Included in general and administrative expenses in the financial statements

2 For the three months ended March 31, 2020 includes \$277 of stock based compensation expense reported as general and administrative expenses and \$67 reported as research and development expense. For the three months ended March 31, 2019 includes \$285 of stock based compensation expense reported as general and administrative expenses and \$174 reported as research and development expense.

3 Included in other income and expenses

## Conference Call and Webcast

The Company will hold a conference call and webcast today at 4:30 p.m. Eastern time. During the call, Lishan Aklog, M.D., Chairman and Chief Executive Officer of the Company, will provide a business update including an overview of the Company's near-term milestones and growth strategy. In addition, Dennis McGrath, President and Chief Financial Officer, will review first quarter 2020 financial results.

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](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 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: 13703671. The webcast will be available for replay on the investor relations section of the Company's website at [www.pavmed.com](http://www.pavmed.com).

## **About PAVmed**

PAVmed Inc. is a highly differentiated, multiproduct 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 Infusion Platform Technology), 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](#).

## **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, 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; 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 Reports 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)



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