



## PAVmed Reports Fourth Quarter 2018 Financial Results and Provides Business Update

*Conference call to be held on April 4, 2019 at 4:30 p.m. Eastern time*

NEW YORK, Apr. 4, 2019 (GLOBE NEWSWIRE) -- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ)** (the “Company” or “PAVmed”), a highly differentiated, multiproduct medical device company, today reported financial results for the three and 12 months ended December 31, 2018 and provided a business update.

### MANAGEMENT COMMENTARY

“I am very pleased with the progress PAVmed has made during what has been a very active and productive fourth quarter of 2018 and in recent months,” said Lishan Aklog, M.D., PAVmed’s Chairman and Chief Executive Officer. “We have achieved several important milestones across our lead product pipeline and are poised to complete several more in this quarter.”

### Highlights

- Refinanced senior secured debt under favorable terms, including a lower coupon rate and no attached warrants, strengthening our balance sheet by removing the July 2019 debt maturity overhang and increasing our working capital runway;
- Reached a consensus with the FDA on the parameters of the CarpX™ minimally-invasive carpal tunnel device’s first-in-human (FIH) safety study and completed the complex logistics necessary to initiate and complete the treatment phase of the study in Christchurch, New Zealand in the coming weeks;
- Completed the EsoGuard™ (formerly EsoCheck™ Dx) methylated DNA biomarker diagnostic test’s Laboratory Developed Test (LDT) validation process and filed for a Proprietary Laboratory Analysis (PLA) diagnostic CPT billing code through the American Medical Association, which is the first step in securing Medicare reimbursement;
- Completed the EsoCheck™ esophageal cell collection device’s GLP animal study as well as additional manufacturing verifications requested by FDA to support its 510(k) pathway regulatory clearance;
- Launched a world-class Lucid Diagnostics medical advisory board consisting of internationally renowned experts in gastroesophageal reflux disease (GERD), Barrett’s Esophagus (BE) and esophageal cancer, with specific expertise and experience in developing the current published society guidelines on the management of BE;
- Appointed a veteran life sciences industry executive with extensive experience in the development and execution of clinical and regulatory strategy, including sophisticated clinical trials, as Lucid’s Chief Medical Officer;
- Completed the PortIO™ implantable intraosseous vascular access device’s GLP animal study, requested by the FDA to support its *de novo* pathway regulatory clearance;

- Completed a PortIO pilot animal study demonstrating an unprecedented maintenance-free implant duration of over 60 days, which a former president of the Society of Interventional Radiology described as a “truly groundbreaking accomplishment” which would represent “one of the most important advances in long-term vascular access”;
- Completed a series of bench-top tests of the NextFlo™ Infusion System demonstrating flow accuracy comparable to expensive electronic infusion pumps, independent of intravenous (IV) bag height, which a leading critical care physician described as a breakthrough which would “revolutionize how we deliver infusions to patients while significantly lowering costs”.

## CarpX

CarpX is a minimally invasive device designed to treat carpal tunnel syndrome, which PAVmed believes will dramatically reduce recovery times compared to traditional open surgery and target an estimated immediately addressable domestic market opportunity of over \$1 billion.

PAVmed has been working closely with the FDA to secure its U.S. 510(k) regulatory clearance of CarpX. During a pre-submission meeting earlier this year, the FDA recommended clinical testing to definitively document procedural safety in humans and indicated that data from a clinical study outside of the U.S. would be acceptable, precluding the need to engage in the FDA’s time-consuming IDE process required for U.S. studies. PAVmed offered to amend its previously planned FIH clinical trial ([ClinicalTrials.gov Identifier: NCT03747510](https://clinicaltrials.gov/ct2/show/study/NCT03747510)) in Christchurch, New Zealand to meet this clinical testing recommendation and postponed the initiation of the study until study parameters were finalized with the FDA and local logistical matters could be finalized.

Following multiple discussions, PAVmed reached a consensus with the FDA on the parameters of the study – a single-arm, two-center, two-surgeon, 20-patient study of the CarpX procedure in carpal tunnel syndrome patients, with a device safety primary endpoint over a limited 90-day follow-up period. Final logistical matters led to a brief delay in the initiation of the study which was exacerbated by a temporary freeze on all elective surgeries following the tragic events in Christchurch last month. These logistical matters have now been addressed and the elective surgery freeze has been lifted, allowing treatment to be initiated and completed in the coming weeks.

## EsoGuard/EsoCheck

The EsoGuard (formerly EsoCheck Dx) DNA biomarker diagnostic test and the EsoCheck device, which collect cells from a targeted region of the esophagus in a five-minute office-based procedure, are revolutionary technologies licensed by PAVmed’s majority-owned subsidiary, Lucid Diagnostics Inc. (“Lucid”). Lucid decided to rename the diagnostic test EsoGuard to better distinguish it from the EsoCheck cell collection device since each technology has promising applications that are independent of the other. This change will be formally introduced at the major upcoming gastroenterology meeting, Digestive Diseases Week (DDW), where Lucid will have a strong presence including exhibits and presentations. Lucid is pursuing a two-phase regulatory and commercialization strategy which seeks to maximize the technologies’ long-term commercial opportunity while providing near-term value-inflection commercial milestones.

EsoGuard is a methylated DNA biomarker diagnostic test which has been shown in a published human study to be highly accurate at detecting Barrett’s Esophagus (BE), a pre-cursor to highly lethal esophageal cancer in patients with chronic heart burn or acid reflux (GERD). Lucid believes that the EsoGuard diagnostic test, when performed on samples collected by EsoCheck, has the potential to save many lives through early BE detection. The estimated immediately addressable domestic market

opportunity for EsoGuard is at least \$2 billion based on tens of millions of U.S. GERD patients who are BE screening candidates according to published guidelines.

The EsoGuard Laboratory Developed Test (LDT) validation process has been completed at the central reference laboratory in Cleveland. This week the American Medical Association (AMA) confirmed receipt of Lucid's application for a Proprietary Laboratory Analysis (PLA) diagnostic CPT billing code for EsoGuard. This is the first step towards securing Medicare and subsequently private payor reimbursement for the diagnostic test.

Lucid's efforts to secure regulatory clearance for EsoCheck through the FDA's 510(k) pathway are progressing well. The FDA requested some additional manufacturing verifications and a small GLP animal study to document device effectiveness and safety relative to a commercially available endoscopic brush. This work has been completed with excellent results and will be submitted to FDA as part of a formal response shortly, with final clearance expected soon thereafter.

The second phase of Lucid's strategy to secure a specific indication, based on published guidelines, for widespread BE screening using EsoGuard on samples collected with EsoCheck is progressing at an accelerated pace. In addition to a full-time Chief Medical Officer focused on planning and executing the necessary Lucid-sponsored clinical studies, Lucid has secured multiple other world-class resources for this effort including two clinical operations consultants, a biostatistician and a team of regulatory consultants consisting of former FDA officials. Draft protocol synopses have been finalized and will be a central part of a pre-submission package which will soon be filed with the FDA along with a meeting request to discuss its clinical data requirements for a *de novo* or Pre-Market Approval (PMA) pathway submission.

#### Other Lead Products

The PortIO implantable intraosseous vascular access device continues to advance through the FDA's *de novo* pathway as it seeks an initial 7-day implant duration indication for use. The GLP animal study requested by the FDA has been completed along with supplementary cadaver and acute animal studies. A pre-submission package incorporating these data will be submitted to FDA in the coming weeks. Groundbreaking data from a recently completed pilot animal study demonstrated an unprecedented maintenance-free implant duration of over 60 days. Based on these results, PAVmed is planning to initiate a long-term (90-day implant duration) FIH series in Colombia, South America this quarter. CE Mark submission is scheduled for Q2-2019 and the Company continues to explore potential strategic partnerships, including acquisition of PortIO.

The NextFlo disposable intravenous (IV) infusion set recently achieved a key milestone in its quest to eliminate the need for complex and expensive electronic infusion pumps for most of the estimated one million infusions of fluids, medications and other substances delivered each day in hospitals and outpatient settings in the United States. NextFlo is designed to deliver highly-accurate gravity-driven infusions independent of the height of the IV bag. It maintains constant flow by incorporating a proprietary, passive, pressure-dependent variable flow-resistor consisting entirely of inexpensive, easy-to-manufacture disposable mechanical parts. NextFlo testing has demonstrated constant flow rates across a wide range of IV bag heights, with accuracy rates comparable to electronic infusion pumps. ([NextFlo Demonstration Video](#)). This major technological breakthrough has generated significant interest from potential strategic partners, as a result, PAVmed is gearing up to initiate a formal M&A process for NextFlo in the coming weeks.

Finally, a three-month animal study of the DisappEAR™ resorbable, antimicrobial pediatric ear tube animal study has been completed. The proprietary silk ear tubes performed very well and demonstrated

certain additional unanticipated benefits which if replicated in humans could significantly enhance their clinical value. The full data set is being analyzed and will be reported shortly. Upon completion, data from this animal study will be used to support a planned FDA 510(k) submission in 2019.

## **FINANCIAL RESULTS**

For the three months ended December 31, 2018, research and development expenses were \$1,371,011 and general and administrative expenses were \$1,940,883. GAAP net loss attributable to common stockholders was \$6,896,010, or \$(0.26) per common share. As illustrated below and for the purpose of helping the reader understand the effect of derivative accounting for 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, 2018 of \$2,888,857, or \$(0.11) per common share.

PAVmed had cash and cash equivalents of \$8,222,119 as of December 31, 2018, compared with \$1,535,022 as of December 31, 2017.

The audited financial results for the year ended December 31, 2018 as reported to the SEC on Form 10-K 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 and year ended December 31, 2018 and 2017 is as follows:

	Three Months Ended Dec 31,		For the Year Ended December 31,	
	2018	2017	2018	2017
<b>Net income (loss) per common share, basic and diluted</b>	\$ (0.26)	\$ 0.02	\$ (0.84)	\$ (0.77)
<b>Net loss attributable to common stockholders</b>	(6,896,010)	309,685	(18,750,798)	(10,398,134)
Preferred Stock dividends and deemed dividends	64,196	560,160	981,289	878,865
Series B Preferred stock issued upon exchange of Series A and Series A-1 Preferred stock	-	-	(199,241)	-
<b>Net income (loss) as reported</b>	(6,831,814)	869,845	(17,968,750)	(9,519,269)
Adjustments:				
Depreciation expense <sup>1</sup>	3,546	1,803	9,790	7,110
Interest expense, net <sup>1</sup>	684,125	362,542	2,392,447	724,684
<b>EBITDA</b>	(6,144,143)	1,234,190	(15,566,513)	(8,787,475)
<b>Other non-cash expenses:</b>				
Stock-based compensation expense <sup>2</sup>	329,050	248,846	1,228,699	1,048,127
Loss from issuance of Preferred Stock <sup>3</sup>	-	-	-	3,124,285
Change in fair value of Series A Warrant Liability <sup>3</sup>	-	(3,342,820)	96,480	(1,942,501)
Change in fair value of Series A Preferred Stock conversion option embedded derivative liability <sup>3</sup>	-	-	(64,913)	(643,318)
Debt extinguishment <sup>3</sup>	1,408,296	-	1,408,296	-
Change in FV convertible debt <sup>3</sup>	903,000	-	903,000	-
Offering costs convertible debt <sup>3</sup>	614,940	-	614,940	-
Modification of warrant or UPO agreement <sup>3</sup>	-	222,000	2,259,367	222,000
<b>Non-GAAP adjusted (loss)</b>	(2,888,857)	(1,637,784)	(9,120,644)	(6,978,882)
Basic and Diluted shares outstanding	26,575,588	13,983,689	22,276,347	13,495,951
Non-GAAP adjusted (loss) income per share	(\$0.11)	(\$0.12)	(\$0.41)	(\$0.52)

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

<sup>2</sup> For the three months ended December 31, 2018 includes \$246,969 of stock based compensation expense reported as general and administrative expenses and \$82,081 reported as research and development expense. For the three months ended December 31, 2017 includes \$217,946 of stock based compensation expense reported as general and administrative expenses and \$30,900 reported as research and development expense. For the year ended December 31, 2018 includes \$948,143 of stock based compensation expense reported as general and administrative expenses and \$280,556 reported as research and development expense. For the year ended December 31, 2017 includes \$925,534 of stock based compensation expense reported as general and administrative expenses and \$122,593 reported as research and development expense.

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

## **Conference Call and Webcast**

The Company will hold a conference call and webcast on Thursday, April 4, 2019 beginning 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, the Company's Chief Financial Officer, will discuss fourth quarter 2018 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: 13688196. 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 medical device company employing a unique business model designed to advance innovative products to commercialization much more rapidly and with significantly 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. PAVmed's diversified pipeline of products address unmet clinical needs encompassing a broad spectrum of clinical areas with attractive regulatory pathways and market opportunities. Its five lead products provide groundbreaking approaches to carpal tunnel syndrome (CarpX™), precancerous conditions of the esophagus (EsoCheck™), vascular access (PortIO™), pediatric ear infections (DisappEAR™) and medical infusions (NextFlo™). The company is also developing innovative products in other areas, such as catheters and tissue ablation, while seeking to further expand its pipeline through engagements with clinician innovators and leading academic medical centers. 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](#).

## **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, factors affecting the timing and effectiveness of the registration statement for our proposed rights offering; 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 any of its products. 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 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)