

November 15, 2018

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

*Conference call to be held on November 15, 2018 at 4:30 p.m. Eastern time*

NEW YORK, Nov. 15, 2018 (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 nine months ended September 30, 2018 and provided a business update.

## **Management Commentary**

“PAVmed had a strong third quarter of 2018,” said Lishan Aklog, M.D., PAVmed’s Chairman and Chief Executive Officer. “During this quarter and in recent weeks we saw steady progress towards our strategic goals, including advancing our lead products towards regulatory and commercial milestones. We remain in a strong financial position with more than \$9 million in cash at the end of the quarter and a cash runway that extends well past critical value-inflection milestones in 2019.”

CarpX™, PAVmed’s most important lead product, is a minimally invasive device designed to treat carpal tunnel syndrome. The Company believes CarpX will dramatically reduce recovery times compared to traditional open surgery and will target an estimated immediately addressable domestic market opportunity of over \$1 billion. The Company has been working closely with the U.S. Food and Drug Administration (FDA) during this past year to secure U.S. regulatory clearance of CarpX through the FDA’s 510(k) pathway, which is based on demonstrating substantial equivalence to a previously cleared predicate device. In August, the FDA notified the Company that it had not reached a consensus within the review period allotted and recommended that the Company extend the review process through resubmission of the 510(k) application following an in-person pre-submission meeting.

“During the past several months we have been working diligently and methodically to ensure that we enter the FDA pre-submission meeting in the strongest possible position and with the highest probability of securing near-term clearance,” Dr. Aklog explained. “First, we formally engaged the founding partner of one of nation’s leading FDA law firms to advise us through this process. We then prepared a pre-submission package which carefully codified the large amount of testing data and other documentation generated during the review of the original application, in a manner and structure easily digestible by newly-assigned FDA personnel.”

PAVmed submitted this comprehensive package last month. A pre-submission meeting with the FDA has been scheduled for January 7, 2019. The lead branch for this resubmission remains unchanged but the FDA has assigned a new, more senior, lead reviewer. He will work closely with the lead branch reviewer and chief who participated in the review of the initial application.

“We are excited to have secured a pre-submission meeting with the FDA and eagerly anticipate the opportunity to make our case that CarpX is substantially equivalent to the predicate device and should be granted 510(k) marketing clearance,” Dr. Aklog said. “We anticipate that, as requested, specified senior FDA personnel empowered to make executive decisions on our application will be present at the meeting. PAVmed management will be joined at the meeting by a world-class team, including our FDA counsel and recognized experts in carpal tunnel surgery who strongly support CarpX’s substantial equivalence arguments.

“We continue to advance towards several other important CarpX milestones,” Dr. Aklog added. Next week we expect to secure Ethics Committee approval which should allow us to perform our first-in-human CarpX clinical series in New Zealand in December. The ISO 13485 certification process and quality management system setup required for CE Mark submission in 2019 are both well underway. We also continue our efforts to establish a commercial infrastructure through active discussions with distributors in the U.S. and abroad.”

EsoCheck™, is a revolutionary technology which PAVmed subsidiary, Lucid Diagnostics Inc., licensed from Case Western Reserve University earlier this year and has been highlighted as one of the year’s significant advances in cancer prevention in the National Cancer Institute’s [2020 Annual Plan and Budget Proposal](#) to Congress. The technology is designed to allow patients to undergo a non-invasive five-minute office-based procedure to detect Barrett’s Esophagus (BE), a pre-cursor to highly lethal esophageal cancer, which occurs in patients with chronic heart burn or acid reflux (GERD). The Company believes the EsoCheck technology has the potential to save many lives through the early detection of BE, which can be carefully monitored and treated with non-surgical approaches if

detected before cancer develops. The immediately addressable domestic market opportunity for EsoCheck is estimated to be at least \$2 billion based on over 20 million U.S. patients with GERD who are candidates for BE screening based on existing American College of Gastroenterology (ACG) guidelines.

EsoCheck CCD™ is a balloon catheter designed to collect cells for diagnostic testing from a targeted region of the esophagus without the need for endoscopy. EsoCheck Dx™ is a methylated DNA biomarker test (mVIM + mCCNA1) which has been shown in a published human study to be highly accurate at detecting BE. The Company is pursuing a two-phase regulatory and commercialization strategy which seeks to maximize EsoCheck's long-term commercial opportunity while providing near-term value-inflection commercial milestones. Phase I seeks to commercially launch EsoCheck CCD as a 510(k)-cleared cell collection device and EsoCheck DX as a Laboratory Developed Test (LDT) which does not currently require FDA review. Phase II seeks a specific indication for widespread BE screening using EsoCheck based on ACG guidelines.

"I am very pleased with the excellent progress we are making in both phases of our EsoCheck regulatory and commercialization strategy," Dr. Aklog stated. "We expect to submit EsoCheck CCD for 510(k) clearance next week and, given the excellent predicate and low risk profile, I am optimistic that it will be cleared expeditiously. EsoCheck DX continues to undergo a battery of tests to secure CLIA certification and is on schedule to achieve LDT designation in late Q1-2019. We are working with a leading consulting firm to apply for EsoCheck Dx reimbursement codes through the AMA's Proprietary Laboratory Analysis (PLA) process. Phase II is also off to an excellent start. The ongoing multi-center National Institutes of Health funded clinical trial comparing EsoCheck with endoscopy has enrolled well over 100 patients. In addition, we have retained a leading regulatory firm, whose many ex-FDA partners include the former director of the FDA's Office of In Vitro Diagnostics, to help us move toward an FDA pre-submission meeting in early 2019."

PAVmed's lead product pipeline includes PortIO™, an implantable intraosseous vascular access device; DisappEAR™, a resorbable, antimicrobial pediatric ear tube; and NextFlo, a fixed-rate infusion set based on a proprietary variable flow-resistor.

"The remaining lead products in our pipeline are progressing well and we believe will provide additional opportunities to enhance shareholder value by mitigating risk through diversification and offering potential sources of non-dilutive capital," Dr. Aklog explained. "PortIO continues to progress well along the FDA's *de novo* pathway. The FDA-requested GLP animal study will be completed this quarter and will likely be followed by a small clinical trial in 2019. We have engaged a major investment bank which has begun a process to explore potential strategic partnerships including acquisition of PortIO. The DisappEAR™ three-month animal study to evaluate resorption rates will also be initiated this quarter and if successful will support a planned FDA 510(k) submission in 2019. Finally, benchtop testing of the NextFlo™ prototype is showing excellent results and we look forward to finalizing the product design very soon and proceeding to FDA 510(k) submission in 2019."

"PAVmed continues to grow and strengthen as a company," Dr. Aklog stated. "During this quarter and in recent weeks we have added three employees (a chief commercial officer, a director of investor relations and a second product development engineer) and expanded our consulting teams across multiple products. We have upgraded our communications through a brand-new website, active social media platforms and periodic blast emails. Finally, we expect to further strengthen our financial position by refinancing our senior secured debt this quarter, well ahead of its July 2019 maturity."

## **Financial Results**

For the three months ended September 30, 2018, research and development expenses were \$1,171,324 and general and administrative expenses were \$1,397,500. GAAP net loss attributable to common stockholders was \$3,311,124, or \$(0.12) 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 September 30, 2018 of \$2,209,281, or \$(0.08) per common share.

PAVmed had cash and cash equivalents of \$9,241,534 as of September 30, 2018, compared with \$1,535,022 as of December 31, 2017.

The unaudited financial results for the three and nine months ended September 30, 2018 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 of the Series A Preferred Stock Units, the change in fair value of the Series A Warrant liability and the change in fair value of the Series A Convertible Preferred Stock conversion option embedded derivative liability. 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 of the Series A Preferred Stock Units and the corresponding derivative 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 nine months ended September 30, 2018 and 2017 is as follows:

	Three Months Ended Sept 30,		Nine Months Ended Sept 30,	
	2018	2017	2018	2017
<b>Net income (loss) per common share, basic and diluted</b>	\$ (0.12 )	\$ (0.40 )	\$ (0.57 )	\$ (0.80 )
<b>Net loss attributable to common stockholders</b>	(3,311,124 )	(5,370,313 )	(11,854,787 )	(10,707,819 )
Preferred Stock dividends and deemed dividends	64,897	240,995	917,092	318,706
Series B Preferred stock issued upon exchange of Series A and Series A-1 Preferred stock	-	-	(199,241 )	-
<b>Net loss as reported</b>	(3,246,227 )	(5,129,318 )	(11,136,936 )	(10,389,113 )
Adjustments:				
Depreciation expense <sup>1</sup>	2,639	1,802	6,244	5,307
Interest expense, net	707,714	362,142	1,708,322	362,142
Income tax (benefit) expense	-	-	-	-
<b>EBITDA</b>	(2,535,874 )	(4,765,374 )	(9,422,370 )	(10,021,664 )
<b>Other non-cash expenses:</b>				
Stock-based compensation expense <sup>2</sup>	324,473	272,301	899,649	799,281
Loss from issuance of Preferred Stock <sup>3</sup>	-	-	-	3,124,285
Change in fair value of Series A Warrant Liability <sup>3</sup>	-	2,215,671	96,480	680,851
Change in fair value of Series A Preferred Stock conversion option embedded derivative liability <sup>3</sup>	-	583,517	(64,913 )	76,150
Modification of warrant or UPO agreement <sup>3</sup>	2,120	-	2,259,367	-
<b>Non-GAAP adjusted (loss)</b>	(2,209,281 )	(1,693,885 )	(6,231,787 )	(5,341,097 )
Basic and Diluted shares outstanding	26,538,632	13,332,629	20,827,519	13,331,585
Non-GAAP adjusted (loss) income per share	(\$ 0.08 )	(\$ 0.13 )	(\$ 0.30 )	(\$ 0.40 )

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

<sup>2</sup> For the three months ended Sept 30, 2018 includes \$247,818 of stock-based compensation expense reported as general and administrative expenses and \$76,655 reported as research and development expense. For the three months ended Sept 30, 2017 includes \$241,401 of stock-based compensation expense reported as general and administrative expenses and \$30,900 reported as research and development expense. For the nine months ended Sept 30, 2018 includes \$701,174 of stock-based compensation expense reported as general and administrative expenses and \$198,475 reported as research and development expense. For the nine months ended Sept 30, 2017 includes \$707,588 of stock-based compensation expense reported as general and administrative expenses and \$91,693 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, November 15, 2018 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 third quarter 2018 financial results.

To access the conference call, U.S.-based listeners should dial (877) 407-0784 and international listeners should dial (201) 689-8560. 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: 13684328. 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 four lead products provide groundbreaking approaches to carpal tunnel syndrome (CarpX™), precancerous conditions of the esophagus (EsoCheck™), vascular access (PortIO™) and pediatric ear infections (DisappEAR™). The company is also developing innovative products in other areas, such as medical infusions 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.

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