

May 22, 2018



# PAVmed Reports First Quarter 2018 Financial Results

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

NEW YORK--(BUSINESS WIRE)-- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ)** (the “Company” or “PAVmed”), a highly differentiated, multiproduct medical device company, today reports financial results for the three months ended March 31, 2018 and provides a business update.

## **Management Commentary**

“During the first quarter of 2018 and in recent weeks, PAVmed has added the groundbreaking EsoCheck technology to its lead product portfolio, continued to advance its other lead products, CarpX™, PortIO™, and DisappEAR™, toward important regulatory and commercial milestones and took concrete steps to strengthen its financial position and streamline its capital structure,” said Lishan Aklog, M.D., PAVmed’s Chairman and Chief Executive Officer. “We look forward to achieving several important regulatory and development milestones during the upcoming weeks and months.

“CarpX, our minimally invasive device to treat carpal tunnel syndrome, remains our most important lead product and near-term commercial opportunity. Since receiving the U.S. Food and Drug Administration’s (FDA) initial response to our 510(k) submission earlier this year, we have been working closely with the agency to satisfy their request for additional non-clinical data to support our submission. We have completed the requested animal study documenting that the device’s bipolar electrode design results in minimal spread of thermal energy. The requested additional physician usability testing in cadavers will be completed this week. We remain on target to file our resubmission incorporating these data to the agency by the end of this month and look forward to an expeditious review and final positive response from the FDA soon thereafter.

“As a result of intense international interest in this product, we have decided to accelerate our CarpX activities outside the United States. We have targeted next month to have a leading hand surgeon in New Zealand perform a first-in-man clinical series using CarpX. In addition, we have identified an EU notified body and are taking the additional requisite steps to submit our application for CE mark in Europe, targeted for the late third quarter of this year. Finally, we have received multiple inquiries from entities in Europe, Asia and South America seeking to commercially partner with us on CarpX in their regions and have initiated dialogues to explore possible partnerships. We continue to believe that CarpX represents a significant global commercial opportunity exceeding \$1 billion and look forward to achieving these many catalysts in the coming quarters.

“Our newest lead product, EsoCheck, a revolutionary technology that we believe will save many lives through the early detection of pre-cancerous conditions of the esophagus, has immediately joined CarpX as one of our most important products in terms of near-term

commercial opportunity and potential blockbuster status,” Dr. Aklog continued. “Newly-formed PAVmed subsidiary Lucid Diagnostics Inc. recently entered into a definitive licensing agreement with Case Western Reserve University to commercialize and develop EsoCheck. The fact that PAVmed was selected to be the exclusive commercial partner over much larger medical device and diagnostic companies is a testament to our business model and the team’s commercialization track record. Pursuant to the definitive licensing agreement, Lucid Diagnostics Inc. now holds an exclusive worldwide license of the intellectual property rights for the EsoCheck cell sampling device and DNA biomarker test and all improvements. The licensed portfolio includes additional biomarkers under a broad field of use. PAVmed retains an 82% equity stake in Lucid and three of its four board seats are held by PAVmed designees.

“EsoCheck is a five-minute office-based alternative to diagnostic endoscopy that combines a non-invasive targeted cell sampling device with a DNA biomarker test. Together these have been shown to be highly accurate in detecting Barrett’s Esophagus, the primary precursor to the most common and lethal form of esophageal cancer caused by Gastroesophageal Reflux Disease (GERD), commonly known as heart burn or acid reflux. Barrett’s Esophagus can be successfully treated, usually with non-surgical approaches, if detected before cancer develops. However, endoscopy, the standard diagnostic test, is neither practical nor cost effective as a widespread screening tool. We believe widespread EsoCheck screening has the potential to have as great an impact on esophageal cancer as widespread Pap screening has had in preventing cervical cancer. Such widespread screening will eventually target the estimated 50 million Americans, with and without heartburn, who are at risk, representing an estimated immediately addressable domestic market of several billion dollars.

“There are several reasons we believe EsoCheck represents an extremely valuable addition to PAVmed’s portfolio. The existing human clinical data, published in a landmark *Science Translational Medicine* paper, is very powerful, showing that the EsoCheck cell-sampling device and DNA biomarker test is highly accurate in detecting Barrett’s Esophagus. The clinical evidence will grow substantially as a result of a large multicenter National Institutes of Health (NIH) study of EsoCheck which is actively enrolling patients at Case Western Reserve University Hospital, along with other leading academic medical centers including the Cleveland Clinic, Johns Hopkins, Mayo Clinic, Washington University St. Louis and the University of North Carolina. Finally, the EsoCheck device is already being manufactured for human use in clinical trials and the EsoCheck DNA biomarker test is already being performed at a reference laboratory, which expects to receive CLIA certification later this year. As such, we will be able to aggressively pursue EsoCheck commercialization by seeking U.S. Food and Drug Administration (FDA) 510(k) clearance of the cell sampling device and a Laboratory Developed Test designation of the DNA biomarker test. We are targeting the first quarter of 2019 for the launch of the first commercial product in the U.S.

“With respect to our third lead product PortIO™, our implantable intraosseous vascular access device, we are pursuing FDA clearance for a seven-day implant indication through the *de novo* pathway and are following detailed guidance from the agency received during a pre-submission review meeting earlier this year. We completed a successful pilot animal study that showed excellent device function over the seven-day implant period and complete healing upon explant. We have submitted the protocol for the definitive animal study based on this pilot study and expect to receive the agency’s feedback and initiate the definitive animal study in the coming weeks. In anticipation of having to follow-up the animal study

with a human clinical safety trial, we accelerated our strategic partnership efforts to include support of the expected clinical study as part of a broader distribution, licensing or acquisition agreement. We are preparing an IDE application in anticipation of a formal request for this small clinical study and plan to use an improved second-generation device. We are also pursuing a first-in-man human clinical series in New Zealand and European CE Mark submission along the same timeline as CarpX.

“With respect to our final lead product DisappEAR™, our resorbable, antimicrobial pediatric ear tube, we have recently identified a corporate partner who will provide us with commercially applicable silk monoblocks from which to manufacture the ear tube. This important step will significantly shorten the development timeline for this product since sourcing commercial silk has been the major obstacle to date. We are now able to proceed with optimizing the manufacturing process for the ear tubes and initiate a small animal study to document resorption rates. We are targeting 510(k) submission before the end of this calendar year.”

Dr. Aklog concluded, “Finally, during the first quarter of 2018, we took important steps to streamline our capital structure by consolidating several classes of preferred securities, eliminating burdensome anti-dilution provisions and decreasing our warrant overhang through a successful tender offer whereby more than 96% of the warrants issued in our IPO were exchanged for half as many six-year Series Z Warrants which now trade on Nasdaq under the ticker symbol PAVMZ. Also, during the first quarter and in recent weeks we have been raising capital to strengthen our balance sheet and extend our cash runway. We raised approximately \$4.3 million in net proceeds from an underwritten shelf offering of common stock, providing us with adequate capital into the first quarter of 2019. We also took the necessary steps to initiate a rights offering which we expect to launch this week. Pursuant to the rights offering, holders of common stock as of yesterday, the record date, will be granted one right to purchase a new unit consisting of a share of common stock and a Series Z Warrant for \$2.25. In anticipation of the rights offering, we lowered the exercise price of these warrants to \$1.60. Anticipated proceeds from the exercise of these rights will be used to extend our working capital runway, accelerate the commercialization of CarpX once cleared and potentially retire debt.”

## **Financial Results**

For the three months ended March 31, 2018, research and development expenses were \$562,535 and general and administrative expenses were \$1,381,167. GAAP net loss attributable to common stockholders was \$3,414,700, or \$(0.21) 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 March 31, 2018 of \$1,670,613, or \$(0.10) per common share.

PAVmed had cash and cash equivalents of \$3,630,692 as of March 31, 2018, compared with \$1,535,022 as of December 31, 2017. In January 2018, the Company completed a public offering of common stock for net proceeds of approximately \$4.3 million.

The unaudited financial results for the three months ended March 31, 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) in our Quarterly Report on Form 10-Q, 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 months ended March 31, 2018 and 2017 is as follows:

	Three Months Ended March 31,	
	2018	2017
<b>Net income (loss) per common share, basic and diluted</b>	\$ (0.21)	\$ (0.32)
<b>Net loss attributable to common stockholders</b>	(3,414,700)	(4,296,528)
Preferred Stock dividends and deemed dividends	788,572	26,440
Series B Preferred stock issued upon exchange of Series A and Series A-1 Preferred stock	(199,241)	-
<b>Net loss as reported</b>	(2,825,369)	(4,270,088)
Adjustments:		
Depreciation expense <sup>1</sup>	1,803	1,702
Interest expense, net	500,304	-
Income tax (benefit) expense	-	-
<b>EBITDA</b>	(2,323,262)	(4,268,386)

**Other non-cash expenses:**

Stock-based compensation expense <sup>2</sup>	271,286	272,680
Loss from issuance of Preferred Stock	-	3,124,285
Change in fair value of Series A Warrant Liability <sup>3</sup>	96,480	(786,397)
Change in fair value of Series A Preferred Stock conversion option embedded derivative liability <sup>3</sup>	(64,913)	(224,065)
Modification of Series A and A-1 warrant agreement for Z warrants <sup>3</sup>	349,796	-
<b>Non-GAAP adjusted (loss)</b>	<u>(1,670,613)</u>	<u>(1,881,883)</u>
Basic and Diluted shares outstanding at December 31	16,544,221	13,330,891
Non-GAAP adjusted (loss) income per share	(\$0.10)	(\$0.14)

1 Included in general and administrative expenses in the financial statements

2 For the three months ended March 31, 2018 includes \$238,029 of stock based compensation expense reported as general and administrative expenses and \$33,257 reported as research and development expense. For the three months ended March 31, 2017 includes \$242,451 of stock based compensation expense reported as general and administrative expenses and \$30,228 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 on May 30, 2018 beginning at 4:30 p.m. Eastern time. During the call, Dr. Aklog 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 first quarter 2018 financial results.

To access the conference call, U.S.-based listeners should dial (888) 803-5993 and international listeners should dial (706) 634-5454. All listeners should provide the operator with the following passcode: 9098516. Individuals interested in listening to the live conference call via the internet may do so by visiting the Company's website at [www.pavmed.com](http://www.pavmed.com). Following the conclusion of the conference call, a replay will be available through June 6, 2018 and can be accessed by dialing (855) 859-2056 from within the U.S. or (404) 537-3406 from outside the U.S. To access the replay, all listeners should provide the following passcode: 9098516. The webcast will be available for a period of time on 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 three 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 further

information, please visit [www.pavmed.com](http://www.pavmed.com).

## **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.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20180522005507/en/>

Investors

LHA Investor Relations

Kim Sutton Golodetz, 212-838-3777

[kgolodetz@lhai.com](mailto:kgolodetz@lhai.com)

or

Media

PAVmed Inc.

212-949-4319

[info@pavmed.com](mailto:info@pavmed.com)

Source: PAVmed Inc.