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## **PAVmed Reports Second Quarter 2019 Financial Results and Provides Business Update**

*Conference call to be held on September 5, 2019 at 4:30 p.m. Eastern time*

NEW YORK, Sept. 05, 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 six months ended June 30, 2019 and provided a business update.

"The second quarter and early third quarter has been a period of solid progress for PAVmed," said Lishan Aklog, M.D., PAVmed's Chairman and Chief Executive Officer. "We advanced our lead product portfolio on multiple fronts, including the recent successful completion of all procedures in the CarpX™ clinical safety study. This progress has set up the remainder of the year to be an exciting period of major milestones, including the full U.S. commercial launch of EsoGuard™ and the upcoming FDA 510(k) re-submission of CarpX."

### **UPCOMING MILESTONES**

- Complete post-operative clinical follow-up of remaining patients in the CarpX first-in-human (FIH) clinical safety study in New Zealand, all of whom have met the study's primary effectiveness endpoint by successfully completing their CarpX procedures and await electrodiagnostic testing at 90 days to document that they have met the study's primary safety endpoint;
- Resubmit CarpX's 510(k) application to the U.S. Food and Drug Administration (FDA);
- Complete transfer of EsoGuard assay from an academic medical center laboratory to ResearchDx, Inc. one of the nation's leading commercial contract diagnostic organizations;
- Begin full U.S. commercial launch of EsoGuard as a Laboratory Developed Test (LDT), the first such test designed to detect Barrett's Esophagus, a precursor to deadly esophageal cancer which affects millions of patients;
- Complete Center for Medicare and Medicaid Services (CMS) process to secure a reimbursement code for EsoGuard LDT;
- Accelerate commercial launch of the EsoCheck™ Esophageal Cell Collection Device with Collect+Protect™ technology;
- Secure FDA sign-off on EsoGuard IVD clinical trial protocol during an in-person pre-submission meeting scheduled for October 9, 2019;
- Complete creation of EsoGuard IVD clinical trial operations infrastructure required to establish EsoGuard as an FDA-registered In-Vitro Diagnostic (IVD);
- Begin recruiting clinical trial sites and enroll first patient in the EsoGuard IVD clinical trial;
- Initiate pilot human clinical trials using EsoCheck in other prevalent diseases including eosinophilic esophagitis and infectious fungal/viral esophagitis in immunocompromised patients;

- Complete recently initiated formal M&A process led by global professional services firm Alvarez & Marsal to secure a strategic partner or acquirer for the NextFlo Infusion System and provide a source of non-dilutive capital to the Company;
- Secure FDA sign-off on protocol for a small PortIO™ clinical safety study in New Zealand during an in-person pre-submission meeting with the FDA in support of PortIO's *de novo* application;
- Initiate FIH clinical study for long-term PortIO use in dialysis patients and those with poor venous access in Columbia, South America;
- Complete PortIO animal study documenting unprecedented six-month maintenance-free patency; and
- Complete DisappEAR six-month GLP animal study to support future FDA 510(k) submission.

## **PRODUCT UPDATES**

### ***CarpX Minimally Invasive Carpal Tunnel Device***

- 20 patients underwent successful CarpX procedures in New Zealand, which completed the enrollment and treatment portion of the CarpX first-in-human (FIH) clinical safety study in support of CarpX's FDA 510(k) re-submission.
- All patients met the study's primary effectiveness endpoint.
- All patients who have completed their 90-day follow-up, met the study's primary safety endpoint and the remaining are fully expected to meet it based on clinical observations to date.
- The U.S. Patent and Trademark Office (USPTO) granted PAVmed a broad patent covering the technology underlying the CarpX device, expanding the PAVmed intellectual property (IP) portfolio that now includes over 75 patents and patent applications across 10 families.

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 \$1 billion immediately addressable domestic market opportunity, but do so much less invasively, using catheters, balloons, radiofrequency energy and other established tools of the percutaneous intervention and minimally invasive surgery revolutions. The balloon catheter device is inserted under the scarred ligament in a minimally invasive fashion, tensioning the ligament while pushing the nerve and tendons away. When activated, bipolar radiofrequency electrodes precisely cut the ligament from the inside out in a matter of seconds. The device design provides physicians with ongoing feedback to optimize the safety and completeness of the procedure.

The 20-patient CarpX clinical safety study nearing completion in New Zealand uses a protocol developed in close consultation with the FDA to support a 510(k) pre-market re-submission to commercially market the device for minimally invasive carpal tunnel release. It builds on extensive pre-clinical work documenting a narrow sliver of thermal spread, as well as safety and effectiveness substantially equivalent to a predicate. The study's primary effectiveness endpoint is intraoperative confirmation of complete transverse carpal ligament division by endoscopic visualization of its cut edges across its entire width. The study's primary safety endpoint is the absence of nerve injury as documented by two electrodiagnostic motor nerve tests performed at a 90-day follow up visit.

As noted, all 20 study patients underwent successful minimally invasive carpal tunnel release using the CarpX device and met the study's primary effectiveness endpoint. There were no device-related adverse events. Key intra- and post-operative observations which strongly support CarpX's clinical and commercial potential include:

- The final set of procedures were completed in 15-20 minutes "skin-to-skin", indicating that the CarpX procedure can be performed in the same or less time as traditional carpal tunnel release after only a short learning curve.

- As they gained experience, surgeons were able to use progressively smaller incisions. The final set of procedures were performed through the smallest keyhole incisions that would pass the introducer sheath, approximately 5-10 mm each, with no incision crossing the base of the palm, the problematic area for healing, recovery and persistent pain after traditional surgery.
- CarpX's balloon appeared to create more space within the carpal tunnel at completion of the procedure compared to traditional surgery, a unique feature which has the potential to enhance both short and long-term outcomes.
- CarpX required less power and lower balloon pressures to cut the scarred ligament in live human patients than it had previously demonstrated in cadavers, an unexpected positive finding which should further enhance procedure safety and effectiveness.
- Most importantly, initial patient feedback has been very positive, including one patient who noted his recovery was much faster than a friend who had a "mini-open" carpal tunnel release and insisted the procedure on his other hand be performed with CarpX.

As noted, all patients who have completed their 90-day follow-up testing have met the study's primary safety endpoint and, based on clinical observations, it is expected that all the remaining patients will meet it as well. PAVmed will resubmit the CarpX 510(k) application incorporating the study's clinical safety and effectiveness data once 90-day follow-up is completed in all 20 patients.

U.S. Patent 10,335,189 entitled "Systems and Methods for Percutaneous Division of Fibrous Structures", was recently granted by the USPTO and includes broad independent claims covering a device such as CarpX with a catheter, an expandable member such as a balloon, and a cutting element such as a pair of bipolar radiofrequency electrodes. The claims are not limited to CarpX or carpal tunnel syndrome and cover device embodiments which can be developed to treat a broad spectrum of conditions, such as plantar fasciitis and compartment syndromes, where compression by fibrous tissue causes pain or other debilitating symptoms. The CarpX IP portfolio also includes multiple international and follow-on patent applications.

### ***EsoGuard Esophageal DNA Test and EsoCheck Esophageal Cell Collection Device***

- Received FDA 510(k) marketing clearance for the EsoCheck™ Cell Collection Device with Collect +Protect technology.
- Engaged ResearchDx Inc., one of the nation's leading full-service commercial contract diagnostic organizations (CDO), and initiated transfer of the EsoGuard Esophageal DNA test from the clinical laboratory at the academic medical center which developed the test to ResearchDx.
- Successfully replicated the EsoGuard assay at ResearchDx and began validation testing to establish the EsoGuard Laboratory Developed Test (LDT) under ResearchDx's CLIA/CAP certificate.
- Filed pre-submission package and scheduled October 9, 2019 pre-submission meeting to secure FDA sign-off on the EsoGuard IVD clinical trial protocol to support a future *de novo* or Pre-Market Approval (PMA) application, which will seek a specific Barrett's Esophagus screening indication for EsoGuard on samples collected with EsoCheck in high-risk GERD patients.
- Hired former director of global clinical trial operations of a large multi-billion-dollar Fortune 500 medical device company to serve as Lucid's Chief Operating Officer, tasked with building the clinical trial operations infrastructure for the upcoming EsoGuard IVD clinical trials.
- Secured CPT reimbursement code for the EsoGuard LDT under the Proprietary Laboratory Analysis (PLA) process, and successfully advanced the code through the CMS Clinical Laboratory Fee Schedule (CLFS) process, leading to an in-person meeting with CMS to discuss reimbursement under this code.

EsoGuard and EsoCheck are revolutionary technologies licensed in 2018 by PAVmed's majority-owned subsidiary, Lucid Diagnostics Inc. ("Lucid"), from Case Western Reserve University.

The EsoCheck cell collection device, which is now FDA 510(k)-cleared, is a non-invasive device designed to sample cells from a targeted region of the esophagus in a five-minute office-based procedure, without the need for endoscopy. ([EsoCheck animation](#)). The sampled cells can then be subjected to any commercially available diagnostic test including EsoGuard.

EsoGuard is an esophageal DNA test which has been shown in a 408-patient human study published in *Science Translational Medicine* to be highly accurate at detecting Barrett's Esophagus (BE), a pre-cursor to highly lethal esophageal cancer (EAC) in patients with chronic heart burn or acid reflux (GERD).

Even though published society guidelines recommend screening in high-risk patients to detect and treat BE before it progresses to EAC, very few such patients currently undergo screening. In fact, most patients diagnosed with EAC are neither aware of their underlying BE, nor that they missed the opportunity to undergo treatment which could have prevented progression to EAC if the BE had been diagnosed earlier.

The estimated immediately addressable domestic market opportunity for EsoGuard is at least \$2 billion based on very modest penetration of tens of millions of U.S. GERD patients currently recommended for BE screening according to published society guideline.

EsoGuard uses next generation sequencing (NGS) of bisulfite-converted DNA to detect methylation at 31 sites on two genes (VIM and CCNA1). Complex bioinformatic algorithms are used to quantify the percentage of DNA with methylation at more than a specified proportion of sites, generating a binary result on whether or not the patient has BE. Clinical studies of EsoGuard have demonstrated greater than 90% sensitivity and specificity at detecting BE.

Lucid's strategy is to advance EsoGuard down two parallel paths, denoted EsoGuard LDT and EsoGuard IVD, which allows it to enter the commercial market and generate revenue while seeking to maximize the long-term value of the product as a widespread screening test.

EsoGuard LDT is a Laboratory Developed Test which uses the above DNA NGS assay to detect BE. Although EsoGuard has completed CLIA/CAP certification and is available as an LDT from the clinical laboratory affiliated with the academic medical center which developed the test, Lucid decided to transfer EsoGuard LDT to a high-capacity commercial laboratory before initiating marketing and a full commercial launch.

As noted, ResearchDx Inc., one of the nation's leading full-service commercial contract diagnostic organizations (CDO), has initiated transfer of the EsoGuard assay. Their team has quickly replicated, with near perfect correlation, the results from the academic laboratories that had previously performed the assay and has begun the validation testing required to establish EsoGuard as an LDT under their CLIA/CAP certificate. Once this transfer is complete, Lucid will initiate a full commercial launch of EsoGuard LDT. ResearchDx is also manufacturing the custom EsoGuard specimen collection kits and will be performing the assay for the EsoGuard IVD clinical trial.

The process to secure CMS and subsequently private payor coverage for EsoGuard LDT is steadily progressing. Since securing a CPT reimbursement code from the American Medical Association (AMA) under the Proprietary Laboratory Analysis (PLA), EsoGuard LDT has cleared additional hurdles, including technical advisory review, the CPT Editorial Review Panel, the CMS Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting and the CLFS panel. Lucid has engaged a leading law firm whose CMS reimbursement consultants previously served in leadership positions in the CMS group which reviews LDT reimbursement codes and held an in-person meeting with CMS to discuss the EsoGuard LDT code.

The EsoGuard IVD path seeks to secure a specific Barrett's Esophagus screening indication for EsoGuard as an FDA-cleared In-Vitro Diagnostic (IVD) device in high-risk GERD patients as

defined by published society guidelines. This will allow EsoGuard and EsoCheck to be broadly marketed together as a single diagnostic tool to screen patients for BE. It requires a *de novo* or PMA submission to the FDA supported by strong clinical data demonstrating that EsoGuard performed on samples collected with EsoCheck is sufficiently sensitive and specific to serve as a widespread screening tool in high-risk GERD patients recommended for screening.

Lucid, its world class medical advisors, which include the authors of the published society guidelines, and its regulatory advisors, which includes the former head of the FDA's IVD branch, have designed a robust two-arm clinical study to support an FDA *de novo* or PMA submission. The screening arm will enroll GERD patients without a prior diagnosis of BE who satisfy the American College of Gastroenterology (ACG) BE screening guidelines. The case control arm will enroll patients with a previous diagnosis of non-dysplastic BE, dysplastic BE or EAC. In both arms EsoGuard/EsoCheck will be compared to the goal standard of endoscopy with biopsies.

Lucid recently hired Randy W. Brown, former director of global clinical trial operations of a large multi-billion-dollar Fortune 500 medical device company, to serve as Lucid's Chief Operating Officer. He is tasked with building the clinical trial operations infrastructure for the EsoGuard/EsoCheck clinical trials, including a contract clinical research organization (CRO) partner, allied clinical research personnel and the quality design control process required to establish EsoGuard as an FDA-registered In-Vitro Diagnostic (IVD). Lucid plans to begin recruiting clinical trial sites soon and is targeting enrollment the first EsoGuard IVD clinical trial patient by the end of 2019.

Since EsoCheck is FDA-cleared as a generic esophageal cell collection device, Lucid is also aggressively pursuing market opportunities in prevalent esophageal conditions other than BE.

Eosinophilic esophagitis (EoE) is a common inflammatory condition of the esophagus whose incidence has grown dramatically in the past two decades and frequently coexists with Inflammatory Bowel Disease (IBD). EoE patients currently undergo multiple invasive endoscopies to monitor response to treatment. The University of Pennsylvania is initiating a Lucid-sponsored pilot study to determine whether EsoCheck can replace endoscopy in the surveillance of EoE patients, which would have a dramatic clinical and economic impact on the disease.

Patients with compromised immune systems, such as bone marrow transplant and HIV patients, often undergo endoscopy to evaluate swallowing difficulties to rule out fungal or viral infectious esophagitis. Lucid is engaged with physicians caring for these patients to determine whether these conditions can be diagnosed with EsoCheck instead of endoscopy in these compromised patients.

### ***Other Lead Products***

PAVmed's PortIO™ is an implantable intraosseous vascular access device which allows direct access to the bone marrow, a well-established route for the delivery of medications, fluids and other substances, addressing an estimated \$700 million market opportunity based on patients with poor veins and those with renal failure whose veins must be carefully preserved for current or future hemodialysis.

PortIO continues to advance through the FDA's *de novo* pathway as PAVmed seeks an initial 7-day implant duration. The FDA-requested GLP animal study has been completed along with supplementary cadaver and acute animal studies. This excellent pre-clinical data will form the basis of an upcoming in-person pre-submission meeting to secure FDA sign-off on the protocol for a small PortIO clinical safety study in New Zealand in support of PortIO's *de novo* application.

A separate animal study has now documented that PortIO remains patent and functional for an unprecedented four months, without fluid flushes or any other form of maintenance, with full expectation that this will remain the case when the six-month study is completed in a few weeks. This is highly differentiating because all other vascular access devices require regular flushes with

anti-coagulants or other substances to maintain their patency and functionality.

Based on this encouraging animal data, PAVmed will initiate a first-in-human clinical study for long-term (up to 60 days) PortIO use in dialysis patients and those with poor venous access in Columbia, South America.

PAVmed's NextFlo™ disposable intravenous (IV) infusion set seeks 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, using 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](#)). PAVmed has finalized commercial-ready and packaged working samples of the NextFlo infusion set for use in strategic discussions.

PAVmed recently engaged Deloitte Consulting LLP to perform a comprehensive market research and strategic analysis of NextFlo. They demonstrated a very large addressable market and recommended PAVmed seek a long-term strategic partnership or acquisition for NextFlo. PAVmed subsequently engaged the global professional services firm Alvarez and Marsal, which, armed with the detailed Deloitte Consulting report, has initiated a formal M&A process targeting over 70 potential strategic partners or acquirers, including the market leader in the space, who has contacted the company expressing interest in the technology.

PAVmed's DisappEAR™ resorbable pediatric ear tubes, manufactured from a proprietary aqueous silk technology licensed from Tufts University and two Harvard teaching hospitals, seeks to revolutionize the care of the estimated one million children who undergo bilateral ear tube placement each year to treat complex or recurrent middle ear infections or fluid collections, by eliminating the need for a second procedure as well as the standard difficult-to-administer post-operative ear drop regimen.

A three-month animal study of DisappEAR to support a future FDA 510(k) submission has been completed with excellent results. The resorbable ear tubes, machined from blocks of proprietary silk, performed very well from a functional and anatomic point of view, retaining their position and remaining patent for the duration of the study. In addition, the ear tubes demonstrated unexpected surfactant properties which appear to provide several unique benefits over traditional plastic tubes, including enhanced flow of fluids in and out of the tube and potential intrinsic antimicrobial properties.

Additional animals are being followed for longer durations to confirm device stability and corroborate these findings. In vitro antimicrobial testing is also being performed to determine whether the surface properties have an intrinsic antimicrobial effect which would obviate the need for antibiotic coating. A separate GLP animal study is comparing DisappEAR to standard plastic ear tubes with and without antibiotic ear drops.

### ***Other Recent Corporate Highlights***

- Engaged an external investor and public relations firm, KCSA Strategic Communications, to assist in raising PAVmed's profile within the investment community;
- Joined the Russell Microcap® Index on July 1<sup>st</sup> which results in automatic inclusion in the appropriate growth and value style indexes; and
- Closed on a registered direct offering of common stock for net proceeds of approximately \$1.8 million in late June.

## **FINANCIAL RESULTS**



For the three months ended June 30, 2019, research and development expenses were \$1,405,060 and general and administrative expenses were \$1,914,154. GAAP net loss attributable to common stockholders was \$3,660,403, or \$(0.13) 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 June 30, 2019 of \$2,782,047, or \$(0.10) per common share.

PAVmed had cash and cash equivalents of \$6,908,068 as of June 30, 2019, compared with \$8,222,119 as of December 31, 2018.

The audited financial results for the three and six months ended June 30, 2019 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 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 six months ended June 30, 2019 and 2018 is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
<b>Net income (loss) per common share, basic and diluted</b>	\$ (0.13)	\$ (0.31)	\$ (0.84)	\$ (0.77)

<b>Net loss attributable to common stockholders</b>	(3,660,403)	(5,128,963)	(18,750,798)	(10,398,134)
Preferred Stock dividends and deemed dividends	66,792	63,623	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>	<u>(3,593,611)</u>	<u>(5,065,340)</u>	<u>(17,968,750)</u>	<u>(9,519,269)</u>
Adjustments:				
Depreciation expense <sup>1</sup>	3,282	1,802	9,790	7,110
Interest expense, net <sup>3</sup>	-	500,304	2,392,447	724,684
<b>EBITDA</b>	<u>(3,590,329)</u>	<u>(4,563,234)</u>	<u>(15,566,513)</u>	<u>(8,787,475)</u>
<b>Other non-cash expenses:</b>				
Stock-based compensation expense <sup>2</sup>	388,363	303,890	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>	-	-	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>	258,811	-	1,408,296	-
Change in FV convertible debt <sup>3</sup>	161,108	-	903,000	-
<b>Non-GAAP adjusted (loss)</b>	<u>(2,782,047)</u>	<u>(4,259,344)</u>	<u>(9,120,644)</u>	<u>(6,978,882)</u>
Basic and Diluted shares outstanding	27,149,095	16,544,221	22,276,347	13,495,951
Non-GAAP adjusted (loss) income per share	(\$0.102)	(\$0.26)	(\$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 March 31, 2019 includes \$284,663 of stock-based compensation expense reported as general and administrative expenses and \$174,023 reported as research and development expense. For the three months ended March 31, 2018 includes \$219,394 of stock-based compensation expense reported as general and administrative expenses and \$51,892 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, September 5, 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, President and Chief Financial Officer, will review second quarter 2019 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. The conference call will also be available via a live listen-only webcast, which can be accessed 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 (domestic) or (412) 317-6671 (international). To access the replay, all listeners should provide the following pin number: 13692960. The webcast also 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 technologies provide groundbreaking approaches to carpal tunnel syndrome (CarpX™), precancerous conditions of the esophagus (EsoGuard™/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](#). 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 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 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.

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