November 21, 2019

PAVmed Reports Third Quarter 2019 Financial Results and Provides Business Update

Conference call to be held on November 21, 2019 at 4:30 p.m. Eastern time

NEW YORK, Nov. 21, 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 nine months ended September 30, 2019 and provided a business update.

"The third quarter and recent weeks have been highly productive as we secured financing on favorable terms and approach exciting upcoming milestones which include the commercial launch of EsoGuard," said Lishan Aklog, M.D., PAVmed's Chairman and Chief Executive Officer.

UPCOMING MILESTONES

- Complete CLIA/CAP certification and commercially launch the EsoGuard™ Esophageal DNA Test as a Laboratory Developed Test (LDT) – the first such DNA test designed to detect Barrett's Esophagus, a precursor to deadly esophageal cancer, in December;
- Launch two multi-center EsoGuard/EsoCheck clinical trials to support regulatory clearance as an FDA-registered In-Vitro Diagnostic (IVD) Barrett's Esophagus screening test, in January;
- Resubmit CarpX™ U.S. Food and Drug Administration (FDA) 510(k) application in early January, incorporating data from successful first-in-human (FIH) clinical safety study;
- Complete ongoing formal M&A process seeking 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 during a scheduled January 8, 2020 in-person pre-submission meeting – the final requirement to support PortIO's FDA *de novo* application – and launch the study in New Zealand in Q1 2020;
- Launch a long-term PortIO clinical study in Columbia, South America to demonstrate up to 60-day maintenance free implant durations in humans, in Q1 2020;
- Initiate a pilot human clinical trial of EsoCheck in Eosinophillic Esophagitis (EoE), a prevalent inflammatory disease of the esophagus, in Q1 2020;
- Complete DisappEAR six-month GLP animal study and finalize partnership agreement with large strategic partner to produce commercial-scale aqueous silk to support future FDA 510(k) submission and commercialization.

PRODUCT UPDATES

CarpX Minimally Invasive Carpal Tunnel Device

- 20 patients underwent successful CarpX procedures, completing the enrollment and treatment portion of the FIH clinical safety study;
- All 20 patients met the study's primary effectiveness endpoint;
- All 17 patients who completed their final 90-day follow-up have met the study's primary safety endpoint;
- PAVmed expects to achieve 100% follow-up with the three remaining patients who are scheduled to complete their 90-day follow-up in the coming days;
- FDA 510(k) re-submission targeted for early January.

CarpX is a minimally invasive device designed to treat carpal tunnel syndrome. PAVmed believes CarpX will

dramatically reduce recovery times compared to traditional open surgery – targeting an estimated $1 billion immediately addressable domestic market opportunity. The balloon catheter device is inserted under the scarred ligament, tensioning it 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 Company is seeking FDA 510(k) clearance to commercially market the device for minimally invasive carpal tunnel release. Extensive pre-clinical work, performed under close FDA consultation, favorably documented a narrow sliver of thermal spread, as well as safety and effectiveness substantially equivalent to a predicate. The FDA then recommended a small clinical safety study to support 510(k) resubmission and consulted closely during development of the study protocol. The primary effectiveness endpoint is intraoperative confirmation of complete transverse carpal ligament division and primary safety endpoint is the absence of nerve injury measured by electrodiagnostic motor nerve tests performed at the 90-day follow up visit.

The CarpX first-in-human (FIH) clinical safety study, performed in New Zealand, is nearly complete. All 20 patients underwent successful minimally invasive carpal tunnel release using the CarpX device and met the study's primary effectiveness endpoint. The 17 patients who have completed their final 90-day follow-up all met the study's primary safety endpoint. The remaining three patients are scheduled to complete their 90-day follow-up in the coming days. There have been no device-related adverse events.

PAVmed anticipates it will be able to incorporate the data from the clinical safety study and resubmit the CarpX FDA 510(k) application in early January 2020.

Additional observations from the clinical study strongly support CarpX's clinical and commercial potential. Procedural times fell to 15-20 minutes following a short learning curve, which is comparable to, or shorter than, traditional carpal tunnel release. The final set of procedures were performed through the 5-10 mm keyhole incisions, 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 favorably create more space within the carpal tunnel compared to traditional surgery. Subjective patient feedback has been very positive.

EsoGuard Esophageal DNA Test and EsoCheck Esophageal Cell Collection Device

- Initiated marketing and educational program for FDA 510(k)-cleared EsoCheck Cell Collection Device targeting gastroenterology community;
- Successfully transferred EsoGuard Esophageal DNA Test and associated bioinformatic software to commercial diagnostic laboratory partner ResearchDx Inc. and completed CLIA/CAP laboratory validations;
- Final CLIA/CAP certification and commercial launch of EsoGuard as a Laboratory Developed Test (LDT) to detect Barrett's Esophagus targeted for December;
- Successfully advanced EsoGuard CPT reimbursement code through the CMS Clinical Laboratory Fee Schedule (CLFS) process securing the gap-fill designation and thereby permitting initiation of coverage discussions with designated Medicare contractor;
- Positive October 9th FDA pre-submission meeting to review two multi-center clinical trial protocols to support regulatory clearance of EsoGuard/EsoCheck as an FDA-registered In-Vitro Diagnostic (IVD) with a specific Barrett's Esophagus screening indication for high-risk GERD patients;
- Launch of EsoGuard/EsoCheck IVD clinical trials targeted for January;
- Received IRB approval for pilot human clinical study at the University of Pennsylvania to evaluate EsoCheck in patients with eosinophilic esophagitis (EoE) with study launch targeted for Q1 2020.

EsoGuard and EsoCheck are revolutionary technologies licensed in 2018 by PAVmed's majority-owned subsidiary, Lucid Diagnostics Inc. ("Lucid"). They are designed to facilitate the diagnosis of Barrett's Esophagus (BE) with and without dysplasia, a progression of precursor conditions to highly lethal esophageal cancer (EAC), as well as EAC itself, in patients with chronic heart burn, also known as gastroesophageal reflux disease (GERD). Screening is recommended in millions of high-risk patients to detect and treat BE before it progresses to EAC but performed in only a small subset. 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. As a result, over 80% die within five years of diagnosis. The estimated immediately addressable domestic market opportunity for EsoGuard/ EsoCheck is at least $2 billion based on very modest penetration of U.S. GERD patients currently recommended for BE screening according to published society

guidelines.

The FDA 510(k)-cleared EsoCheck Cell Collection Device with Collect+Protect™ technology 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. Since receiving marketing clearance, Lucid has been increasing awareness of EsoCheck in the gastroenterology community through a broad marketing and educational program, including through digital and print outlets and strong, well-received, activities at the major gastroenterology meetings. Lucid is also pursuing market opportunities in prevalent esophageal conditions other than BE, including Eosinophilic esophagitis (EoE), a common inflammatory condition and fungal or viral infectious esophagitis. To this end, investigators at the University of Pennsylvania have received IRB approval for a small pilot human study, targeted to launch in Q1 2020, which will be comparing EsoCheck to endoscopy to monitor response to treatment in EoE patients.

The EsoGuard Esophageal DNA Test performs next generation sequencing (NGS) of bisulfite-converted DNA to detect methylation at 31 sites on two genes (VIM and CCNA1). EsoGuard has been shown in a 408-patient human study published in *Science Translational Medicine* to be highly accurate at detecting Barrett's Esophagus (BE) with and without dysplasia, as well as EAC, with greater than 90% sensitivity and specificity.

Lucid is advancing EsoGuard as a Laboratory Developed Test (LDT) at ResearchDx Inc., one of the nation's leading full-service commercial contract diagnostic organizations (CDO) based in Irvine, California. Lucid has successfully transferred the assay and associated bioinformatic software from the university laboratory to ResearchDx Inc., with near perfect correlation, and has completed the laboratory validations of the CLIA/CAP certification process which is expected to be completed in December, at which point Lucid will commercially launch EsoGuard as an LDT, starting with major gastroenterology centers of excellence.

The EsoGuard LDT secured a CPT reimbursement code from the American Medical Association (AMA) under the Proprietary Laboratory Analysis (PLA) process and successfully advanced the code through the CMS Clinical Laboratory Fee Schedule (CLFS) process securing the gap-fill designation permitting initiations of coverage discussions with designated Medicare contractor and private payers.

In parallel to the LDT commercial path, Lucid is seeking to significantly expand its market opportunity by advancing EsoGuard/EsoCheck as an FDA-registered In-Vitro Diagnostic (IVD), with a specific Barrett's Esophagus screening indication for high-risk GERD patients recommended for screening in published society guidelines.

Lucid's EsoGuard/EsoCheck IVD regulatory strategy was developed in conjunction with the former director of the FDA's IVD branch and includes two multi-center clinical trials in support of an FDA PMA submission. The screening study will enroll GERD patients without a prior diagnosis of BE or EAC who satisfy American College of Gastroenterology (ACG) BE screening guidelines. The case control study will enroll patients with a previous diagnosis of non-dysplastic BE, dysplastic BE (both low and high-grade) or EAC. In both studies, EsoGuard/EsoCheck will be compared to the gold standard of endoscopy with biopsies. Nicholas J. Shaheen MD, MPH, Professor and Chief of the Division of Gastroenterology and Hepatology at UNC HealthCare, and lead author of the most recent ACG guidelines, will serve as lead investigator for both studies.

The EsoGuard/EsoCheck IVD clinical study protocols were the subject of a positive October 9th FDA pre-submission meeting. Lucid has built a robust clinical trial operations infrastructure for the EsoGuard/EsoCheck clinical trials and the trial is targeted to launch in January.

Lucid is also in active discussions with the FDA to designate EsoGuard/EsoCheck as a Breakthrough Device, which recognizes promising medical devices that deliver more effective treatment or diagnosis for life-threatening conditions. FDA Breakthrough Device Designation provides accelerated FDA assessment and review and can accelerate CMS coverage and boost reimbursement.

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. PAVmed was recently granted two patents with broad independent claims covering the device technology and methods underlying PortIO.

PAVmed is seeking an initial seven-day implant duration indication for PortIO through the FDA's *de novo* pathway. The Company has successfully completed extensive pre-clinical animal and cadaver testing in close consultation

with the FDA, in support of its application. An FDA pre-submission meeting is scheduled for January 8, 2020, during which it will review the clinical protocol for a small single-center clinical safety study in New Zealand in up to 25 patients with 30-day post-explant follow-up. The Company will launch the clinical safety study in support of its *de novo* application after receiving FDA feedback on the protocol during and after the pre-submission meeting.

A long-term animal study of PortIO has demonstrated unprecedented six-month maintenance-free implant duration. These unprecedented results stand in stark contrast to all other commercially available vascular access devices which require regular flushes to prevent occlusions and device failure. In Q1 2020, PAVmed will launch a 60-day implant duration PortIO clinical study in dialysis patients and those with poor venous access in Columbia, South America, to demonstrate this long-term maintenance-free implant duration in humans.

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). Deloitte Consulting LLP recently completed 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. The global professional services firm Alvarez and Marsal has been running a formal M&A process for NextFlo targeting strategic or financial partners. The process is active with several promising opportunities in both groups.

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.

An eight-month animal study of DisappEAR has been completed with excellent results. The ear tubes appear to possess unexpected surfactant properties which would provide several unique benefits over traditional plastic tubes, including enhanced flow of fluids in and out of the tube and potential intrinsic antimicrobial properties. A six-month GLP animal study to support future FDA 510(k) submission will be completed next month. The Company is in active discussions with a large strategic partner to produce commercial-scale aqueous silk to support a future FDA 510(k) submission and commercialization.

Finally, PAVmed and its recently formed subsidiary Solys Diagnostics Inc. entered into definitive license and shareholder agreements with Airware Inc. and its subsidiary Liquid Sensing Inc to develop and commercialize non-invasive diagnostic products using Nondispersive Infrared (NDIR) technology developed by laser technology pioneer Dr. Jacob Wong. The technology promises to fulfill a decades-long goal of noninvasively measuring glucose, electrolytes and other important biochemical substances in patients, without the need for blood draws, needle sticks or other invasive maneuvers. The companies have jointly embarked on a rigorous six-month research and development program to advance the technology to a milestone based on regulatory standards for blood glucose diagnostic device accuracy. Once the accuracy milestone is reached, Solys will proceed to develop, seek regulatory clearance for, and commercialize noninvasive diagnostic products for inpatient applications while retaining a 15% nondilutive equity stake in Liquid Sensing as it seeks to develop wearable glucose monitors, a multi-billion market opportunity that has been an area of keen interest and massive investment by major Silicon Valley technology companies.

FINANCIAL RESULTS

For the three months ended September 30, 2019, research and development expenses were $1,519,415 and general and administrative expenses were $1,724,265. GAAP net loss attributable to common stockholders was $3,084,960, or $(0.10) per common share. As illustrated below and for the purpose of helping the reader understand the effect of derivative accounting and other non-cash income and expenses on the Company's financial results, the Company reported a non-GAAP adjusted loss for the three months ended September 30, 2019 of $2,723,319, or $(0.09) per common share.

PAVmed had cash and cash equivalents of $4,097,520 as of September 30, 2019, compared with $8,222,119 as of December 31, 2018. Subsequently, in November 2019, the Company received net proceeds of approximately $5.9 million from a private placement with two institutional investors for the sale of two Series A Senior Secured Convertible Notes. Additionally, the Company entered into a Series B Senior Secured Convertible Note with each of

the Series A investors that will be funded upon achieving certain equity conditions and other milestones provided in the Series B Senior Secured Convertible Note. This provides the Company with the option for an additional $5.9 million upon meeting these conditions early next year.

The audited financial results for the three and nine months ended September 30, 2019 as reported to the SEC on Form 10-Q can be obtained at www.pavmed.com or 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 nine months ended September 30, 2019 and 2018 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Net income (loss) per common share, basic and diluted	$ (0.10)	$ (0.12)	$ (0.36)	$ (0.57)
Net loss attributable to common stockholders	(3,153,089)	(3,311,124)	(10,413,835)	(11,854,787)
Preferred Stock dividends and deemed dividends	68,129	64,897	200,402	190,561
Series B Preferred stock issued upon exchange of Series A and Series A-1 Preferred stock	-	-	-	527,290
Net income (loss) as reported	(3,084,960)	(3,246,227)	(10,213,433)	(11,136,936)
Adjustments:				
Depreciation expense[1]	3,779	2,639	10,328	6,244
Interest expense, net[3]	-	707,714	-	1,708,322
EBITDA	(3,081,181)	(2,535,874)	(10,203,105)	(9,422,370)
Other non-cash expenses:				
Stock-based compensation expense[2]	330,233	324,473	1,177,282	899,649
Change in fair value of Series A Warrant Liabiity[3]	-	-	-	96,480
Change in fair value of Series A Preferred Stock conversion option embedded derivative liabiity[3]	-	-	-	(64,913)

Debt extinguishment[3]	406,858	-	666,670	-
Change in FV convertible debt[3]	(379,229)	-	340,830	-
Modification of warrant or option agreement[3]	-	2,120	-	2,259,367
Non-GAAP adjusted (loss)	(2,723,319)	(2,209,281)	(8,018,323)	(6,231,787)
Basic and Diluted shares outstanding	31,030,929	26,538,632	29,211,694	20,827,519
Non-GAAP adjusted (loss) income per share	($ 0.09)	($ 0.08)	($ 0.27)	($ 0.30)

[1] Included in general and administrative expenses in the financial statements

[2] For the three and nine months ended September 30, 2019 includes $268,859 and $852,868, respectively, of stock-based compensation expense reported as general and administrative expenses and $61,374 and $324,473, respectively, reported as research and development expense. For the three months and nine months ended September 30, 2018 includes $247,818 and $701,174, respectively, of stock-based compensation expense reported as general and administrative expenses and $76,655 and $198,475 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 Thursday, November 21, 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 third 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. 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.

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: 13694902. The webcast will be available for replay on the investor relations section of the Company's website at 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, 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, 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 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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