PAVmed Reports First Quarter 2019 Financial Results and Provides Business Update

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

NEW YORK, May 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 months ended March 31, 2019 and provided a business update.

MANAGEMENT COMMENTARY

"The first quarter and recent weeks have been perhaps the most exciting period in PAVmed's history, anchored by a long-anticipated major clinical milestone for our leading product, multiple technological breakthroughs across our portfolio and several key patent allowances," said Lishan Aklog, M.D., PAVmed's Chairman and Chief Executive Officer.

Highlights

- Successfully treated the first nine carpal tunnel syndrome patients in the CarpX™ device's first-in-human (FIH) safety study at St. George's Hospital in Christchurch, New Zealand;
- Received a positive substantial equivalence opinion from FDA of the EsoCheck™ device's GLP animal study through a pre-submission review;
- Established a strong presence for Lucid Diagnostics ("Lucid") and its EsoGuard™ and EsoCheck™ products at the major annual gastroenterology meeting, garnering excellent physician feedback and overall excitement from this key constituency;
- Advanced the EsoGuard Proprietary Laboratory Analysis (PLA) process to secure CMS reimbursement through two key steps – technical advisory review and CPT Editorial Review Panel;
- Recruited the director of clinical operations of a large multinational medical device company to serve as Lucid's Chief Operating Officer, starting in early June, to oversee clinical operations of upcoming Lucid-sponsored clinical trials, as well as operations of the EsoGuard Laboratory Developed Test (LDT);
- Engaged a leading contract diagnostic organization to build custom EsoGuard specimen kits and perform key portions of the assay;
- Completed a PortIO pilot animal study demonstrating an unprecedented maintenance-free implant duration of over 60 days;
- Completed a series of bench-top tests of the NextFlo™ Infusion System demonstrating flow accuracy comparable to expensive electronic infusion pumps, independent of intravenous (IV) bag height;
- Completed a three-month animal study of the DisappEAR™ resorbable pediatric ear tubes with excellent results including several unique benefits over traditional plastic ear tubes;

- Closed on two registered direct offerings of common stock in April and May for net proceeds of approximately $3.6 million.

CarpX Minimally Invasive Carpal Tunnel Device

CarpX is a minimally invasive device designed to treat carpal tunnel syndrome, which PAVmed believes will dramatically reduce recovery times compared to traditional open surgery and target an estimated immediately addressable domestic market opportunity of over $1 billion. CarpX is designed to closely mimic the anatomic results of invasive carpal tunnel surgery, but do so much less invasively, using catheters, balloons, radiofrequency energy and other established tools that have contributed to percutaneous and minimally invasive revolutions in the treatment of other conditions. The balloon catheter device is designed to be inserted under the scarred ligament in a minimally invasive fashion, 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.

Yesterday, we announced that the first group of nine patients with carpal tunnel syndrome underwent successful CarpX procedures as part of the first-in-human (FIH) clinical safety study PAVmed is conducting in support of its planned U.S. Food and Drug Administration (FDA) 510(k) re-submission.

The procedures were performed at St. George's Hospital in Christchurch, New Zealand by veteran plastic, reconstructive and hand surgeons Terrence A. Creagh MBChB, MRCS(Eng), FRACS(Plast) and Howard W. Klein M.D. FRACS, FRCSC, FACS. Nine patients with a clinical diagnosis of carpal tunnel syndrome underwent successful minimally invasive carpal tunnel release using the CarpX device. The device functioned as a precision cutting instrument consistent with its design and extensive preclinical testing. Complete division of the transverse carpal ligament, the protocol's effectiveness endpoint, was confirmed by endoscopic visualization and there were no device-related adverse events.

The CarpX procedure was technically straightforward with a short learning curve. Procedure times fell rapidly with each successive case and should be similar to or possibly shorter than traditional surgery. Certain procedural steps were successfully enhanced to address anatomic and tissue property differences between normal cadavers and living patients with carpal tunnel syndrome. In particular, the CarpX device required less power and lower balloon pressures to cut the ligament in human patients than it had in cadavers, an unexpected positive finding which should further enhance the procedure.

As per the protocol, these patients will undergo post-operative clinical follow-up at two weeks and 90 days, with repeat electrodiagnostic testing during the 90-day follow-up to document the protocol's safety endpoint. Another group of patients are scheduled to undergo CarpX procedures in the coming weeks. Once these procedures and their 90-day follow-up are completed, PAVmed will resubmit the CarpX 510(k) application incorporating the clinical safety and effectiveness data from the study.

EsoGuard Esophageal DNA Test and EsoCheck Cell Collection Device

The EsoGuard esophageal DNA test and the EsoCheck cell collection device are revolutionary technologies licensed in 2018 by PAVmed's majority-owned subsidiary, Lucid Diagnostics Inc., from Case Western Reserve University.

EsoGuard is an esophageal DNA test which uses 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 published human study 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).

Most individuals with BE are unaware that they have BE and thus are unaware of their risk of developing EAC. Lucid believes that the EsoGuard diagnostic test, when performed on samples collected by EsoCheck, has the potential to save many lives through early BE detection. The estimated immediately addressable domestic market opportunity for EsoGuard is at least $2 billion based on tens of millions of U.S. GERD patients who are BE screening candidates according to published guidelines.

EsoCheck is a non-invasive cell collection device that is designed to sample cells from a targeted region of the esophagus in a five-minute office-based procedure, without the need for endoscopy. The sampled cells can then be subjected to any commercially available diagnostic test.

Lucid had a very strong presence at this week's Digestive Diseases Week (DDW) meeting, the major annual gastroenterology meeting sponsored by the American Gastroenterological Association. Its booth introduced an array of new educational materials on EsoGuard and EsoCheck including a new EsoCheck animation. A leading gastroenterologist gave a well-attended presentation on both technologies and was the lead author on two EsoGuard/EsoCheck related abstracts. Booth traffic was strong with excellent feedback and overall excitement from the gastroenterology community. This excitement was partly driven by perceived advantages of EsoGuard and EsoCheck over their main competitors in esophageal cell sampling and BE detection space, as demonstrated by clinical results of these competitors presented at the meeting which were inferior to published EsoGuard/EsoCheck results.

The process to secure CMS and subsequently private payor reimbursement for the EsoGuard Laboratory Developed Test (LDT) is progressing steadily and on schedule. At the end of March, Lucid submitted EsoGuard to the American Medical Association (AMA) as the first step the Proprietary Laboratory Analysis (PLA) process to secure a diagnostic CPT billing code. Since then EsoGuard has cleared two additional hurdles – technical advisory review and the CPT Editorial Review Panel. Next month Lucid is scheduled to participate in the next step in the process, the CMS Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting, where actual proposed payment methodology and amounts will be presented. In addition, Lucid has engaged a leading contract diagnostic organization to build custom EsoGuard specimen kits and perform key portions of the assay to support the marketing of the EsoGuard LDT.

Lucid's efforts to secure regulatory clearance for EsoCheck through the FDA's 510(k) pathway are nearing completion. In order to expedite the review process, Lucid chose to submit the excellent data from the GLP animal study documenting device effectiveness and safety for FDA review through an accelerated pre-submission process while it finalizes some sterilization validation work. That process has been completed and the FDA recently provided the opinion that the results do support substantial equivalence of EsoCheck safety and effectiveness, clearing the major hurdle to EsoCheck 510(k) clearance. Once the final validation step is completed in the coming weeks, we expect a quick review of these matters and final clearance.

Lucid is pursuing other indications for EsoCheck beyond its use to collect cells for the EsoGuard DNA test. It has engaged key advisors to begin utilizing EsoCheck in other common esophageal conditions such as Esophageal Candidiasis (a yeast infection of the esophagus which occurs in patients with compromised immune systems) and Eosinophillic Esophagitis (a common inflammatory condition of the esophagus).

Lucid's long-term strategy is to secure a specific indication, based on published guidelines, for widespread BE screening using EsoGuard on samples collected with EsoCheck. This requires having the EsoGuard system cleared by the FDA as an In-Vitro Diagnostic (IVD) device, a process which is progressing at an accelerated pace in close collaboration with its medical and regulatory advisors, including the former of director of the FDA's IVD office. An FDA pre-submission package outlining Lucid-

sponsored clinical studies to be performed in support of this indication is complete and will be submitted in the coming weeks along with a meeting request to discuss its clinical data requirements for a *de novo* or Pre-Market Approval (PMA) pathway submission. In June, Lucid's new Chief Operating Officer, who most recently served as the director of clinical operations of a large multinational medical device company, will begin to oversee clinical operations planning of these upcoming Lucid-sponsored clinical trials as well as operations of the EsoGuard Laboratory Developed Test (LDT).

Other Lead Products

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

The NextFlo™ disposable intravenous (IV) infusion set recently achieved a key milestone in its quest to eliminate the need for complex and expensive electronic infusion pumps for most of the estimated one million infusions of fluids, medications and other substances delivered each day in hospitals and outpatient settings in the United States. NextFlo is designed to deliver highly accurate gravity-driven infusions independent of the height of the IV bag. It maintains constant flow by incorporating a proprietary, passive, pressure-dependent variable flow-resistor consisting entirely of inexpensive, easy-to-manufacture disposable mechanical parts. PAVmed anticipates NextFlo will be a Class I device whose market introduction will not require FDA 510(k) clearance. 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 is finalizing a commercial-ready packaged version of the NextFlo device before demonstrating it to potential acquirers including the market leader in the space, who recently contacted the company expressing interest in the technology.

Finally, a three-month animal study of the DisappEAR™ resorbable, antimicrobial pediatric ear tube animal study has been completed with excellent results. The resorbable ear tubes, machined from blocks of a proprietary silk technology, 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. Finally, there were no cases of otorrhea, which is a difficult to manage condition where pus and fluid drains out of the middle ear and into the ear canal. When traditional plastic ear tubes are used in clinical practice, as well as in this animal model, otorrhea typically occurs in at least 25-30% of recipients, despite administration of antibiotic ear drops. Additional animals are being followed for longer durations to confirm device stability and corroborate the low incidence of otorrhea. In vitro antimicrobial testing is also being performed to determine whether the surface properties have antimicrobial properties without the need for antibiotic coating.

FINANCIAL RESULTS

For the three months ended March 31, 2019, research and development expenses were $1,450,950 and general and administrative expenses were $1,692,711. GAAP net loss attributable to common stockholders was $3,600,343, 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 March 31, 2019 of $2,512,957, or $(0.09) per common share.

PAVmed had cash and cash equivalents of $4,190,445 as of March 31, 2019, compared with $8,222,119 as of December 31, 2018. Subsequently, in April and May 2019, the Company received net proceeds of approximately $3.6 million from the sale of common stock.

The audited financial results for the three months ended March 31, 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 months ended March 31, 2019 and 2018 is as follows:

	Three Months Ended Mar 31,	
	2019	**2018**
Net income (loss) per common share, basic and diluted	$ (0.13)	$ (0.21)
Net loss attributable to common stockholders	(3,600,343)	(3,414,700)
Preferred Stock dividends and deemed dividends	65,481	62,041
Series B Preferred stock issued upon exchange of Series A and Series A-1 Preferred stock	-	527,290
Net income (loss) as reported	(3,534,862)	(2,825,369)
Adjustments:		
Depreciation expense[1]	3,267	1,803
Interest expense, net[3]	-	500,304
EBITDA	(3,531,595)	(2,323,262)
Other non-cash expenses:		
Stock-based compensation expense[2]	458,686	271,286
Loss from issuance of Preferred Stock[3]	-	349,796
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]	1,001	-
Change in FV convertible debt[3]	558,951	-
Non-GAAP adjusted (loss)	(2,512,957)	(1,670,613)
Basic and Diluted shares outstanding	27,149,095	16,544,221
Non-GAAP adjusted (loss) income per share	($0.09)	($0.10)

1 Included in general and administrative expenses in the financial statements.

2 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.

3 Included in other income and expenses.

Conference Call and Webcast

The Company will hold a conference call and webcast on Tuesday, May 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, the Company's President and Chief Financial Officer, will discuss first 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: 13690282. 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.

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.

Contacts:

Investors
Mike Havrilla
Director of Investor Relations
(814) 241-4138
JMH@PAVmed.com

Media
Shaun O’Neil
Chief Commercial Officer
(518) 812-3087
SMO@PAVmed.com