NEW YORK, Jan. 10, 2019 (GLOBE NEWSWIRE) -- PAVmed Inc. (Nasdaq: PAVM, PAVMZ) (the “Company” or “PAVmed”), a highly differentiated, multiproduct medical device company, today provided an update on its business.

“The PAVmed team and its partners had a very active and productive finish to 2018, including multiple U.S. product regulatory filings, preparations for a human clinical study in New Zealand, multiple pre-clinical studies in animals and cadavers, diagnostic laboratory validation and certification studies, long-term regulatory and commercial strategic work, discussions with potential strategic partners and the refinancing of our senior secured debt,” said Lishan Aklog M.D., PAVmed’s Chairman and CEO. “All of this important work has laid a foundation for what we expect to be an even more active and productive 2019, with multiple upcoming regulatory and commercial value-creating milestones across our entire portfolio of products. This week, we participated in an important 510(k) pre-submission meeting and follow-up discussions with the U.S. Food and Drug Administration (FDA) for our CarpX™ product, which makes this an opportune time to provide a full business update.”

CarpX Update
CarpX is a minimally invasive device designed to treat carpal tunnel syndrome. The Company believes CarpX will dramatically reduce recovery times compared to traditional open surgery and target an estimated immediately addressable domestic market opportunity of over $1 billion. PAVmed has been working closely with the FDA over the past year to secure U.S. regulatory clearance of CarpX through the FDA’s 510(k) pathway,
which is based on demonstrating substantial equivalence (SE) to a previously cleared predicate device. The review period for the initial 510(k) submission expired in August 2018, before the FDA branches were able to reach a consensus on its SE to the predicate. The agency recommended that PAVmed resubmit the 510(k) application following an in-person pre-submission meeting. PAVmed added the founding partner of one of nation’s leading FDA law firms and the chief of hand surgery of a prestigious academic center to its team and filed a pre-submission package in October 2018. The package included an explicit request that specified senior FDA personnel with oversight over both branches be present at the meeting. The pre-submission meeting was held on January 7, 2019 as scheduled. Six PAVmed officers and consultants were joined by nine FDA personnel across both lead and consulting branches, including two deputy directors and a branch chief.

“I am very pleased with how this week’s pre-submission meeting and follow-up interactions with the FDA have gone,” said Dr. Aklog. “The goal of the pre-submission process is to receive clear and definitive guidance on what the company needs to do to demonstrate substantial equivalence. I am grateful that the FDA personnel showed up in force, despite the government shutdown, and engaged in a substantive conversation during which we were able to secure that guidance.

“In written and verbal feedback, the FDA indicated that its remaining SE issues focused on protection of important structures during the procedure. It recommended clinical testing to definitively document procedural safety in humans and provided initial guidance on parameters for this testing. Perhaps most importantly, it indicated that data from a properly structured clinical study outside of the U.S. (OUS) would be acceptable, precluding the need to engage in the FDA’s time-consuming Investigational Device Exemption (IDE) process required for U.S. studies. The meeting and follow-up were dominated by a discussion of these parameters and PAVmed was able to provide strong arguments backed by substantive data from the literature to limit the scope of this testing to what is required to directly address the remaining SE issues.

“There are three important reasons that I am very satisfied with the outcome of this week’s FDA discussions,” Dr. Aklog explained. “First, although a few details remain, I believe we
are at or very close to a consensus with the FDA on the parameters of the study. The proposed study is a small single-arm two-center study of the CarpX procedure in patients with documented carpal tunnel syndrome, with a primary endpoint of device safety defined as the absence of certain serious device-related adverse events over a limited follow-up period. I believe we can complete this proposed study expeditiously and within our current budget.

“Second, as we have previously disclosed, we have been working to initiate a first-in-human (FIH) clinical study in New Zealand (ClinicalTrials.gov Identifier: NCT03747510). We have received both nationwide Ethics Committee approval and local hospital approval at one site. Five patients are enrolled and scheduled to undergo the CarpX procedure at the end of this month. We are extremely fortunate that the FIH study parameters line up very closely with the FDA’s requests. As a result, we will be able to transform the actively enrolling FIH study into the FDA clinical safety study in support of our 510(k) re-submission, greatly mitigating the impact of the FDA’s request for clinical testing. Our goal is to add the second NZ site in February.

“Finally, although the clinical study request will extend the commercial timeline, once cleared, we will be able to launch CarpX in the U.S. armed with human clinical data demonstrating safety and effectiveness and having already honed the procedural steps in humans. This will permit a broader commercial launch with an accelerated ramp up in both the domestic and OUS markets,” Dr. Aklog concluded.”

CarpX is being manufactured in Massachusetts by a leading medical device contract manufacturer with lines scalable to accommodate demand for the foreseeable future. The manufacturing process qualifications and validations required to start delivering commercial product are scheduled to be completed by the end of this quarter as is European CE Mark submission. ISO certification of the quality system required for CE Mark clearance and European commercial launch is scheduled to be completed soon thereafter.

EsoCheck™ Update
EsoCheck is a revolutionary technology licensed by PAVmed’s majority-owned subsidiary,
The Company believes the EsoCheck technology has the potential to save many lives through the early detection of BE, which can be carefully monitored and treated with non-surgical approaches if detected before cancer develops. The immediately addressable domestic market opportunity for the EsoCheck technology is estimated to be at least $2 billion based on tens of millions of U.S. patients with GERD who are candidates for BE screening based on existing American College of Gastroenterology (ACG) guidelines.

The Company is pursuing a two-phase regulatory and commercialization strategy which seeks to maximize the technology’s long-term commercial opportunity while providing near-term value-inflection commercial milestones. Phase I seeks to commercially launch EsoCheck CCD as a 510(k)-cleared cell collection device and separately launch EsoCheck Dx as a Laboratory Developed Test (LDT), which does not currently require FDA review. Phase II seeks a specific indication for widespread BE screening using the two EsoCheck products based on ACG guidelines.

“We continue to make excellent progress in both phases of our EsoCheck regulatory and commercial strategy,” Dr. Aklog said. “In terms of Phase I, we submitted the EsoCheck CCD cell sampling device for FDA 510(k) clearance in late November and expect to receive an initial response from the FDA soon. Based on the excellent predicates and low-risk profile, I remain optimistic that EsoCheck CCD will be cleared expeditiously. EsoCheck CCD is being manufactured in Ohio with lines scalable to accommodate commercial and clinical research demand for the foreseeable future. The manufacturing process qualifications and validations required to start delivering commercial product are...
scheduled to be completed by the end of this quarter.

“The EsoCheck Dx methylated DNA biomarker test continues to undergo a battery of laboratory and clinical validation tests to secure CLIA certification. It remains on schedule to achieve LDT designation at its designated clinical reference laboratory in Cleveland this quarter. We are prepared to file for EsoCheck Dx reimbursement codes through the American Medical Association’s Proprietary Laboratory Analysis (PLA) process as soon as the test is available as an LDT.

“Phase II is also proceeding well. The multi-center National Institutes of Health funded clinical trial comparing EsoCheck CCD+Dx to endoscopy is progressing well with interim abstracts and academic presentations expected this spring. We are also working closely with former FDA officials at a leading regulatory firm on our long-term regulatory strategy. We expect to file a pre-submission package and meeting request with the FDA in the coming weeks and secure a meeting date to discuss its clinical data requirements for a de novo or Pre-Market Approval (PMA) pathway submission to support Phase II’s goal of a specific indication for widespread BE screening using EsoCheck technology.”

Other Products
PAVmed’s other lead product pipeline devices include PortIO™, an implantable intraosseous vascular access device; DisappEAR™, a silk-based resorbable, antimicrobial pediatric ear tube; and NextFlo™, a fixed-rate intravenous infusion set based on a proprietary variable flow-resistor.

“The remaining lead products in our pipeline are progressing well and we believe will provide additional opportunities to enhance shareholder value by mitigating risk through diversification and offering potential sources of non-dilutive capital,” Dr. Aklog explained.

“PortIO continues to advance along the FDA’s de novo pathway. The FDA-requested GLP animal study implants have been completed. Device explants will be completed this month followed by pathologic analysis of the implant sites. We are planning an FIH series in Columbia and exploring the possibility of fulfilling the likely FDA request for human clinical data with an OUS study. CE Mark submission is scheduled for Q2-2019. We continue to
explore potential strategic partnerships including acquisition of PortIO.

“The DisappEAR™ animal study to evaluate resorption rates was initiated last quarter with successful implants of machined silk ear tubes. The ear tubes remain secure on serial examination and the first set will be explanted and evaluated at three months. If the animal study is successful it will be used to support a planned FDA 510(k) submission in 2019.

“Finally, NextFlo’s variable flow-resistor has generated outstanding bench-top data, demonstrating that it is able to passively adjust its resistance and deliver constant flow across a wide, clinically-relevant pressure range. The project has moved into the industrial/human factors design phase, whereby the technology will be incorporated into a standard intravenous infusion set. Full design verification and validation testing will follow to support an FDA 510(k) submission later this year and we believe will be limited to bench-top testing.

Other Corporate Matters

“Eighteen months ago, we raised $5 million in debt financing by issuing 15% senior secured notes to Scopia Holdings LLC to fund our ongoing operations,” Dr. Aklog noted. “Two weeks ago, we closed a refinancing of this senior secured debt, well ahead of its 2019 maturity date and under terms favorable to the company, including a lower coupon rate and no attached warrants. This has further strengthened our balance sheet through key 2019 value-inflection milestones by removing the July 2019 debt maturity overhang and increasing our working capital runway by a meaningful amount.”

PAVmed issued $7.75 million of two-year 7.875% convertible senior secured notes to a single institutional investor which yielded net cash proceeds of approximately $6.45 million after deducting the original issue discount and transaction fees. The Company used $5 million of the net cash proceeds to repay the outstanding principal of the 15% senior secured notes held by Scopia Holdings. In addition, Scopia Holdings agreed to accept 600,000 shares of PAVmed common stock at a price of approximately $1.30/share (a 41% premium over the price on the closing date) for payment of all due and accrued interest. The $1.45 million in net proceeds will be used as working capital to advance its lead products towards commercialization.
The new notes are convertible at $1.60 (a premium of 74% over the price on the closing date). They include an interest-only period with the first of 37 bi-monthly installment payments due on June 28, 2019 and a maturity date of December 31, 2020. PAVmed has the option to make installment payments in cash or by issuing shares of common stock valued at a modest discount to the volume-weighted average price (VWAP) of its common stock at the time of payment. The payment in cash or stock is fundamentally at PAVmed’s discretion. The note includes customary covenants, equity and capital market conditions as well as the opportunity to accelerate payments under certain mutually beneficial conditions. The detailed terms of the transaction as reported to the SEC on Form 8-K filed December 27, 2018 can be obtained at [www.pavmed.com](http://www.pavmed.com) or [www.sec.gov](http://www.sec.gov).