

November 17, 2020



PAVmed Reports Third Quarter 2020 Financial Results and Provides Business Update

Conference call to be held today at 4:30 p.m. Eastern time

NEW YORK, Nov. 17, 2020 (GLOBE NEWSWIRE) -- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ)** (the “Company” or “PAVmed”), a highly differentiated, multi-product, commercial-stage medical device company, today provided a business update for the Company and its subsidiaries, Lucid Diagnostics Inc. (“Lucid”) and Solys Diagnostics Inc. (“Solys”) and discussed financial results for the three and nine months ended September 30, 2020.

“During the third quarter of 2020 and subsequent weeks, we have seen commercial activity accelerate as we gain solid traction for PAVmed’s lead products in the medical community,” said Lishan Aklog, M.D., PAVmed’s Chairman and Chief Executive Officer. “Our expanding commercial team has delivered exponential growth in EsoGuard[®] testing and EsoCheck[®] procedures, despite the challenges of the pandemic, as well as growing, palpable enthusiasm among physicians for these devices for their potential to save lives through early detection of precursors of highly lethal esophageal cancer. With final U.S. Center for Medicare and Medicare Services (“CMS”) payment determination now secured, we look forward to translating this into a solid, growing revenue stream when CMS payment becomes effective in the New Year.”

RECENT ACCOMPLISHMENTS

- Secured U.S. Center for Medicare and Medicare Services (“CMS”) Clinical Laboratory Fee Schedule Test Code Final Determination for EsoGuard[®] Esophageal DNA Test (CPT code 0114U) of \$1,938.01, effective January 1, 2021.
- Expanded sales management team to 5 professionals (CarpX[®] national sales manager and 4 Lucid regional sales managers) and independent sales network to 38 representatives.
- Rapidly accelerated EsoGuard testing and EsoCheck procedural activity, doubling their rates approximately every 4-6 weeks.
- Expanded EsoGuard marketing activities and disease-related educational activities targeting physicians and consumers, including a widely distributed *Access Health segment* aired on the Lifetime Network, highlighting the relationship between Gastroesophageal Reflux Disease (GERD), Barrett’s Esophagus (BE) and highly lethal esophageal cancer (EAC), as well as the role of EsoGuard in early detection and cancer prevention.

- Received U.S. Patent and Trademark Office trademarks for EsoGuard[®] and CarpX[®].
- Completed European Union (EU) CE Mark regulatory submission for EsoCheck and confirmed that EsoGuard falls under the self-declaration category of the EU IVDD requirements, clearing the path to European commercialization of both products.
- Achieved multiple critical PAVmed and Lucid quality management system milestones, including passing stage 2 audits for both, receiving ISO 13485:2016 certification for Lucid and recommendation for certification for PAVmed, clearing the path for EU CE Mark submissions for EsoCheck, CarpX, PortIO[™], NextFlo[™] and all future PAVmed and Lucid products.
- Recruited hand surgeon advisory board to perform initial U.S. procedures and serve as trainers, proctors, educators, and ambassadors for the CarpX minimally invasive device to treat carpal tunnel syndrome. Completed initial cadaver training in advance of first U.S. commercial cases.
- Accelerated enrollment at 21 active U.S. sites for ESOGUARD BE-1 and 2 clinical trials in support of FDA registration of EsoGuard/EsoCheck as an In-Vitro Diagnostic (IVD) device with 33 patients enrolled and tested to date, with no serious adverse events recorded.
- Completed enrollment in pilot clinical trial evaluating EsoCheck in Eosinophilic Esophagitis (EoE) patients at the University of Pennsylvania.
- Completed initial diabetic rat model prototype testing of Solys non-invasive glucose monitoring system, achieving R&D plan milestone as defined in license agreement.
- Continued to expand and advance extensive intellectual property portfolio of 150 issued and pending, owned, assigned or licensed patents across PAVmed and its subsidiaries.
- Received approximately \$7 million in net proceeds from a private placement of Senior Secured Convertible Promissory Notes with an existing institutional investor.

UPCOMING KEY ACTIVITIES AND MILESTONES

- Initiate claims submission and billing at \$1,938.01 for each EsoGuard test performed under CPT code 0114U, effective January 1, 2021.
- Continue to expand sales management team and independent sales representative network for both EsoGuard/EsoCheck and CarpX.
- Continue to drive acceleration in EsoGuard testing and EsoCheck procedural activity, targeting both large medical centers and small-medium practices. Continue to optimize sales and training activities as pandemic-related restrictions wax and wane.
- Perform initial U.S. CarpX procedures by initial cohort of trained experts and subsequently expand clinical and commercial activities to broader group of hand surgeons and other proceduralists.

- Secure CMS local coverage determinations for EsoGuard and extend payment and coverage process to private payors.
- Secure EsoCheck and CarpX CE Mark approvals and EsoGuard CE Mark self-certification. Launch EsoGuard, EsoCheck and CarpX in Europe.
- Accelerate enrollment at U.S. sites for ESOGUARD-BE-1 and 2 screening and case control clinical trials.
- Launch additional Lucid-sponsored clinical trials of EsoGuard and EsoCheck to support commercial activities including American Foregut Society sponsored EsoGuard Registry, BE EGD Yield study and population study of active measures to enhance BE-EAC screening using EsoGuard.
- Launch clinical trial of EsoCheck with BE progression markers at Fred Hutchinson Cancer Research Center in Seattle.
- Continue to explore role of EsoCheck in diagnosing and managing Eosinophilic Esophagitis (EoE) based on results of University of Pennsylvania pilot study and potential EoE biomarkers under development.
- Complete M&A process and consummate licensing agreement for NextFlo™ technology in disposable infusion pumps.
- Complete device qualification and FDA 510(k) submission for NextFlo Intravenous Infusion System. Commercially launch NextFlo IV Infusion system at targeted large medical centers following FDA 510(k)-clearance.
- Secure FDA clearance for an Investigational Device Exemption (IDE) to begin a clinical safety study in the U.S. evaluating PortIO™ Intraosseous Infusion Device in dialysis patients with a one-week implant duration to support its *de novo* application.
- Enroll first patients in PortIO long-term clinical study in Colombia, South America to demonstrate up to 60-day maintenance free implant durations in humans.
- Complete development work and animal testing of EsoCure™ Esophageal Ablation Device in support of FDA 510(k) submission in 2021.
- Continue to advance development of Solys non-invasive glucose monitoring system towards accuracy milestones sufficient for FDA regulatory submission and commercialization.

FINANCIAL RESULTS

For the three months ended September 30, 2020, research and development expenses were \$2.6 million and general and administrative expenses were \$2.9 million, in-line with the previous quarter. GAAP net loss attributable to common stockholders was \$5.6 million, or \$(0.11) 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, 2020 of \$4.5 million, or \$(0.09) per common share.

PAVmed had cash and cash equivalents of \$8.3 million as of September 30, 2020, compared with \$6.2 million as of December 31, 2019.

The unaudited financial results for the three and nine months ended September 30, 2020 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, 2020 and 2019 is as follows:

(ooo's except per-share amounts)	For the three months ended September 30,		For the nine months ended September 30,	
	2020	2019	2020	2019

Net income (loss) per common share, basic and diluted	(\$ 0.11)	(\$ 0.10)	(\$ 0.57)	(\$ 0.36)
Net loss attributable to common stockholders	(5,557)	(3,153)	(25,751)	(10,414)
Preferred Stock dividends and deemed dividends	74	68	215	201
Net income (loss) as reported	<u>(5,483)</u>	<u>(3,085)</u>	<u>(25,536)</u>	<u>(10,213)</u>
Adjustments:				
Depreciation expense ¹	7	4	17	10
Interest expense, net ³	-	-	53	-
EBITDA	<u>(5,476)</u>	<u>(3,081)</u>	<u>(25,466)</u>	<u>(10,203)</u>
Other non-cash or financing related expenses:				
Stock-based compensation expense ²	586	330	1,458	1,177
Debt extinguishment ³	663	407	4,600	666
Change in FV convertible debt ³	(367)	(379)	5,521	341
Offering costs convertible debt ³	50	-	660	-
Non-GAAP adjusted (loss)	<u>(4,544)</u>	<u>(2,723)</u>	<u>(13,227)</u>	<u>(8,019)</u>
Basic and Diluted shares outstanding	48,381	31,031	45,564	29,212
Non-GAAP adjusted (loss) income per share	(\$ 0.09)	(\$ 0.09)	(\$ 0.29)	(\$ 0.27)

¹ Included in general and administrative expenses in the financial statements

² For the three months ended September 30, 2020 includes \$448 of stock based compensation expense reported as general and administrative expenses and \$138 reported as research and development expense. For the three months ended September 30, 2019 includes \$269 of stock based compensation expense reported as general and administrative expenses and \$61 reported as research and development expense. For the nine months ended September 30, 2020 includes \$1,132 of stock based compensation expense reported as general and administrative expenses and \$326 reported as research and development expense. For the nine months ended September 30, 2019 includes \$853 of stock based compensation expense reported as general and administrative expenses and \$324 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 today 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 2020 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: 13712132. 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, multi-product, commercial-stage medical device company employing a unique business model designed to advance innovative products to commercialization rapidly and with 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 while seeking to further expand its pipeline through relationships with its network of clinician innovators at leading academic centers. PAVmed's diversified product pipeline addresses unmet clinical needs encompassing a broad spectrum of clinical areas with attractive regulatory pathways and market opportunities. Its four operating divisions include GI Health (EsoGuard[®] Esophageal DNA Test, EsoCheck[®] Esophageal Cell Collection Device, and EsoCure[™] Esophageal Ablation Device with Calvus[™] Technology), Minimally Invasive Interventions (CarpX[™] Minimally Invasive Device for Carpal Tunnel Syndrome), Infusion Therapy (PortIO[™] Implantable Intraosseous Vascular Access Device and NextFlo[™] Highly Accurate Disposable Intravenous Infusion Set), and Emerging Innovations (non-invasive laser-based glucose monitoring, pediatric ear tubes, and mechanical circulatory support). 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](#). For detailed information on EsoGuard, please visit www.EsoGuard.com and follow us on [Twitter](#), [Facebook](#) and [Instagram](#).

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 to 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 many of its products. The Company has been monitoring the COVID-19 pandemic and its impact on our business. The Company expects the significance of the COVID-19 pandemic, including the extent of its effect on the Company's financial and operational results, to be dictated by, among other things, the success of efforts to contain it and the impact of actions taken in response. 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 Report 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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