
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): **August 18, 2020**

PAVMED INC.

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-37685

(Commission
File Number)

47-1214177

(IRS Employer
Identification No.)

One Grand Central Place, Suite 4600, New York, New York

(Address of Principal Executive Offices)

10165

(Zip Code)

Registrant's telephone number, including area code: **(212) 949-4319**

N/A

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value \$0.001 Per Share	PAVM	The Nasdaq Stock Market LLC
Series Z Warrants to Purchase Common Stock	PAVMZ	The Nasdaq Stock Market LLC
Series W Warrants to Purchase Common Stock	PAVMW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On August 18, 2020, PAVmed Inc. (the “Company”) issued a press release providing a business update and announcing its financial results for the quarter ended June 30, 2020. Attached as Exhibit 99.1 to this Current Report is a copy of the press release, which is incorporated herein by reference.

The information furnished under this Item 2.02, including the exhibits related thereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any disclosure document of the Company, except as shall be expressly set forth by specific reference in such document.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release.</u>

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: August 18, 2020

PAVMED INC.

By: /s/ Dennis M. McGrath

Dennis M. McGrath
President and Chief Financial Officer



PAVmed Reports Second Quarter 2020 Financial Results and Provides Business Update

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

NEW YORK, Aug. 18, 2020 (GLOBE NEWSWIRE) — **PAVmed Inc. (Nasdaq: PAVM, PAVMZ)** (the “Company” or “PAVmed”), a highly differentiated, multi-product, commercial-stage medical device company, today reported financial results for the three and six months ended June 30, 2020 and provided a business update for the Company and its subsidiaries, Lucid Diagnostics Inc. (“Lucid”) and Solys Diagnostics Inc. (“Solys”).

“The second quarter of 2020 and subsequent weeks constitute an unprecedented period of major accomplishments for PAVmed and its subsidiaries, despite significant Covid-19 headwinds in the late spring and early summer,” said Lishan Aklog, M.D., PAVmed’s Chairman and Chief Executive Officer. “These accomplishments include a preliminary CMS payment determination, FDA clearance and commercial launch of a lead product, consummation of critical partnership agreements, and steady progress on the commercial, clinical, regulatory, development and intellectual property fronts. Our expanding team of talented professionals, joined by world-class partners and advisors, and supported by a strong balance sheet, are well-poised to build on these accomplishments and achieve important value-inflection milestones in the coming months.”

RECENT ACCOMPLISHMENTS

- Secured U.S. Center for Medicare and Medicare Services (“CMS”) Clinical Laboratory Fee Schedule Test Code Preliminary Determination for EsoGuard™ Esophageal DNA Test (CPT code 0114U) of \$1,938.01 in 38 states and \$2,690.00 in 12 states (including Florida, New Jersey and Pennsylvania) and two U.S. territories.
 - Received 510(k) marketing clearance from the U.S. Food and Drug Administration (“FDA”) for CarpX™ minimally invasive carpal tunnel device.
 - Commercially launched CarpX, including FDA commercial device registration and listing in the GUDID database, as well as the initial release of inventory for fulfillment by third party logistics and warehousing partner HealthLink Europe and International.
 - Expanded commercial management team to seven professionals adding in the quarter a CarpX national sales manager, a Lucid regional sales manager, and a marketing director to support an independent sales organization of 35 professionals.
 - Accelerated Lucid commercial activities, with active sales processes involving over 500 customers and product in stock at approximately 50 clinical sites. Resumed in-person procedural training.
 - Activated 27 sites for ESOGUARD BE-1 and 2 clinical trials in support of FDA registration of EsoGuard/EsoCheck as an In-Vitro Diagnostic (IVD) device. Resumed enrollment with six new patients and successful EsoCheck administration in all patients.
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- Enrolled first patient in clinical trial evaluating EsoCheck in Eosinophilic Esophagitis (EoE) patients at the University of Pennsylvania.
- Entered into a definitive agreement with global manufacturer Canon Inc.'s United States manufacturing and technology center, Canon Virginia, Inc. to develop and utilize Canon Virginia's commercial grade aqueous silk fibroin molding process to manufacture its DisappEAR™ molded pediatric ear tubes for commercialization.
- Entered into a manufacturing agreement with medical device contract manufacturer Coastline International Inc. to serve as a high-volume, lower-cost manufacturer of PAVmed and Lucid products including EsoCheck and NextFlo.
- Successfully completed European Union notified body stage 1 audits of PAVmed and Lucid quality management systems in support of upcoming CE Mark regulatory submissions of PAVmed and Lucid products.
- Successfully completed pre-clinical feasibility animal study of its EsoCure™ Esophageal Ablation Device demonstrating excellent, controlled circumferential ablation of the esophageal mucosal lining.
- Successfully completed preliminary human testing of Solys laser-based non-invasive blood glucose device demonstrating testing accuracy within established FDA and ISO 15197 regulatory standards in normal human volunteers with moderate post-prandial hyperglycemia.
- Granted U.S. patent for EsoCheck™ Cell Collection Device (10,660,621) and CalduS™ Technology underlying EsoCure (10,687,883) as well as Chinese patent for CarpX.
- Diagnostics industry titan, Stanley Lapidus, founder, former Chairman and CEO of Exact Sciences, joined Lucid as a Strategic Advisor.
- Received approximately \$10.6 million in net proceeds from two private placements of Senior Convertible Promissory Notes with an existing institutional investor.

UPCOMING KEY ACTIVITIES AND MILESTONES

- Accelerate and expand EsoGuard and EsoCheck commercial activities as elective clinical procedures continue to resume from Covid-19 limitations.
 - Expand EsoGuard educational and marketing activities targeting physicians and consumers, including upcoming Access Health segment on the Lifetime Network highlighting Barrett's Esophagus as well as the role of EsoGuard and EsoCheck.
 - Begin CarpX commercial activities focusing on key opinion leaders and innovators capable of serving as CarpX trainers, proctors and educators.
 - Secure CMS coverage determination for EsoGuard and extend payment and coverage process to private payors.
 - Complete stage 2 audits of PAVmed and Lucid's quality management systems and submit EU CE Mark regulatory clearance applications for EsoCheck, EsoGuard, CarpX and PortIO™.
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- Activate remaining 27 U.S. and European clinical trial sites for ESOGUARD-BE-1 and 2 and accelerate clinical trial enrollment as elective clinical procedures continue to resume from Covid-19 limitations.
- Complete ongoing clinical trial evaluating EsoCheck in EoE patients at the University of Pennsylvania.
- Launch clinical trial of EsoCheck with BE progression markers at Fred Hutchinson Cancer Research Center in Seattle.
- Launch additional Lucid-sponsored clinical trials of EsoGuard and EsoCheck to support commercial activities including EsoGuard registry, Barrett's Esophagus EGD Yield study and Integrated Health System Referral study.
- 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.
- Secure FDA clearance for an Investigational Device Exemption (IDE) to begin a clinical safety study in the U.S. evaluating PortIO in dialysis patients with a one-week implant duration to support its *de novo* application.
- Initiate PortIO long-term clinical study in Colombia, South America to demonstrate up to 60-day maintenance free implant durations in humans.
- Advance Solys development to achieve FDA and ISO 15197 accuracy standards for a full range of glucose measurements including severe hyperglycemia.

FINANCIAL RESULTS

For the three months ended June 30, 2020, research and development expenses were \$2.1 million and general and administrative expenses were \$2.9 million. GAAP net loss attributable to common stockholders was \$5.6 million, or \$(0.13) 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 June 30, 2020 of \$4.2 million, or \$(0.09) per common share.

PAVmed had cash and cash equivalents of \$7.1 million as of June 30, 2020, compared with \$6.2 million as of December 31, 2019. Subsequently, in early August 2020, the Company received approximately \$7 million in proceeds from a private placement with an existing institutional investor for the sale of a Senior Secured Convertible Note.

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

(ooo's except per-share amounts)	For the three months ended June 30,		For the six months ended June 30,	
	2020	2019	2020	2019
Net income (loss) per common share, basic and diluted	\$ (0.13)	\$ (0.13)	\$ (0.46)	\$ (0.27)
Net loss attributable to common stockholders	(5,649)	(3,660)	(20,194)	(7,261)
Preferred Stock dividends and deemed dividends	71	66	141	132
Net income (loss) as reported	<u>(5,578)</u>	<u>(3,594)</u>	<u>(20,053)</u>	<u>(7,129)</u>
Adjustments:				
Depreciation expense ¹	5	3	9	7
Interest expense, net ³	-	-	52	-
EBITDA	<u>(5,573)</u>	<u>(3,591)</u>	<u>(19,992)</u>	<u>(7,122)</u>
Other non-cash or financing related expenses:				
Stock-based compensation expense ²	529	388	873	847
Debt extinguishment ³	2,750	259	3,937	260
Change in FV convertible debt ³	(2,120)	161	5,888	720
Offering costs convertible debt ³	200	-	610	-
Non-GAAP adjusted (loss)	<u>(4,214)</u>	<u>(2,783)</u>	<u>(8,684)</u>	<u>(5,295)</u>
Basic and Diluted shares outstanding	44,781	27,606	44,140	27,344
Non-GAAP adjusted (loss) income per share	\$ (0.09)	\$ (0.10)	\$ (0.20)	\$ (0.19)

1 Included in general and administrative expenses in the financial statements

2 For the three months ended June 30, 2020 includes \$407 of stock based compensation expense reported as general and administrative expenses and \$122 reported as research and development expense. For the three months ended June 30, 2019 includes \$299 of stock based compensation expense reported as general and administrative expenses and \$89 reported as research and development expense. For the six months ended June 30, 2020 includes \$684 of stock based compensation expense reported as general and administrative expenses and \$189 reported as research and development expense. For the six months ended June 30, 2019 includes \$584 of stock based compensation expense reported as general and administrative expenses and \$263 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 second 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: 13707223. 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 CalduS™ Technology), Minimally Invasive Interventions (CarpX™ Minimally Invasive Device for Carpal Tunnel Syndrome), Infusion Therapy (PortIO™ Implantable Intraosseus 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.

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 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 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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