

**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): October 3, 2017

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)).

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 8.01. Other Events.

PAVmed Inc. (the “Company”) has received a letter from the Food and Drug Administration (the “FDA”) regarding its PortIO Intraosseous Infusion System. The Company had previously submitted a 510(k) premarket notification relying upon substantial equivalence to a previously approved predicate device with an indication for use for up to 24 hours. The Company has been engaged with the FDA on the issue of substantial equivalence, including an in-person meeting in July 2017, and had submitted a response based on the FDA’s feedback which included narrower indications and inclusion of a needle in the kit. Despite these modifications, the FDA determined that PortIO is not substantially equivalent to the proposed predicate and encouraged the Company to instead pursue classification under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act, also referred to as de novo classification. The Company has decided to follow the FDA’s encouragement and pursue a de novo classification for PortIO under a broader indication, for up to seven days, and intends to immediately pursue a pre-submission meeting with the FDA.

Forward-Looking Statements

This Form 8-K includes forward-looking statements that involve risks and uncertainties. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are based upon the current beliefs and expectations of the Company’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, the uncertainties inherent in research and development, including the cost and time required to advance our products to regulatory submission; whether regulatory authorities will be satisfied with the design of and results from our preclinical studies; whether and when our products are cleared by regulatory authorities; market acceptance of our products once cleared and commercialized; our ability to raise additional funding; and other competitive developments. The Company 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 our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item IA, “Risk Factors,” in our 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 us after our most recent Annual Report. We disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our 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.

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: October 3, 2017

PAVMED INC.

By: /s/ Lishan Aklog

Lishan Aklog, M.D.
Chief Executive Officer

