

NEPHROS INC
Form 8-K
August 18, 2016

**UNITES STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 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 15, 2016

NEPHROS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware **001-32288** **13-3971809**
(State or other jurisdiction (Commission (IRS Employer
of incorporation) File Number) Identification No.)

41 Grand Avenue, River Edge, New Jersey 07661

(Address of principal executive offices, including ZIP code)

(201) 343-5202

(Registrant's telephone number, including area code)

Not Applicable

(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:

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))

Item 8.01 Other Events.

On August 15, 2016, Nephros, Inc. (the “Company”) had a teleconference with the staff of the U.S. Food and Drug Administration (“FDA”), including reviewers from both the Infection Control Devices Branch and Renal Devices Branch, regarding the Company’s Special 510(k) submissions for the 10” PathoGuard™ and 10” EndoPur™ filters. As a result of this teleconference, the Company believes it understands the additional testing and information requested by the FDA to complete the submission package, and the Company expects to be able to complete the additional testing and submit the additional information before the end of October 2016. Subject to, and depending upon the timing of, FDA clearance, the Company expects to begin commercial sales of these products before the end of 2016. The timing of commercial sales of these products may delay the Company’s achievement of positive cash flow into early in the first quarter of fiscal 2017.

Forward-Looking Statements

This Form 8-K contains forward-looking statements that are subject to various risks and uncertainties. Such statements include statements regarding the FDA clearance process for the EndoPur™ and PathoGuard™ filters, including the timing of completion of testing and submission of additional paperwork; the commercial launch of the filters; the Company’s expectations regarding cash flow; and other statements that are not historical facts, including statements which may be accompanied by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “p,” “estimates,” “aims,” “believes,” “hopes,” “potential” or similar words. Actual results could differ materially from those described in these forward-looking statements due to certain factors, including potential delays in the regulatory approval process, changes in business, economic and competitive conditions, the availability of capital when needed, our dependence on third party manufacturers, regulatory reforms, uncertainties in litigation or investigative proceedings, and the availability of financing. These and other risks and uncertainties are detailed in Nephros Inc.’s reports filed with the U.S. Securities and Exchange Commission, including with respect to Nephros, its Annual Report on Form 10-K for the year ended December 31, 2015. Nephros, Inc. does not undertake any responsibility to update the forward-looking statements in this Form 8-K.

SIGNATURES

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.

Nephros, Inc.

Dated: August 18, 2016 By: */s/ Daron Evans*

Daron Evans

President & Chief Executive Officer

