

NEPHROS INC
Form 8-K
May 03, 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): April 28, 2016

NEPHROS, INC.

(Exact name of Registrant as Specified in its Charter)

| | | |
|---|-----------------------------|--------------------------------------|
| Delaware | 001-32288 | 13-3971809 |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer 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.

As previously announced in a press release dated April 21, 2016, Nephros, Inc. (the “Company”) submitted a Special 510(k) application to the U.S. Food and Drug Administration (“FDA”) for its EndoPur™ ultrafilter designed to provide hemodialysis quality water. On April 28, 2016, the Company received a response from FDA, in which FDA noted that it had determined that the Special 510(k) should be converted to a Traditional 510(k). FDA requested additional information on the 20”, 30” and 40” filter sizes and on the reusable external filter housing. Following discussions with FDA, the Company converted the Special 510(k) submission to a Traditional 510(k) submission for the 20”, 30” and 40” filter sizes. The Company intends to file a separate Special 510(k) for the EndoPur™ 10” filter size in the near term.

Due to the longer FDA review process associated with a Traditional 510(k) submission, the Company aims to launch the 20”, 30” and 40” filter sizes early in the fourth quarter of 2016, subject to completion of the FDA clearance process. As the 10” filter size still qualifies for the Special 510(k) process, the Company aims to launch the 10” filter size early in the third quarter of 2016, subject to completion of the FDA clearance process.

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 EndoPur™, including the eligibility of its various filter sizes for Traditional 510(k) clearance or Special 510(k) clearance, the timing of commercial launch of the various filter sizes, and other statements that are not historical facts, including statements which may be accompanied by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “believes,” “hopes,” “p” 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: May 3, 2016 By: */s/ Daron Evans*

Daron Evans

President & Chief Executive Officer

