NEPHROS INC
Form 8-K
June 02, 2015

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): May 25, 2015

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.

Notice of Allowance for U.S. Patent

On May 25, 2015, Nephros, Inc. (the "Company") received a Notice of Allowance for U.S. Patent Application No. 13/888,645, "Method and Apparatus of Flush Pump Feature for Portable Liquid Purifying Filter" (the "Patent"). The Notice of Allowance covers claims relating to certain accessories used with the Company's HydraGuard individual water purifier devices. The HydraGuard ultrafilter membrane provides a barrier to block sediment, bacteria, parasites, viruses and cysts from water filtered by the membrane. The flush pump apparatus, as described in the Patent claims, provides a mechanism to provide real-time verification of filter integrity, to enable the user to clean the filter membrane while inside the filter casing, and to purge the filter for lighter storage or for protection against freeze-related damage in cold environments. The combination of the Company's ultrafilter membrane and the Company's flush pump apparatus enabled the HydraGuard to pass the NSF Protocol P248 for Military Operations Microbiological Water Purifiers.

Barring any unforeseen circumstances, the Company believes the Patent should be valid until May 2033 given the Patent filing occurred in May 2013. The Company licensed all intellectual property relating to the HydraGuard individual water purifier devices, including the Patent, to Camelbak Products, LLC as part of a Sublicense Agreement on May 6, 2015. The Sublicense Agreement expires on December 31, 2022, unless terminated sooner in accordance with the terms of the agreement.

FDA Warning Letter

On May 28, 2015, the Company received a warning letter dated May 27, 2015 (the "Warning Letter"), from the U.S. Food and Drug Administration (the "FDA") resulting from an inspection of the Company's facility in River Edge, New Jersey by the FDA's New Jersey District Office that occurred during October 2014. The Warning Letter alleges deficiencies relating to the Company's compliance with the Quality System regulation and the Medical Device Reporting regulation. The Company takes the matters identified in the Warning Letter seriously and is in the process of evaluating the corrective actions required to address the matters raised in the Warning Letter. The Company also is in the process of preparing a response to the Warning Letter and intends to respond fully to the issues raised by the FDA within 15 business days as requested by the FDA, and to work diligently and expeditiously to resolve the issues raised by the FDA. The Warning Letter does not restrict the manufacture, production or shipment of any of the Company's products, nor require the withdrawal of any product from the marketplace. However, failure to promptly address the issues raised in the Warning Letter to the FDA's satisfaction or to comply with U.S. medical device regulatory requirements in general could result in regulatory action being initiated by the FDA. These actions could include, among other things, delays in approval of any FDA applications, product seizures, injunctions and civil monetary penalties. Any such actions could disrupt our ongoing business and operations and potentially have a material adverse impact on our financial condition and operating results. A copy of the Warning Letter is attached hereto as Exhibit 99.1.

This Current Report on Form 8-K includes forward-looking statements as defined in the Private Securities Litigation Act of 1995, particularly statements regarding expectations about future events affecting the Company and are subject to risks and uncertainties, many of which are difficult to predict and many of which are beyond the Company's control and could cause the Company's actual results to differ materially and adversely from those expressed in its forward-looking statements as a result of various factors, including but not limited to: risks related to the Company's assumptions regarding its ability to timely and effectively respond to the Warning Letter, additional actions by or requests from the FDA and unanticipated costs or delays associated with resolution of these matters; as well as other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission ("SEC"), which may be obtained for free at the SEC's website at www.sec.gov. Although the Company believes that the expectations reflected in its forward-looking statements are reasonable, it does not know whether its expectations will prove correct. All forward-looking statements included in this Current Report on Form 8-K are expressly qualified in their entirety by the foregoing cautionary statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today's date. The Company does not undertake any obligation to update, amend or clarify these forward-looking statements, except as may be required under applicable securities laws.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Letter from the U.S. Food and Drug Administration to Nephros, Inc. dated May 27, 2015.

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: June 2, 2015 By: /s/ Daron Evans
Daron Evans

President &
Chief Executive
Officer

Index to Exhibits Filed with this Report

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