NEPHROS INC
Form 8-K
August 17, 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): August 12, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 14, 2015, the Board of Directors (the "Board") of Nephros, Inc. (the "Company") appointed Moshe Pinto as a director of the Company. The Company will provide Mr. Pinto with the standard compensation and indemnification approved for non-employee directors.

Mr. Pinto was recently the CEO of Home Dialysis Plus, now Outset Medical, Inc., a Warburg Pincus backed company dedicated to the development and commercialization of a new hemodialysis system, providing an improved experience for patients. Previously, from 2007 through 2010, he was CEO of Spiracur Inc., a developer of innovative wound healing technologies that Mr. Pinto co-founded out of the Stanford University Biodesign Innovation Program. Mr. Pinto also worked for Herzog, Fox & Neeman, a law firm based in Israel. He currently serves on the Board of Directors of Spiracur Inc. Mr. Pinto received an MBA from Stanford University, an LLM from Universita di Bologna, an EMLE from the University of Hamburg, and an LLB in Law from Tel Aviv University.

A copy of the Company's press release announcing the appointment of Mr. Pinto is attached hereto as Exhibit 99.1.

Item 8.01 Other Events.

As previously disclosed, on May 27, 2015, the Company received a warning letter (the "Warning Letter") from the U.S. Food and Drug Administration (the "FDA") resulting from inspections of the Company's facility in River Edge, New Jersey by the FDA's New Jersey District Office that occurred in October 2014. Subsequent to that date, the Company responded to the Warning Letter and has been working to resolve the issues raised by the FDA. On August 12, 2015, the Company received a subsequent letter (the "Subsequent Letter") from the FDA noting that it has received the Company's response correspondence to the Warning Letter detailing the Company's completed corrective actions. The corrective actions included revisions to the Company's standard operating procedures relating to purchasing and supplier controls, adverse event reporting, and complaint handling and monitoring. The Subsequent Letter also noted that the FDA will verify the Company's implementation of corrective measures at its next inspection of the Company's facility.

Neither the Warning Letter nor the Subsequent Letter 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 Subsequent Letter is attached

hereto as Exhibit 99.2.

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 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	Press Release dated August 17, 2015.
99.2	Letter from the U.S. Food and Drug Administration to Nephros, Inc. dated August 12, 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: August 17, 2015 By: /s/ Daron Evans
Daron Evans
President & Chief Executive Officer

Index to Exhibits Filed with this Report

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