NEPHROS INC
Form 8-K
April 11, 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 7, 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 disclosed, on May 27, 2015, Nephros, Inc. (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 worked 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 had 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 would 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 restricted the manufacture, production or shipment of any of the Company's products, nor did they require the withdrawal of any product from the marketplace. In February 2016, the FDA performed another on-site inspection. There were no observations, or 483's, cited at the conclusion of the inspection.

On April 7, 2016, the Company received a letter (the "Third Letter") from the FDA noting that the FDA has completed its evaluation of the Company's corrective actions in response to the Warning Letter and that, based on this evaluation, it appears that the Company has addressed the violations contained in the Warning Letter. A copy of the Third Letter is attached hereto as Exhibit 99.1.

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 April 7, 2016.

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: April 11, 2016 By: */s/ Daron Evans*
Daron Evans
President & Chief Executive Officer

Index to Exhibits Filed with this Report

Exhibit No.	Description
99.1	Letter from the U.S. Food and Drug Administration to Nephros, Inc. dated April 7, 2016.