NEPHROS INC
Form 8-K
October 30, 2013

UNITED 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) October 30, 2013

NEPHROS, INC.

(Exact name of registrant as specified in its charter)

Delaware	
(State or other jurisdiction of incorporation)	
001-32288	13-3971809
(Commission File Number)	(IRS Employer ID Number)
41 Grand Avenue, River Edge, New Jersey	07661
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (201) 343-5202

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.

Nephros, Inc. has initiated voluntary recalls of its point of use (POU) and DSU in-line ultrafilters used in hospital water treatment applications.

Voluntary Recall of SafeSpout, SafeShower FH and SafeShower HH POU ultrafilters

Nephros initiated this voluntary recall of these POU filters because the Food and Drug Administration (FDA) informed the company that promotional materials for these non-medical water filtration products were determined to promote claims which constitute marketing the product as a medical device.

In addition, Nephros has received reports from one customer of high bacterial counts that may be associated with the breakage of fiber in four filters. According to the reports received, one death and one infection may have occurred due to the failure mode associated with this voluntary recall. Investigation into these reports is ongoing. Prior to receiving the complaints mentioned previously, Nephros had received 29 additional complaints of high bacterial counts that may be associated with the breakage of filter fiber, since it began marketing the products. We have had no reports of adverse events associated with these 29 complaints.

Nephros is recalling all production lots of these POU filters, and is also requesting that customers remove and discard certain labeling/promotional materials for the products.

Voluntary Recall of the DSU in-line ultrafilter

Nephros initiated this voluntary recall of the DSU in-line ultrafilter because the FDA informed the company that promotional materials for these non-medical water filtration products were determined to promote claims which constitute marketing the product as a medical device.

Nephros is requesting that customers remove and discard certain labeling/promotional materials for the product.

These voluntary recalls do not affect Nephros dialysis products.

Forward-Looking Statements

This report contains certain “forward-looking statements.” Such statements include statements that are not historical facts, including statements which may be preceded by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “believes,” “hopes,” “potential” or similar words. Forward-looking statements are n guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond our control. Actual results may differ materially from the expectations contained in the forward-looking statements. Factors that may cause such differences include, but are not limited to, the risks that:

- we may not be able to continue as a going concern;
- the voluntary recalls of point of use (POU) and DSU in-line ultrafilters used in hospital water treatment applications and the related circumstances could subject us to claims or proceedings which may adversely impact our sales and revenues;
- we face significant challenges in obtaining market acceptance of our products, which could adversely affect our potential sales and revenues;
- there are product-related deaths or serious injuries or product malfunctions, which could trigger recalls, class action lawsuits and other events that could cause us to incur expenses and may also limit our ability to generate revenues from such products;
- we face potential liability associated with the production, marketing and sale of our products, and/or the expense of defending against claims of product liability, could materially deplete our assets and generate negative publicity which could impair our reputation;
- to the extent our products or marketing materials are found to violate any provisions of the FDC Act or any other statutes or regulations, then we could be subject to enforcement actions by the FDA or other governmental agencies;
- we may not be able to obtain funding if and when needed or on terms favorable to us in order to continue operations;

- we may not have sufficient capital to successfully implement our business plan;
- we may not be able to effectively market our products;
- we may not be able to sell our water filtration products or chronic renal failure therapy products at competitive prices or profitably;
- we may encounter problems with our suppliers, manufacturers and distributors;
- we may encounter unanticipated internal control deficiencies or weaknesses or ineffective disclosure controls and procedures;
- we may not obtain appropriate or necessary regulatory approvals to achieve our business plan;
- products that appeared promising to us in research or clinical trials may not demonstrate anticipated efficacy, safety or cost savings in subsequent pre-clinical or clinical trials;
- we may not be able to secure or enforce adequate legal protection, including patent protection, for our products; and
- we may not be able to achieve sales growth in key geographic markets.

More detailed information about us and the risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this report, is set forth in our filings with the SEC, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and our other periodic reports filed with the SEC. We urge investors and security holders to read those documents free of charge at the SEC's web site at www.sec.gov. We do not undertake to publicly update or revise our forward-looking statements as a result of new information, future events or otherwise, except as required by law.

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.

By: /s/ John C. Houghton
Dated: October 30, 2013 John C. Houghton

President and Chief Executive Officer