NEPHROS INC
Form 10-K
February 26, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

[X] **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2017

[ ] **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number 001-32288

NEPHROS, INC.

(Exact name of registrant specified in its charter)

Delaware	**13-3971809**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

380 Lackawanna Place

South Orange, NJ 07079

(Address of Principal Executive Offices)

(201) 343-5202

(Telephone Number, Including Area Code)

Securities Registered Pursuant to Section 12(b) of the Exchange Act: **None**

Securities registered pursuant to Section 12(g) of the Exchange Act:

Common Stock, $.001 par value per share

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes [ ] No [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant’s knowledge, in definitive proxy or information

statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a smaller reporting company, or emerging growth company. See definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer [ ]	Accelerated filer [ ]
Non-accelerated filer [ ] (Do not check if a smaller reporting company)	Smaller reporting company [X]
	Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [ ] No [X]

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2017, was approximately $5,160,000. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the OTCQB Marketplace operated by the OTC Markets Group, Inc., or OTCQB, on June 30, 2017. For purposes of making this calculation only, the registrant has defined affiliates as including only directors and executive officers and shareholders holding greater than 10% of the voting stock of the registrant as of June 30, 2017.

As of February 26, 2018 there were 56,793,267 shares of the registrant’s common stock, $0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant’s Proxy Statement (the “2018 Proxy Statement”), which will be filed with the SEC in connection with the 2018 Annual Meeting of Stockholders, are incorporated by reference into Part III of this Form 10-K. The 2018 Proxy Statement will be filed within 120 days of December 31, 2017.

NEPHROS, INC. AND SUBSIDIARY

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FORWARD LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K constitute “forward-looking statements”. Such statements include statements regarding the efficacy and intended use of our technologies under development, the timelines and strategy for bringing such products to market, the timeline for regulatory review and approval of our products, the availability of funding sources for continued development of such products, our ability to continue as a going concern and other 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 Forward-looking statements are not 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;
- we face significant challenges in obtaining market acceptance of our products, which could adversely affect our potential sales and revenues;
- product-related deaths or serious injuries or product malfunctions 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 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 U.S. Food, Drug and Cosmetic Act (the “FDC Act”) or any other statutes or regulations, then we could be subject to enforcement actions by the U.S. Food and Drug Administration (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 Annual Report on Form 10-K, is set forth in our filings with the U.S. Securities and Exchange Commission (the "SEC"), including 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.

PART I

Item 1. Business

Overview

We are a commercial stage medical device and commercial products company that develops and sells high performance liquid purification filters and hemodiafiltration ("HDF") systems. Our filters, which are generally classified as ultrafilters, are primarily used in hospitals for the prevention of infection from water-borne pathogens, such as legionella and pseudomonas, and in dialysis centers for the removal of biological contaminants from water and bicarbonate concentrate. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they minimize exposure to a wide variety of bacteria, viruses, fungi, parasites, and endotoxins.

Our OLpūr H2H Hemodiafiltration System, used in conjunction with a standard hemodialysis machine, is the only FDA 510(k) cleared medical device that enables nephrologists to provide hemodiafiltration treatment to patients with end stage renal disease ("ESRD"). Additionally, we sell hemodiafilters, which serve the same purpose as dialyzers in a hemodialysis treatment, and other disposables used in the hemodiafiltration treatment process.

We were founded in 1997 by healthcare professionals affiliated with Columbia University Medical Center/New York-Presbyterian Hospital to develop and commercialize an alternative method to hemodialysis. We have extended our filtration technologies to meet the demand for liquid purification in other areas, in particular water purification.

Our Products

Presently, we produce two core product lines: water ultrafiltration products and HDF systems. Our ultrafiltration technology was originally developed as a component of the HDF system. HDF is a long-term investment that we expect to grow as we develop a second-generation system and as the U.S. dialysis market reimbursement environment migrates to full capitation. Water ultrafiltration is our primary near-term market opportunity, which we expect to continue to grow rapidly as we launch new products and further penetrate the market.

Ultrafiltration Products

Our ultrafilters are used in both medical and non-medical applications. Like competing filters, they purify by passing liquids through the pores of polysulfone hollow fiber. Our filters' pores are significantly smaller than those of competing products, resulting in highly effective elimination of water-borne pathogens, including legionella bacteria (the cause of Legionnaires disease). Additionally, the fiber structure and pore density in our hollow fiber enables significantly higher flow rates than in other polysulfone hollow fiber.

During 2016 and 2017, we developed several ultrafilter cartridge products that are designed to fit directly into existing water filtration systems, eliminating the need for plumbing modifications during installation and replacement. These "plug and play" systems are an important part of our strategy to penetrate the water filtration market.

Our sales strategy is a combination of direct selling to end customers and indirect selling through value-added resellers ("VARs"). Leveraging VARs has enabled us to expand rapidly our access to target customers in the medical market without significant sales staff expansion. In addition, while we are currently focused in medical markets, the VARs that support these customers also support a wide variety of commercial and industrial customers. We believe that our VAR relationships will facilitate growth in filter sales outside of the medical industry.

Target Markets

Our ultrafiltration products currently target the following markets:

Hospitals and Other Healthcare Facilities: Filtration of water for washing and drinking as an aid in infection control. The filters produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures, and washing of surgeons' hands.