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## PRESS RELEASE

### **Nephros Receives initial FDA response to 510(k) Application for Hemodiafiltration System**

RIVER EDGE, N.J., November 10, 2011 /PRNewswire-FirstCall/ -- Nephros, Inc. (OTC Bulletin Board: NEPH) announced that it has received the initial review by the Food and Drug Administration ("FDA") of the 510(k) application for marketing clearance of the company's hemodiafiltration system.

On August 11, 2011 Nephros submitted a new 510(k) application to market its hemodiafiltration (HDF) system for end-stage renal disease. On November 8, 2011 Nephros received the initial FDA review of its new 510(k) application (K112314), which included a request for additional information.

As the next step, Nephros will respond to the FDA's request for more information. Nephros intends to provide its response within 30 days or request an extension of time to respond, if necessary.

The application details Nephros's OLpur MD220 hemodiafilter and Nephros's OLpur H<sub>2</sub>H Hemodiafiltration module. Nephros's OLpur MD220 is a dialyzer designed expressly for HDF therapy that employs Nephros's proprietary Mid-Dilution hemodiafiltration technology. Nephros's OLpur H<sub>2</sub>H Hemodiafiltration module is designed to enable the most common types of standard dialysis machines to perform HDF therapy. Nephros believes that, if cleared, its technology would be the first approved on-line HDF therapy available in the U.S.

### **About Nephros, Inc.**

Nephros, Inc., headquartered in River Edge, New Jersey, is a medical device company developing and marketing filtration products for therapeutic applications, infection control, and water purification.

The Nephros hemodiafiltration (HDF) system is designed to improve the quality of life for the End-Stage Renal Disease (ESRD) patient while addressing the critical financial and clinical needs of the care provider. ESRD is a disease state characterized by the irreversible loss of kidney function. The Nephros HDF system removes a range of harmful substances more effectively, and with greater capacity, than existing ESRD treatment methods, particularly with respect to substances known collectively as "middle molecules." These molecules have been

found to contribute to such conditions as dialysis-related amyloidosis, carpal tunnel syndrome, degenerative bone disease and, ultimately, mortality in the ESRD patient.

The Nephros Dual Stage Ultrafilter (DSU) is the basis for the Nephros line of water filtration products, which includes the MSU and SSU ultrafilters. The patented dual stage cold sterilization ultrafilter has the capability to filter out bacteria and, due to its exceptional filtration levels, filter out many viruses, parasites and biotoxins. The Nephros DSU, MSU, and SSU are FDA cleared for the filtration of biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures. Nephros' DSU ultrafilters are being evaluated at several major U.S. medical centers for infection control. Nephros ultrafilter technology has also been selected for further development by the U.S. Marine Corps for purification of drinking water by soldiers in the field.

For more information about Nephros, please visit the company's website at [www.nephros.com](http://www.nephros.com).

### **Forward-Looking Statements**

This press release contains certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Such statements include statements regarding the efficacy and intended use of our technologies under development, the timelines for bringing such products to market and the availability of funding sources for continued development of such products 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 similar words. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. 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 the risks that:

- we may not be able to continue as a going concern;
- 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 obtain appropriate or necessary regulatory approvals to achieve our business plan or effectively market our products including, without limitation, FDA approval of our HDF system;
- 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 encounter problems with our suppliers and manufacturers;
- we may encounter unanticipated internal control deficiencies or weaknesses or ineffective disclosure controls and procedures;
- HDF therapy may not be accepted in the United States and/or our technology and products may not be accepted in current or future target markets, which could lead to failure to achieve market penetration of our products;
- we may not be able to sell our ESRD therapy or water filtration products at competitive

- prices or profitably;
- 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 Europe and Canada or expand into other 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 press release, is set forth in our filings with the SEC, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, as amended 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](http://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.

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