

NEPHROS INC  
Form 424B3  
November 09, 2018

**Prospectus Supplement Filed Pursuant to Rule 424(b)(3)**

**Registration No. 333-225109**

**PROSPECTUS SUPPLEMENT NO. 2 DATED NOVEMBER 9, 2018**

**(To Prospectus Dated June 22, 2018)**

**NEPHROS, INC.**

This is a supplement (“Prospectus Supplement No. 2”) to our prospectus, dated June 22, 2018 (the “Prospectus”), relating to up to 6,540,669 shares of our common stock.

This Prospectus Supplement No. 2 is not complete without, and may not be delivered or utilized except in connection with, the Prospectus, including any amendments or supplements thereto.

**Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2018**

On November 8, 2018, we filed with the Securities and Exchange Commission a quarterly report on Form 10-Q for the quarter ended September 30, 2018 (the “Form 10-Q”). The Form 10-Q, as filed (but without the exhibits filed with the Form 10-Q), is set forth below.

The information contained in this Prospectus Supplement No. 2 supplements and supersedes, in relevant part, the information contained in the Prospectus, as amended and supplemented. This Prospectus Supplement No. 2 is incorporated by reference into, and should be read in conjunction with, the Prospectus, as amended and supplemented, and is not complete without, and may not be delivered or utilized except in connection with, the Prospectus, as amended and supplemented.

All references in the Prospectus to “this prospectus” are amended to read “this prospectus (as supplemented and amended).”

**Investing in our common stock involves substantial risks. See “Risk Factors” beginning on page 8 of the Prospectus to read about important factors you should consider before purchasing our common stock.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus SUPPLEMENT NO. 2. Any representation to the contrary is a criminal offense.**

The date of this Prospectus Supplement No. 2 is November 9, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON D.C. 20549**

**FORM 10-Q**

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: **September 30, 2018**

OR

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 as specified in its charter)

**DELAWARE**

**13-3971809**

(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)

**380 Lackawanna Place**

**07079**

**South Orange, NJ**

(Address of principal executive offices) (Zip Code)

**(201) 343-5202**

Registrant's telephone number, including area code

N/A

(Former name, former address and former fiscal year, if changed since last report)

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. [X] YES [ ] NO

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). [X] YES [ ] NO

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

Large accelerated filer [ ] Accelerated filer [ ]  
Non-accelerated filer [ X ] 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. [ ]

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

As of November 6, 2018, 64,166,988 shares of the registrant's common stock, \$0.001 par value per share, were outstanding.

**NEPHROS, INC. AND SUBSIDIARIES**

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## PART I - FINANCIAL INFORMATION

## Item 1. Financial Statements.

**NEPHROS, INC. AND SUBSIDIARIES**

## CONDENSED CONSOLIDATED BALANCE SHEETS

**(In thousands, except share amounts)**

|   | (Unaudited)<br>September<br>30, 2018 | (Audited)<br>December<br>31, 2017 |
|---|--------------------------------------|-----------------------------------|
| <b>ASSETS</b>   |                                      |                                   |
| Current assets:   |                                      |                                   |
| Cash  | \$ 5,322                             | \$2,194                           |
| Accounts receivable, net  | 1,508                                | 836                               |
| Investment in lease, net-current portion  | 24                                   | 20                                |
| Inventory, net  | 1,459                                | 674                               |
| Prepaid expenses and other current assets   | 63                                   | 85                                |
| Total current assets  | 8,376                                | 3,809                             |
| Property and equipment, net   | 20                                   | 52                                |
| Investment in lease, net-less current portion   | 26                                   | 39                                |
| License and supply agreement, net   | 971                                  | 1,072                             |
| Other asset   | 11                                   | 11                                |
| Total assets  | \$ 9,404                             | \$4,983                           |
| <b>LIABILITIES, NONCONTROLLING INTEREST AND STOCKHOLDERS' EQUITY</b>  |                                      |                                   |
| Current liabilities:  |                                      |                                   |
| Secured revolving credit facility   | \$ 163                               | \$711                             |
| Current portion of secured note payable   | 191                                  | -                                 |
| Accounts payable  | 562                                  | 872                               |
| Accrued expenses  | 524                                  | 218                               |
| Deferred revenue, current portion   | -                                    | 70                                |
| Total current liabilities   | 1,440                                | 1,871                             |
| Secured note payable, net of current portion  | 897                                  | -                                 |
| Unsecured long-term note payable, net of debt issuance costs and debt discount of \$0 and \$233, respectively | -                                    | 954                               |
| Long-term portion of deferred revenue   | -                                    | 208                               |
| Total liabilities   | 2,337                                | 3,033                             |

Commitments and Contingencies (Note 18)

|   |            |           |
|---|------------|-----------|
| Noncontrolling interest   | 3,000      | -         |
| Stockholders' equity:   |            |           |
| Preferred stock, \$.001 par value; 5,000,000 shares authorized at September 30, 2018 and December 31, 2017; no shares issued and outstanding at September 30, 2018 and December 31, 2017                                    | -          | -         |
| Common stock, \$.001 par value; 90,000,000 shares authorized at September 30, 2018 and December 31, 2017; 64,166,988 and 55,293,267 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively | 64         | 55        |
| Additional paid-in capital  | 127,419    | 122,924   |
| Accumulated other comprehensive income  | 73         | 77        |
| Accumulated deficit   | (123,489 ) | (121,106) |
| Total stockholders' equity  | 4,067      | 1,950     |
| Total liabilities, noncontrolling interest and stockholders' equity   | \$ 9,404   | \$4,983   |

*The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.*



## NEPHROS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

(Unaudited)

|   | Three Months Ended<br>September 30, |            | Nine Months Ended<br>September 30, |            |
|---|-------------------------------------|------------|------------------------------------|------------|
|   | 2018                                | 2017       | 2018                               | 2017       |
| Net revenues:   |                                     |            |                                    |            |
| Product revenues  | \$ 1,648                            | \$ 841     | \$ 3,822                           | \$ 2,316   |
| License, royalty and other revenues   | 76                                  | 75         | 253                                | 193        |
| Total net revenues  | 1,724                               | 916        | 4,075                              | 2,509      |
| Cost of goods sold  | 772                                 | 384        | 1,826                              | 1,005      |
| Gross margin  | 952                                 | 532        | 2,249                              | 1,504      |
| Operating expenses:   |                                     |            |                                    |            |
| Research and development  | 352                                 | 237        | 993                                | 744        |
| Depreciation and amortization   | 42                                  | 60         | 123                                | 178        |
| Selling, general and administrative   | 1,069                               | 753        | 3,420                              | 2,405      |
| Total operating expenses  | 1,463                               | 1,050      | 4,536                              | 3,327      |
| Loss from operations  | (511 )                              | (518 )     | (2,287 )                           | (1,823 )   |
| Loss on extinguishment of debt  | -                                   | -          | (199 )                             | -          |
| Interest expense  | (32 )                               | (88 )      | (146 )                             | (218 )     |
| Interest income   | 1                                   | 1          | 3                                  | 3          |
| Other expense   | (8 )                                | (27 )      | (32 )                              | (60 )      |
| Net loss  | (550 )                              | (632 )     | (2,661 )                           | (2,098 )   |
| Less: Undeclared deemed dividend attributable to noncontrolling interest                | (16 )                               | -          | (16 )                              | -          |
| Net loss attributable to Nephros, Inc.  | (566 )                              | (632 )     | (2,677 )                           | (2,098 )   |
| Other comprehensive (loss) income, foreign currency translation adjustments, net of tax | (1 )                                | 1          | (4 )                               | 9          |
| Total comprehensive loss attributable to Nephros, Inc.                                  | \$(567 )                            | \$(631 )   | \$(2,681 )                         | \$(2,089 ) |
| Net loss per common share, basic and diluted  | \$(0.01 )                           | \$(0.01 )  | \$(0.04 )                          | \$(0.04 )  |
| Weighted average common shares outstanding, basic and diluted                           | 64,166,988                          | 54,142,791 | 60,762,239                         | 52,473,518 |

The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.



**NEPHROS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY****(In Thousands, Except Share Amounts)****(Unaudited)**

|  | Common Stock |        | Additional<br>Paid-in<br>Capital | Accumulated<br>Other<br>Comprehensive<br>Income | Accumulated<br>Deficit | Total<br>Stockholders'<br>Equity |
|--|--------------|--------|----------------------------------|---|------------------------|----------------------------------|
|  | Shares       | Amount |                                  |   |                        |                                  |
| Balance, December 31, 2017<br>(audited)                              | 55,293,267   | \$ 55  | \$ 122,924                       | \$ 77   | \$ (121,106 )          | \$ 1,950                         |
| Net loss   |              |        |                                  |   | (2,661 )               | (2,661 )                         |
| Cumulative effect of adoption of<br>ASC 606                          |              |        |                                  |   | 278                    | 278                              |
| Net unrealized losses on foreign<br>currency translation, net of tax |              |        |                                  | (4 )  |                        | (4 )                             |
| Issuance of common stock, net of<br>equity issuance costs of \$19    | 8,440,669    | 9      | 3,769                            |   |                        | 3,778                            |
| Cashless exercise of stock options                                   | 22,245       | -      |                                  |   |                        | -                                |
| Cancelled restricted stock shares                                    | (45,859 )    | -      |                                  |   |                        | -                                |
| Exercise of warrants   | 456,666      | -      | 138                              |   |                        | 138                              |
| Noncash stock-based<br>compensation                                  |              |        | 588                              |   |                        | 588                              |
| Balance, September 30, 2018  | 64,166,988   | \$ 64  | \$ 127,419                       | \$ 73   | \$ (123,489 )          | \$ 4,067                         |

*The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.*

## NEPHROS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

|  | Nine Months<br>Ended September<br>30, |           |
|--|---------------------------------------|-----------|
|  | 2018                                  | 2017      |
| Operating activities:  |                                       |           |
| Net loss   | \$(2,661)                             | \$(2,098) |
| Adjustments to reconcile net loss to net cash used in operating activities:                          |                                       |           |
| Depreciation of property and equipment   | 22                                    | 21        |
| Amortization of license and supply agreement   | 101                                   | 157       |
| Non-cash stock-based compensation, including stock options and restricted stock                      | 588                                   | 508       |
| Loss on extinguishment of debt   | 199                                   | -         |
| Amortization of debt discount  | 34                                    | 84        |
| Inventory reserve  | 65                                    | -         |
| Provision for bad debt expense   | 21                                    | -         |
| Loss on disposal of equipment  | 10                                    | -         |
| (Gain) loss on foreign currency transactions   | (1 )                                  | 16        |
| (Increase) decrease in operating assets:   |                                       |           |
| Accounts receivable  | (684 )                                | (341 )    |
| Inventory  | (850 )                                | (102 )    |
| Prepaid expenses and other current assets  | 22                                    | 10        |
| Increase (decrease) in operating liabilities:  |                                       |           |
| Accounts payable   | (309 )                                | (166 )    |
| Accrued expenses   | 309                                   | 105       |
| Deferred revenue   | -                                     | (53 )     |
| Net cash used in operating activities  | (3,134)                               | (1,871)   |
| Financing activities:  |                                       |           |
| Proceeds from issuance of common stock, net of equity issuance costs of \$19 and \$152, respectively | 3,778                                 | 1,179     |
| Net (payments) proceeds on secured revolving credit facility   | (548 )                                | 563       |
| Proceeds from sale of subsidiary preferred shares to noncontrolling interest                         | 3,000                                 | -         |
| Payments on secured note payable   | (99 )                                 | -         |
| Proceeds from exercise of warrants   | 138                                   | -         |
| Proceeds from issuance of secured note   | 1,187                                 | -         |
| Repayment of unsecured long term note payable  | (1,187)                               | -         |
| Net cash provided by financing activities  | 6,269                                 | 1,742     |
| Effect of exchange rates on cash   | (7 )                                  | 4         |

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|  |         |        |
|--|---------|--------|
| Net increase (decrease) in cash                  | 3,128   | (125 ) |
| Cash, beginning of period                        | 2,194   | 275    |
| Cash, end of period                              | \$5,322 | \$150  |
| Supplemental disclosure of cash flow information |         |        |
| Cash paid for interest                           | \$124   | \$79   |
| Cash paid for income taxes                       | \$7     | \$6    |

*The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.*

## NEPHROS, INC. AND SUBSIDIARIES

### NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

#### Note 1 – Organization and Nature of Operations

Nephros, Inc. (“Nephros” or the “Company”) was incorporated under the laws of the State of Delaware on April 3, 1997. The Company was founded by health professionals, scientists and engineers affiliated with Columbia University to develop advanced end stage renal disease (“ESRD”) therapy technology and products. Today, the Company has two U.S. Food and Drug Administration-cleared products in the hemodiafiltration (“HDF”) market that deliver therapy to ESRD patients. These are the OLpūr mid-dilution HDF filter or “dialyzer,” designed expressly for HDF therapy and the OLpūr H2H HDF module, an add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy.

On June 4, 2003, Nephros International Limited was incorporated under the laws of Ireland as a wholly-owned subsidiary of the Company. In August 2003, the Company established a European office in Dublin, Ireland.

Beginning in 2009, Nephros introduced a complementary business developing and marketing high performance liquid purification filters to meet the demand for water purification in certain medical markets. The Company’s filters, 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. The Company is also exploring water purification applications in several commercial markets, including food and beverage, data center cooling, and military field applications. This water-focused business is a reportable segment, referred to as the Water Filtration segment.

In July 2018, the Company formed a new, wholly-owned subsidiary, Specialty Renal Products, Inc. (“SRP”), to drive the development of its 2<sup>nd</sup> generation HDF system and other products focused on improving therapies for patients with renal disease. The Company transferred three patents to SRP, which were carried at zero book value. SRP is a reportable segment, referred to as the Renal Products segment. On September 5, 2018, SRP completed a private placement transaction whereby SRP sold preferred shares equivalent to 37.5% of its outstanding equity interest for aggregate proceeds of \$3,000,000.

The Company’s U.S. facilities, located at 380 Lackawanna Place, South Orange, New Jersey, 07079, are used to house the Company’s corporate headquarters and research facilities.

## **Note 2 – Basis of Presentation and Liquidity**

### **Interim Financial Information**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 8 and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for annual financial statements. Results as of and for the three and nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018.

The condensed consolidated interim financial statements and notes thereto should be read in conjunction with the consolidated financial statements and notes for the year ended December 31, 2017 included in the Company's Annual Report on Form 10-K.

### **Consolidation**

The accompanying unaudited condensed consolidated financial statements include the accounts of Nephros, Inc. and its subsidiaries, including the entity in which a controlling interest is maintained. For the consolidated subsidiary in which the Company's ownership is less than 100% but greater than 50%, the outside shareholders' interest is shown as noncontrolling interest. All intercompany accounts and transactions were eliminated in the preparation of the accompanying consolidated financial statements.

### **Use of Estimates**

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities, at the date of the financial statements, and the reported amount of revenues and expenses, during the reporting period. Actual results could differ materially from those estimates. Included in these estimates are assumptions about the collection of accounts receivable, value of inventories, useful life of fixed assets and intangible assets, and assumptions used in determining stock compensation such as expected volatility and risk-free interest rate.





## Liquidity

The Company has sustained operating losses and expects such losses to continue over the next several quarters. Net losses from operations since inception have generated an accumulated deficit of approximately \$123,489,000 as of September 30, 2018. In July 2018, the Company formed a new, wholly-owned subsidiary, Specialty Renal Products, Inc. (“SRP”), to drive the development of its 2<sup>nd</sup> generation HDF system and other products focused on improving therapies for patients with renal disease.

During the three months ended March 31, 2018, the Company issued and sold 1,900,000 shares of common stock to Lincoln Park for aggregate proceeds of \$854,000.

On April 10, 2018, the Company completed a private placement transaction whereby the Company sold 6,540,669 shares of its common stock for aggregate proceeds of approximately \$2,943,000.

On September 5, 2018, SRP completed a private placement transaction whereby SRP sold preferred shares equivalent to 37.5% of its outstanding equity interests for aggregate proceeds of \$3,000,000. The proceeds of this placement are restricted to SRP expenses and may not be used for the benefit of the Company or other affiliated entities, except to reimburse for expenses directly attributable to SRP.

Based on cash that is available for Company operations, the results of Company operations through September 30, 2018, and projections of future Company operations, the Company believes that its cash will be sufficient to fund the Company’s current operating plan through at least the next twelve months from the date of issuance of the accompanying condensed consolidated financial statements.

### Note 3 – Major Customers and Concentration of Credit Risk

For the three months ended September 30, 2018 and 2017, the following customers accounted for the following percentages of the Company’s revenues, respectively:

| Customer | 2018 | 2017 |
|----------|------|------|
| A        | 13 % | - %  |
| B        | 13 % | - %  |

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|       |      |      |
|-------|------|------|
| C     | 10 % | 12 % |
| D     | 10 % | 14 % |
| E     | 10 % | 14 % |
| Total | 56 % | 40 % |

For the nine months ended September 30, 2018 and 2017, the following customers accounted for the following percentages of the Company's revenues, respectively:

|          |      |      |
|----------|------|------|
| Customer | 2018 | 2017 |
| D        | 12 % | 18 % |
| C        | 12 % | 13 % |
| E        | 9 %  | 12 % |
| Total    | 33 % | 43 % |

As of September 30, 2018 and December 31, 2017, the following customers accounted for the following percentages of the Company's accounts receivable, respectively:

|          |                       |                      |
|----------|-----------------------|----------------------|
| Customer | September<br>30, 2018 | December<br>31, 2017 |
| B        | 15 %                  | - %                  |
| C        | 10 %                  | 18 %                 |
| F        | 5 %                   | 11 %                 |
| Total    | 30 %                  | 29 %                 |

The Company provides credit terms to customers in connection with purchases of the Company's products. Management periodically reviews customer account activity in order to assess the adequacy of the allowances provided for potential collection issues and returns. Factors considered include economic conditions and each customer's payment and return history and creditworthiness. Adjustments, if any, are made to reserve balances following the completion of these reviews to reflect management's best estimate of potential losses. The allowance for doubtful accounts was approximately \$7,000 and \$1,000 as of September 30, 2018 and December 31, 2017, respectively. There were write offs of accounts receivable to bad debt expense, previously unreserved, of approximately \$15,000 during the three and nine months ended September 30, 2018. There was no allowance for sales returns at September 30, 2018 or December 31, 2017.

**Note 4 – Revenue Recognition**

The Company adopted Accounting Standards Codification (“ASC”) 606, Revenue from Contracts with Customers, as of January 1, 2018 using the modified retrospective method. ASC 606 prescribes a five step model for recognizing revenue, which includes (i) identifying contracts with customers; (ii) identifying performance obligations; (iii) determining the transaction price; (iv) allocating the transaction price; and (v) recognizing revenue.

The Company recognizes revenue related to product sales when product is shipped via external logistics provider and the other criteria of ASC 606 are met. Product revenue is recorded net of returns and allowances. In addition to product revenue, the Company recognizes revenue related to license, royalty and other agreements in accordance with the five step model in ASC 606. License, royalty and other revenue recognized for the three and nine months ended September 30, 2018 and 2017 is comprised of:

|   | <b>Three Months<br/>Ended</b> |             | <b>Nine Months<br/>Ended</b> |             |
|---|-------------------------------|-------------|------------------------------|-------------|
|   | <b>September 30,</b>          |             | <b>September 30,</b>         |             |
|   | <b>2018</b>                   | <b>2017</b> | <b>2018</b>                  | <b>2017</b> |
| Royalty revenue under the Sublicense Agreement with CamelBak <sup>(1)</sup> | \$-                           | \$-         | \$100,000                    | \$25,000    |
| Royalty revenue under the License Agreement with Bellco                     | 21,000                        | 57,000      | 79,000                       | 115,000     |
| License revenue under the License Agreement with Bellco                     | -                             | 18,000      | -                            | 53,000      |
| Other revenue   | 55,000                        | -           | 74,000                       | -           |
| Total license, royalty and other revenue                                    | \$76,000                      | \$75,000    | \$253,000                    | \$193,000   |

In May 2015, the Company entered into a Sublicense Agreement with CamelBak Products, LLC (“CamelBak”). Under the Sublicense Agreement, the Company granted CamelBak an exclusive, non-transferable, worldwide (with the exception of Italy) sublicense and license, in each case solely to market, sell, distribute, import and export the Company’s individual water treatment device. In exchange for the rights granted to CamelBak, CamelBak agreed, <sup>(1)</sup>through December 31, 2022, to pay the Company a percentage of the gross profit on any sales made to a branch of the U.S. military, subject to certain exceptions, and to pay a fixed per-unit fee for any other sales made. CamelBak is also required to meet or exceed certain minimum annual fees payable to the Company, and if such fees are not met or exceeded, the Company may convert the exclusive sublicense to a non-exclusive sublicense with respect to non-U.S. military sales.

**Bellco License Agreement**

The Company has not, and does not intend in the near future, to manufacture any of its products and components. With regard to the OLpūr MD190 and MD220, on June 27, 2011, the Company entered into a License Agreement (the

“License Agreement”), effective July 1, 2011, with Bellco S.r.l. (“Bellco”), an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of the Company’s patented mid-dilution dialysis filters (the “Products”). Under the License Agreement, as amended, the Company granted Bellco a license to manufacture, market and sell the Products under its own name, label, and CE mark in certain countries on an exclusive basis, and to do the same on a non-exclusive basis in certain other countries. Under the License Agreement with Bellco, the Company received upfront payments which were previously deferred and being recognized as license revenue over the term (See ASC 606 Adoption below). The term of the License Agreement with Bellco expires on December 31, 2021.

During the three and nine months ended September 30, 2017, approximately \$18,000 and \$53,000, respectively, was recognized as license revenue.

The License Agreement, as amended, also provides minimum sales targets which, if not satisfied, will, at the discretion of the Company, result in conversion of the license to non-exclusive status. Beginning on January 1, 2015 through and including December 31, 2021, Bellco will pay the Company a royalty based on the number of units of Products sold per year in the covered territory as follows: for the first 125,000 units sold in total, €1.75 (approximately \$2.10) per unit; thereafter, €1.25 (approximately \$1.50) per unit. The License Agreement also provides for a fixed royalty payment payable to the Company for the period beginning on January 1, 2015 through and including December 31, 2021 if the minimum sales targets are not met.

The Company recognized royalty income from Bellco pursuant to the License Agreement for the three months ended September 30, 2018 and 2017 of approximately \$21,000 and \$57,000, respectively. The Company recognized royalty income from Bellco pursuant to the License Agreement for the nine months ended September 30, 2018 and 2017 of approximately \$79,000 and \$115,000, respectively.

### ASC 606 Adoption

In accordance with the adoption of ASC 606, the remaining deferred revenue of approximately \$278,000 related to license revenue as of December 31, 2017 was recognized as a cumulative effect adjustment to accumulated deficit as of January 1, 2018.

The following tables present the Company's revenue for the three and nine months ended September 30, 2018 under the ASC 606 model as compared to revenue under the previous accounting guidance:

|  | Three Months Ended September 30,<br>2018 |  |             |
|--|--|--|-------------|
|  | Revenue as<br>reported                   | Revenue<br>under<br>previous<br>accounting<br>guidance | Difference  |
| Product revenue  | \$1,648,000                              | \$1,648,000  | \$ -        |
| Royalty revenue under the License Agreement with Bellco                | 21,000                                   | 21,000   | -           |
| License revenue under the License Agreement with Bellco <sup>(1)</sup> | -  | 18,000   | (18,000 )   |
| Other revenue  | 55,000                                   | 55,000   | -           |
| Total net revenues   | \$1,724,000                              | \$1,742,000  | \$(18,000 ) |

|  | Nine Months Ended September 30,<br>2018 |  |            |
|--|---|--|------------|
|  | Revenue as<br>reported                  | Revenue<br>under<br>previous<br>accounting<br>guidance | Difference |
| Product revenue  | \$3,822,000                             | \$3,822,000  | \$ -       |
| Royalty revenue under the Sublicense Agreement with CamelBak           | 100,000                                 | 100,000  | -          |
| Royalty revenue under the License Agreement with Bellco                | 79,000                                  | 79,000   | -          |
| License revenue under the License Agreement with Bellco <sup>(1)</sup> | -                                       | 53,000   | (53,000 )  |
| Other revenue  | 74,000                                  | 74,000   | -          |

|                    |             |             |             |
|--------------------|-------------|-------------|-------------|
| Total net revenues | \$4,075,000 | \$4,128,000 | \$(53,000 ) |
|--------------------|-------------|-------------|-------------|

Under ASC 606, amounts received related to the license under the License Agreement with Bellco would have been recognized as revenue at the time that the license was transferred, which was at the time the payments were received<sup>(1)</sup> by the Company. Under previous accounting guidance, amounts received under the License Agreement with Bellco were deferred and recognized as revenue over the term of the License Agreement.

#### **Note 5 – Fair Value of Financial Instruments**

The carrying amounts of cash, accounts receivable, secured revolving credit facility, accounts payable and accrued expenses approximate fair value due to the short-term maturity of these instruments.

The carrying amounts of the investment in lease, net, the secured long-term note payable and the unsecured long-term note payable approximate fair value as of September 30, 2018 and December 31, 2017 because those financial instruments bear interest at rates that approximate current market rates for similar agreements with similar maturities and credit.

#### **Note 6 – Stock Plans and Share-Based Payments**

##### **Stock Options**

The fair value of stock options is recognized as stock-based compensation expense in the Company's condensed consolidated statement of operations and comprehensive loss. The Company calculates employee stock-based compensation expense in accordance with ASC 718. The Company accounts for stock options granted to consultants under the provisions of ASC 505-50 and as such, these stock options are revalued at each reporting period through the vesting period. The fair value of the Company's stock options is estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions and elections including expected stock price volatility and the estimated life of each award. The fair value of stock-based awards is amortized over the vesting period of the award.

## **Stock-Based Compensation**

Stock-based compensation expense related to stock options was approximately \$120,000 and \$110,000 for the three months ended September 30, 2018 and 2017, respectively. For the three months ended September 30, 2018, approximately \$118,000 and \$2,000 are included in selling, general and administrative expenses and research and development expenses, respectively, on the accompanying condensed consolidated statement of operations and comprehensive loss. For the three months ended September 30, 2017, approximately \$103,000 and \$7,000 are included in selling, general and administrative expenses and research and development expenses, respectively, on the accompanying condensed consolidated statement of operations and comprehensive loss.

Stock-based compensation expense related to stock options was approximately \$373,000 and \$323,000 for the nine months ended September 30, 2018 and 2017, respectively. For the nine months ended September 30, 2018, approximately \$356,000 and \$17,000 are included in selling, general and administrative expenses and research and development expenses, respectively, on the accompanying condensed consolidated statement of operations and comprehensive loss. For the nine months ended September 30, 2017, approximately \$299,000 and \$24,000 are included in selling, general and administrative expenses and research and development expenses, respectively, on the accompanying condensed consolidated statement of operations and comprehensive loss. During the three months ended March 31, 2018, previously issued stock options were modified for an employee who is no longer employed with the Company. As a result of this modification, included in the approximately \$17,000 of research and development expenses is approximately \$12,000 of stock option modification expense on the accompanying condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2018.

There was no tax benefit related to expense recognized in the three or nine months ended September 30, 2018 and 2017, as the Company is in a net operating loss position. As of September 30, 2018, there was approximately \$977,000 of total unrecognized compensation expense related to unvested stock-based awards granted under the equity compensation plans. Approximately \$230,000 of the \$977,000 total unrecognized compensation expense will be recognized at the time that certain performance conditions are met. The remaining unrecognized compensation expense of approximately \$747,000 will be amortized over the weighted average remaining requisite service period of 1.9 years. Such amount does not include the effect of future grants of equity compensation, if any.

## **Restricted Stock**

There was no stock-based compensation expense for restricted stock for the three months ended September 30, 2018. Total stock-based compensation expense for restricted stock was approximately \$3,000 for the three months ended September 30, 2017 and is included in selling, general and administrative expenses on the accompanying condensed consolidated statement of operations and comprehensive loss.

Total stock-based compensation expense for restricted stock was approximately \$215,000 and \$185,000 for the nine months ended September 30, 2018 and 2017, respectively. Approximately \$190,000 and \$185,000 are included in selling, general and administrative expenses on the accompanying condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2018 and 2017, respectively. Approximately \$25,000 is included in research and development expenses on the accompanying condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2018.

As of September 30, 2018, there was no unrecognized compensation expense related to restricted stock.

#### **Note 7 – Warrants**

During the nine months ended September 30, 2018, warrants to purchase 456,666 shares of the Company's common stock were exercised, resulting in proceeds of approximately \$138,000 and the issuance of 456,666 shares of the Company's common stock. Of the warrants exercised during the nine months ended September 30, 2018, warrants to purchase 73,333 shares of the Company's common stock were exercised by members of management, resulting in proceeds of approximately \$22,000. There were no warrants exercised during the nine months ended September 30, 2017.

#### **Note 8 – Net Loss per Common Share**

Basic loss per common share is calculated by dividing net loss available to common shareholders by the number of weighted average common shares issued and outstanding. Diluted loss per common share is calculated by dividing net loss available to common shareholders by the weighted average number of common shares issued and outstanding for the period, plus amounts representing the dilutive effect from the exercise of stock options and warrants, as applicable. The Company calculates dilutive potential common shares using the treasury stock method, which assumes the Company will use the proceeds from the exercise of stock options and warrants to repurchase shares of common stock to hold in its treasury stock reserves.



The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as they would be anti-dilutive:

|  | September 30, |           |
|--|---------------|-----------|
|  | 2018          | 2017      |
| Shares underlying warrants outstanding | 6,642,344     | 7,432,342 |
| Shares underlying options outstanding  | 6,619,111     | 5,459,015 |

## Note 9 – Recent Accounting Pronouncements

### Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, “Revenue from Contracts with Customers,” related to revenue recognition. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects to be entitled to in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in prior accounting guidance. ASU 2014-09 provides alternative methods of initial adoption and was to be effective for fiscal years beginning after December 15, 2016 and interim periods within those annual periods. Early adoption was not permitted. In August 2015, the FASB issued ASU No. 2015-14, “Revenue from Contracts with Customers: Deferral of the Effective Date.” This ASU deferred the effective date of ASU No. 2014-09 for all entities for one year. In March, April and May 2016, the FASB issued ASU No. 2016-08, ASU No. 2016-10 and ASU No. 2016-12, respectively, which clarified implementation guidance, including the guidance on principal versus agent considerations, performance obligations and licensing and assessments of collectability and noncash considerations. Public business entities, certain not-for-profit entities, and certain employee benefit plans are required to apply the guidance in ASU 2014-09 to fiscal years beginning after December 15, 2017, including interim reporting periods within that fiscal year. The Company adopted the new revenue recognition standard as of January 1, 2018 using the modified retrospective method, which requires the cumulative effect of adoption, if any, to be recognized as an adjustment to opening accumulated deficit in the period of adoption. The majority of the Company’s revenue relates to the sale of finished products to various customers and the adoption did not have any impact on revenue recognized from these transactions. The Company completed its analysis of the impact on certain less significant transactions involving third-party arrangements and as a result of the analysis, the Company accelerated the remaining approximately \$278,000 of deferred revenue to be recognized under the License Agreement with Bellco as of December 31, 2017 and recorded a cumulative effect adjustment to opening accumulated deficit as of January 1, 2018.

In January 2016, the FASB issued ASU No. 2016-01, “Recognition and Measurement of Financial Assets and Financial Liabilities,” that modifies certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The accounting standard update is effective for fiscal years and interim periods within those years, beginning after December 15, 2017, and early adoption was permitted. The Company adopted this guidance as

of January 1, 2018 and the guidance did not have an impact on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, "Classification of Certain Cash Receipts and Cash Payments," which clarifies how certain cash receipts and cash payments are presented and classified in the statement of cash flows in order to reduce diversity in practice. The guidance was effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption was permitted. The Company adopted the guidance as of January 1, 2018 and the guidance did not have a significant impact on its consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, "Restricted Cash," which clarifies how restricted cash is presented and classified in the statement of cash flows. The guidance was effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption was permitted. The Company adopted the guidance as of January 1, 2018 and the guidance did not have an impact on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, "Clarifying the Definition of a Business," which clarifies the definition of a business in a business combination. The guidance was effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption was permitted. The Company adopted the guidance as of January 1, 2018 and the guidance did not have an impact on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, "Compensation – Stock Compensation," which requires modification accounting to be used on share-based payment awards if the fair value, the vesting conditions, or the classification of the award changes as a result of the change in terms or conditions. The guidance was effective for the Company beginning in the first quarter of fiscal year 2018. The Company adopted the guidance as of January 1, 2018 and the guidance did not have an impact on its consolidated financial statements.

### **Recent Accounting Pronouncements, Not Yet Effective**

In February 2016, the FASB issued ASU No. 2016-02, "Leases," which discusses how an entity should account for lease assets and lease liabilities. The guidance specifies that an entity who is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for the Company beginning in the first quarter of 2019. The adoption will also include updates as provided under ASU 2018-01, "Land Easement Practical Expedient for Transition to Topic 842" and ASU No. 2018-10, "Codification Improvements to Topic 842, Leases." In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The Company is assessing the impact of adopting this guidance on its consolidated financial statements and the additional transition method under ASU 2018-11, "Leases (Topic 842): Targeted Improvements" which allows the Company to recognize the cumulative effect within retained earnings in the period of adoption.

In June 2016, the FASB issued ASU 2016-13, "Measurement of Credit Losses on Financial Instruments," which replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted beginning in the first quarter of fiscal year 2019. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, "Simplifying the Test for Goodwill Impairment," which simplifies the test for goodwill impairment. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted for interim or annual goodwill impairments tests after January 1, 2017. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, "Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception" which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features and recharacterizes the indefinite deferral of certain provisions within the guidance for distinguishing liabilities from equity. The guidance is effective for the Company beginning in the first quarter of fiscal year 2019. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In May 2018, the FASB issued ASU 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting," which expands the scope of ASC 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance is effective for the Company beginning in the first quarter of fiscal year 2019.

Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, “Disclosure Framework-Changes to the Disclosure Requirements for the Fair Value Measurement,” which modifies the disclosure requirements on fair value measurements. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, “Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract,” which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

**Note 10 – Inventory, net**

Inventory is stated at the lower of cost or net realizable value using the first-in, first-out method and consists of raw materials and finished goods. The Company’s inventory as of September 30, 2018 and December 31, 2017 was as follows:

|                         | September<br>30, 2018<br>(Unaudited) | December<br>31, 2017<br>(Audited) |
|-------------------------|--------------------------------------|-----------------------------------|
| Finished goods          | \$ 1,410,000                         | \$ 654,000                        |
| Raw materials           | 93,000                               | 51,000                            |
| Less: inventory reserve | (44,000 )                            | (31,000 )                         |
| Total inventory, net    | \$ 1,459,000                         | \$ 674,000                        |

**Note 11 – Investment in Lease, net**

On October 8, 2015, the Company entered into an equipment lease agreement with Biocon 1, LLC. The lease commenced on January 1, 2016 with a term of 60 months and monthly rental payments of approximately \$1,800 will be paid to the Company. At the completion of the lease term, Biocon 1, LLC will own the equipment provided under the agreement. An investment in lease was established for the direct financing lease receivable at the present value of the future minimum lease payments. Interest income will be recognized monthly over the lease term using the effective-interest method. Cash received will be applied against the direct financing lease receivable and will be presented within changes in operating assets and liabilities in the operating section of the Company's condensed consolidated statement of cash flows. At lease inception, an investment in lease of approximately \$92,000 was recorded, net of unearned interest of approximately \$14,000. Approximately \$1,000 was recognized in interest income during each of the three months ended September 30, 2018 and 2017. Approximately \$3,000 was recognized in interest income during each of the nine months ended September 30, 2018 and 2017. As of September 30, 2018, investment in lease, net-current portion is approximately \$24,000, net of unearned interest of \$2,000. As of September 30, 2018, investment in lease, net-noncurrent portion is approximately \$26,000, net of unearned interest of \$1,000.

As of September 30, 2018, scheduled maturities of minimum lease payments receivable were as follows:

|   |          |
|---|----------|
| 2018  | 9,000    |
| 2019  | 19,000   |
| 2020  | 22,000   |
|   | 50,000   |
| Less: Current portion                           | (24,000) |
| Investment in lease, net – less current portion | \$26,000 |

Included in the above scheduled maturities of minimum lease payments receivable, approximately \$5,000 was due as of September 30, 2018.

**Note 12 – License and Supply Agreement, net**

On April 23, 2012, the Company entered into a License and Supply Agreement (the "License and Supply Agreement") with Medica S.p.A. ("Medica"), an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica's proprietary Medisulfone ultrafiltration technology in conjunction with the Company's filtration products, and for an exclusive supply arrangement for the filtration products. Under the License and Supply Agreement, as amended, Medica granted to the Company an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the filtration products worldwide, with certain limitations on territory, during the term of the License and Supply Agreement. In addition, the Company granted to

Medica an exclusive license under the Company's intellectual property to make the filtration products during the term of the License and Supply Agreement. The filtration covered under the License and Supply Agreement include both certain products based on Medica's proprietary Versatile microfiber technology and certain filtration products based on Medica's proprietary Medisulfone ultrafiltration technology. The term of the License Agreement with Medica expires on December 31, 2025, unless earlier terminated by either party in accordance with the terms of the License and Supply Agreement.

In exchange for the license, the gross value of the intangible asset capitalized was approximately \$2,250,000. License and supply agreement, net, on the condensed consolidated balance sheet is approximately \$971,000 and \$1,072,000 as of September 30, 2018 and December 31, 2017, respectively. Accumulated amortization is approximately \$1,279,000 and \$1,178,000 as of September 30, 2018 and December 31, 2017, respectively. The intangible asset is being amortized as an expense over the life of the License and Supply Agreement. Approximately \$34,000 and \$53,000 has been charged to amortization expense for the three months ended September 30, 2018 and 2017, respectively, on the condensed consolidated statement of operations and comprehensive loss. Approximately \$101,000 and \$157,000 has been charged to amortization expense for the nine months ended September 30, 2018 and 2017, respectively, on the condensed consolidated statement of operations and comprehensive loss.

As of September 2013, the Company has an understanding with Medica whereby the Company has agreed to pay interest to Medica at a 12% annual rate calculated on the principal amount of any outstanding invoices that are not paid pursuant to the original payment terms. For the three and nine months ended September 30, 2018, approximately \$1,000 and \$13,000 of interest, respectively, was recognized as interest expense. For the three and nine months ended September 30, 2017, approximately \$7,000 and \$17,000 of interest, respectively, was recognized as interest expense.

In addition, for the period beginning April 23, 2014 through December 31, 2025, the Company will pay Medica a royalty rate of 3% of net sales of the filtration products sold, subject to reduction as a result of a supply interruption pursuant to the terms of the License and Supply Agreement. Approximately \$48,000 and \$22,000 for the three months ended September 30, 2018 and 2017, respectively, was recognized as royalty expense and is included in cost of goods sold on the condensed consolidated statement of operations and comprehensive loss. Approximately \$113,000 and \$64,000 for the nine months ended September 30, 2018 and 2017, respectively, was recognized as royalty expense and is included in cost of goods sold on the condensed consolidated statement of operations and comprehensive loss. Approximately \$48,000 and \$34,000 in royalties are included in accounts payable as of September 30, 2018 and December 31, 2017, respectively.

**Note 13 – Secured Note Payable**

On March 27, 2018, the Company entered into a Secured Promissory Note Agreement (the “Secured Note”) with Tech Capital, LLC (“Tech Capital”) for a principal amount of \$1,187,000. As of September 30, 2018, the principal balance of the Secured Note was approximately \$1,088,000. The Company used the proceeds from the Secured Note to repay the Company’s 11% unsecured promissory notes issued in June 2016 pursuant to the Note and Warrant Agreement (see Note 15 – Unsecured Promissory Notes and Warrants).

The Secured Note has a maturity date of April 1, 2023. The unpaid principal balance accrues interest at a rate of 8% per annum. Principal and interest payments are due on the first day of each month commencing on May 1, 2018. The Secured Note is subject to the terms and conditions of and is secured by security interests granted by the Company in favor of Tech Capital under the Loan and Security Agreement between the Company and Tech Capital, dated August 16, 2017 and all of the riders and amendments thereto (the “Loan Agreement”) (see Note 14 – Secured Revolving Credit Facility). An event of default under such Loan Agreement shall be an event of default under the Secured Note and vice versa. In the event the principal balance under the Loan Agreement is due, all amounts due under the Secured Note shall also be due.

During the three and nine months ended September 30, 2018, the Company made payments under the Secured Note of approximately \$72,000 and \$144,000, respectively. Included in the total payments made, approximately \$22,000 and \$45,000, respectively, were recognized as interest expense on the condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2018. Debt issuance costs of approximately \$6,000 were recognized as interest expense on the condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2018.

As of September 30, 2018, future principal maturities are as follows:

|       |             |
|-------|-------------|
| 2018  | \$51,000    |
| 2019  | 214,000     |
| 2020  | 231,000     |
| 2021  | 250,000     |
| 2022  | 271,000     |
| 2023  | 71,000      |
| Total | \$1,088,000 |

**Note 14 – Secured Revolving Credit Facility**

On August 17, 2017, the Company entered into the Loan Agreement with Tech Capital. The Loan Agreement provides for a secured asset-based revolving credit facility of up to \$1,000,000, which the Company may draw upon and repay from time to time during the term of the Loan Agreement. The outstanding principal balance of the Loan Agreement was approximately \$163,000 and \$711,000 as of September 30, 2018 and December 31, 2017, respectively. The Company is using these proceeds for working capital and general corporate purposes.

The Loan Agreement has a term of 12 months, which was automatically renewed on August 17, 2018 and will automatically renew for successive 12-month periods unless cancelled. Availability under the Loan Agreement will be based upon periodic borrowing base certifications valuing certain of the Company's accounts receivable and inventory. Outstanding borrowings under the Loan Agreement accrue interest, which shall be payable monthly based on the average daily outstanding balance, at a rate equal to 3.5% plus the prime rate per annum, provided that such prime rate shall not be less than 4.25% per annum. As of September 30, 2018, the current interest rate was 8.75% per annum.

The Company also granted to Tech Capital a first priority security interest in its assets, including its accounts receivable and inventory, to secure all of its obligations under the Loan Agreement. In addition, Nephros International Limited, the Company's wholly-owned subsidiary, unconditionally guaranteed the Company's obligations under the Loan Agreement.

For the three and nine months ended September 30, 2018, approximately \$9,000 and \$18,000, respectively, was recognized as interest expense on the condensed consolidated statement of operations and comprehensive loss. As of September 30, 2018, approximately \$1,000 of the \$18,000 of interest expense incurred for the nine months ended September 30, 2018 is included in accrued expenses on the condensed consolidated balance sheet.



For the three and nine months ended September 30, 2017, approximately \$18,000 was recognized as interest expense on the condensed consolidated statement of operations and comprehensive loss, which includes the debt issuance costs of approximately \$12,000 in addition to interest expense incurred of approximately \$6,000 on the revolving facility.

#### **Note 15 – Unsecured Promissory Notes and Warrants**

In June 2016, the Company entered into a Note and Warrant Agreement (the “Note and Warrant Agreement”) with new creditors as well as existing stockholders under which the Company issued unsecured promissory notes and warrants resulting in total gross proceeds to the Company of approximately \$1,187,000. The outstanding principal under the notes accrued interest at a rate of 11% per annum. The notes required the Company to make interest only payments on a semi-annual basis, with all outstanding principal under the notes being repayable in cash on the third anniversary of the date of issuance. In addition to the notes, the Company issued warrants to purchase approximately 2.4 million shares of the Company’s common stock. The portion of the gross proceeds allocated to the warrants of approximately \$393,000 was accounted for as additional paid-in capital resulting in a debt discount. The debt discount, which included approximately \$9,000 of debt issuance costs in addition to the fair value of the warrants, was being amortized to interest expense using the effective interest method in accordance with ASC 835 over the term of the Note and Warrant Agreement. As of December 31, 2017, the portion of the outstanding notes held by related parties comprised of persons controlled by a member of management and by Lambda Investors LLC (“Lambda”), a significant shareholder, amounted to \$30,000 and \$300,000, respectively. On March 30, 2018, the principal balance of the notes, along with the remaining accrued interest of approximately \$43,000, was repaid in full. While the notes were outstanding, approximately \$195,000 of interest was paid to noteholders. The remaining debt discount of approximately \$199,000 was recorded as loss on extinguishment of debt in the Company’s condensed consolidated statements of operations and comprehensive loss.

For the nine months ended September 30, 2018, approximately \$34,000 was recognized as amortization of debt discount and is included in interest expense on the condensed consolidated statement of operations and comprehensive loss. For the three and nine months ended September 30, 2017, approximately \$30,000 and \$84,000, respectively, was recognized as amortization of debt discount and is included in interest expense on the condensed consolidated statement of operations and comprehensive loss.

For the nine months ended September 30, 2018, approximately \$30,000 of interest expense was incurred. For the three and nine months ended September 30, 2017, approximately \$33,000 and \$99,000, respectively, of interest expense was incurred.

For the nine months ended September 30, 2018, the amount of interest expense recognized related to related parties comprised of entities controlled by a member of management and by Lambda was approximately \$1,000 and \$8,000, respectively. For the nine months ended September 30, 2017, the amount of interest expense recognized related to related parties comprised of entities controlled by a member of management and by Lambda was approximately

\$3,000 and \$24,000, respectively. For the three months ended September 30, 2017, the amount of interest expense recognized related to related parties comprised of entities controlled by a member of management and by Lambda was approximately \$1,000 and \$8,000, respectively.

#### **Note 16 –Noncontrolling Interest**

In July 2018, the Company formed a new, wholly-owned subsidiary, Specialty Renal Products, Inc. (“SRP”), to drive the development of its 2<sup>nd</sup> generation HDF system and other products focused on improving therapies for patients with renal disease.

On September 5, 2018, SRP entered into a Series A Preferred Stock Purchase Agreement with certain purchasers pursuant to which SRP sold 600,000 shares of its Series A Preferred Stock (“Series A Preferred”) for \$5.00 per share. The aggregate purchase price was \$3,000,000. SRP incurred transaction-related expenses of approximately \$30,000, which are included in selling, general and administrative expenses on the accompanying condensed consolidated statement of operations and comprehensive loss. The net proceeds from the issuance of the Series A Preferred are restricted to SRP expenses, and may not be used for the benefit of the Company or other affiliated entities, except to reimburse for expenses directly attributable to SRP. Following the Series A Preferred transaction, the Company retained a 62.5% ownership interest in SRP, holding 100% of the outstanding common shares, and holders of Series A Preferred retained a 37.5% interest in SRP on a fully diluted basis, holding 100% of the outstanding preferred shares. Of the 600,000 shares of Series A Preferred issued, the shares purchased by related parties comprised of persons controlled by members of management and by Lambda, a significant stockholder of the Company, amounted to 18,000 and 400,000 shares, respectively.

Each share of Series A Preferred is initially convertible into one share of SRP common stock, subject to adjustment for stock splits and recapitalization events. Subject to customary exempt issuances, in the event SRP issues additional shares of its common stock or securities convertible into common stock at a per share price that is less than the original Series A Preferred price, the conversion price of the Series A Preferred will automatically be reduced to such lower price.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of SRP, the holders of the Series A Preferred are entitled to be paid out of the assets of SRP available for distribution to its stockholders or, in the case of a deemed liquidation event, out of the consideration payable to stockholders in such deemed liquidation event or the available proceeds, before any payment shall be made to the holders of SRP common stock by reason of their ownership thereof, an amount per share equal to one times (1x) the Series A Preferred original issue price, plus any accruing dividends accrued but unpaid thereon, whether or not declared, together with any other dividends declared but unpaid thereon (the "Series A Liquidation Preference"). If upon any such liquidation, dissolution or winding up of SRP or deemed liquidation event, the assets of SRP available for distribution to its stockholders shall be insufficient to pay the Series A Liquidation Preference in full, the holders of Series A Preferred shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full. After the full payment of the Series A Liquidation Preference, the holders of the Series A Preferred and the holders of common stock will share ratably in any remaining proceeds available for distribution on an as-converted to common stock basis.

Each share of Series A Preferred accrues dividends at the rate per annum of \$0.40 per share. The accruing dividends shall accrue from day to day, whether or not declared, and shall be cumulative and shall be payable only when, as, and if declared by the Board.

Holders of Series A Preferred shall be entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of Series A Preferred held by such holder are convertible as of the record date for determining stockholders entitled to vote. Except as provided by law or by the other provisions, the holders of Series A Preferred vote together with the holders of common stock as a single class. Notwithstanding the foregoing, for as long as at least 150,000 shares of Series A Preferred are outstanding, SRP is required to obtain the affirmative vote or written consent of a majority of the Series A Preferred in order to effect certain corporate transactions, including without limitation, the issuance of any securities senior to or on parity with the Series A Preferred, a liquidation or deemed liquidation of SRP, amendments to SRP's charter documents, the issuance of indebtedness in excess of \$250,000, any annual budget for the Company's operations, and the hiring or firing of any executive officers of SRP. In addition, the holders of the Series A Preferred are entitled to elect two members of SRP's board of directors.

The noncontrolling interest in SRP held by the Holders of Series A has been classified as mezzanine equity on the accompanying condensed consolidated interim balance sheet, as the noncontrolling interest is redeemable upon the occurrence of events that are not solely within the control of the Company.

## **Note 17 – Stockholders' Equity**

### **April 2018 Private Placement**

On April 10, 2018, the Company entered into a Stock Purchase Agreement with certain accredited investors identified therein pursuant to which the Company issued and sold in a private placement 6,540,669 shares of the Company's common stock resulting in gross proceeds to the Company of approximately \$2,943,000. The purchase price for each share was \$0.45. Proceeds, net of equity issuance costs of \$19,000, recorded as a result of the private placement were approximately \$2,924,000. Of the 6,540,669 shares of the Company's common stock issued, 219,000 shares, resulting in proceeds of \$98,000, were sold to members of management, including immediate family members.

### **March 2017 Private Placement**

On March 17, 2017, the Company entered into a Securities Purchase Agreement with certain accredited investors identified therein pursuant to which the Company issued and sold in a private placement 4,059,994 units of its securities resulting in gross proceeds to the Company of approximately \$1,218,000. Each unit consisted of one share of the Company's common stock and a five-year warrant to purchase one additional share of the Company's common stock. The purchase price for each unit was \$0.30. The warrants are exercisable at a price of \$0.30 per share and are indexed to the Company's common stock; therefore, the Company is accounting for the warrants as a component of equity. The portion of the gross proceeds received from certain members of management and existing stockholders amounted to \$315,000. Proceeds, net of equity issuance costs of \$152,000, recorded as a result of the private placement were approximately \$1,066,000. In addition to the equity issuance costs incurred as a result of the private placement, the Company also issued a warrant to purchase 81,199 shares of its common stock to the placement agent engaged in connection with the private placement. The form and terms of the placement agent warrant is substantially the same as the form of warrants issued to the investors under the Securities Purchase Agreement, except that the exercise price is \$0.33 per share.

### **July 2015 Purchase Agreement and Registration Rights Agreement**

On July 24, 2015, the Company entered into both a securities purchase agreement and registration rights agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Under the terms and subject to the conditions of the securities purchase agreement, the Company had the right to sell to Lincoln Park, and Lincoln Park was obligated to purchase, up to \$10.0 million in shares of the Company's common stock, subject to certain limitations, from time to time, over the 36-month period commencing on September 4, 2015. Pursuant to the securities purchase agreement, during the nine months ended September 30, 2018 and 2017, the Company issued and sold 1,900,000 and 300,000 shares of its common stock, respectively, to Lincoln Park. The issuance of the common shares to Lincoln Park resulted in gross proceeds of \$854,000 and \$113,000 for the nine months ended September 30, 2018 and 2017, respectively. The Company did not issue or sell any stock to Lincoln Park during the three months ended September 30, 2018. The securities purchase agreement expired on September 4, 2018.

## Note 18 – Commitments and Contingencies

### Purchase Commitments

In exchange for the rights granted under the License and Supply Agreement with Medica (see Note 12 – License and Supply Agreement, net), the Company agreed to make certain minimum annual aggregate purchases from Medica over the term of the License and Supply Agreement. For the year ended December 31, 2018, the Company has agreed to make minimum annual aggregate purchases from Medica of €2,500,000 (approximately \$3,000,000). As of September 30, 2018, the Company's aggregate purchase commitments totaled approximately €2,254,000 (approximately \$2,706,000).

### Contractual Obligations

The Company entered into an operating lease that began in December 2017 for 380 Lackawanna Place, South Orange, New Jersey 07079, which consists of approximately 7,700 square feet of space. The rental agreement expires in November 2022 with a monthly cost of approximately \$11,000. Approximately \$11,000 related to a security deposit for this U.S. office facility is classified as other assets on the condensed consolidated balance sheet as of September 30, 2018 and December 31, 2017. The Company uses these facilities to house its corporate headquarters and research facilities.

The lease agreement for the office space in Ireland was entered into on August 1, 2018 and includes a twelve month term.

Rent expense for the three months ended September 30, 2018 and 2017 totaled \$37,000 and \$31,000, respectively. Rent expense for the nine months ended September 30, 2018 and 2017 totaled \$125,000 and \$91,000, respectively.

As of September 30, 2018, minimum lease payments are as follows:

|      |          |
|------|----------|
| 2018 | \$33,000 |
| 2019 | 136,000  |
| 2020 | 140,000  |
| 2021 | 145,000  |

2022 136,000

### **Note 19 – Segment Reporting**

During the three months ended September 30, 2018, the Company began reporting the results of SRP as a new segment as a result of the July 2018 formation of the Company’s new subsidiary, SRP. Prior to the formation of SRP, the Company had only a single operating segment. The Company has reflected these new segment measures beginning in the quarter ended September 30, 2018 and prior periods have been restated for comparability.

The Company has defined its two reportable segments as Water Filtration and Renal Products. The Water Filtration segment develops and sells high performance liquid purification filters, known as ultrafilters. The Renal Products segment is focused on the development of medical device products for patients with renal disease, including a 2<sup>nd</sup> generation hemodiafiltration system, for the treatment of patients with ESRD.

The Company’s chief operating decision maker evaluates the financial performance of the Company’s segments based upon segment revenues, gross margin and operating expenses which include research and development and selling, general and administrative expenses.

The accounting policies for the Company’s segments are the same as those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Estimates” contained in Item 7 of Part II and Note 2, “Summary of Significant Accounting Policies,” of the Notes to the Consolidated Financial Statements in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017.

The tables below present segment information reconciled to total Company loss from operations, with segment operating loss including gross profit less direct research and development expenses and direct selling, general and administrative expenses to the extent specifically identified by segment:

|                          | Three Months Ended September 30,<br>2018 |                   |  |
|--------------------------|--|-------------------|--|
|                          | Water<br>Filtration                      | Renal<br>Products | <b>Nephros,<br/>Inc.<br/><br/>Consolidated</b> |
| Total net revenues       | \$1,724,000                              | \$-               | \$1,724,000                                    |
| Gross margin             | 952,000                                  | -                 | 952,000  |
| Total operating expenses | (1,159,000)                              | (304,000)         | (1,463,000 )                                   |
| Loss from operations     | \$(207,000 )                             | \$(304,000)       | \$(511,000 )                                   |

|                          | Nine Months Ended September 30, 2018 |                   |  |
|--------------------------|--------------------------------------|-------------------|--|
|                          | Water<br>Filtration                  | Renal<br>Products | <b>Nephros,<br/>Inc.<br/><br/>Consolidated</b> |
| Total net revenues       | \$4,075,000                          | \$-               | \$4,075,000                                    |
| Gross margin             | 2,249,000                            | -                 | 2,249,000                                      |
| Total operating expenses | (4,019,000)                          | (517,000)         | (4,536,000 )                                   |
| Loss from operations     | \$(1,770,000)                        | \$(517,000)       | \$(2,287,000 )                                 |

|                          | Three Months Ended September 30,<br>2017 |                   |  |
|--------------------------|--|-------------------|--|
|                          | Water<br>Filtration                      | Renal<br>Products | <b>Nephros,<br/>Inc.<br/><br/>Consolidated</b> |
| Total net revenues       | \$916,000                                | \$-               | \$916,000                                      |
| Gross margin             | 532,000                                  | -                 | 532,000  |
| Total operating expenses | (1,034,000)                              | (16,000)          | (1,050,000 )                                   |
| Loss from operations     | \$(502,000 )                             | \$(16,000)        | \$(518,000 )                                   |

|                    | Nine Months Ended September 30,<br>2017 |                   |  |
|--------------------|---|-------------------|--|
|                    | Water<br>Filtration                     | Renal<br>Products | <b>Nephros,<br/>Inc.<br/><br/>Consolidated</b> |
| Total net revenues | \$2,509,000                             | \$-               | \$2,509,000                                    |

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|                          |               |            |                |
|--------------------------|---------------|------------|----------------|
| Gross margin             | 1,504,000     | -          | 1,504,000      |
| Total operating expenses | (3,311,000)   | (16,000)   | (3,327,000 )   |
| Loss from operations     | \$(1,807,000) | \$(16,000) | \$(1,823,000 ) |

As of September 30, 2018, approximately \$3,000,000 of total assets are in the Renal Products segment. The \$3,000,000 consists of cash, as a result of the sale of Series A Preferred Stock during the three month ends September 30, 2018. There were no assets allocated to the Renal Products segment as of December 31, 2017.



Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*This discussion should be read in conjunction with our consolidated financial statements included in this Quarterly Report on Form 10-Q and the notes thereto, as well as the other sections of this Quarterly Report on Form 10-Q, including the "Forward-Looking Statements" section hereof, and our Annual Report on Form 10-K for the year ended December 31, 2017, including the "Risk Factors" and "Business" sections thereof. This discussion contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risk factors described in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2017. Our actual results may differ materially.*

## **Business Overview**

We are a commercial stage medical device and commercial products company that develops and sells high performance liquid purification filters. 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 patient exposure to a wide variety of bacteria, viruses, fungi, parasites, and endotoxins.

Our subsidiary, Specialty Renal Products ("SRP"), is a development stage medical device company focused primarily on developing hemodiafiltration ("HDF") technology. SRP is developing a second generation of the OLpür H2H Hemodiafiltration System, the only U.S. Food and Drug Administration ("FDA") 510(k) cleared medical device that enables nephrologists to provide hemodiafiltration treatment to patients with end stage renal disease ("ESRD").

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 hospital infection control and dialysis center water purification.

## **Our Products**

We develop and sell ultrafiltration products 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) and virus, which is not eliminated by most other microbiological filters on the market. 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, including use in sinks, showers, and ice machines. The filters produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures, and washing of surgeons’ hands.

**Dialysis Centers:** Filtration of water or bicarbonate concentrate used in hemodialysis.

**Commercial Facilities:** Filtration of water for washing and drinking, including use in ice machines and soft drink dispensers.

**Military and Outdoor Recreation:** Individual water purification devices used by soldiers and backpackers to produce drinking water in the field, as well as filters customized to remote water processing systems.

Hospitals and Other Healthcare Facilities. According to the American Hospital Association, approximately 5,700 hospitals, with approximately 915,000 beds, treated over 35 million patients in the United States in 2013. The U.S. Centers for Disease Control and Prevention estimates that healthcare associated infections (“HAI”) occurred in approximately 1 out of every 25 hospital patients, or about 1.4 million patients in 2013. HAIs affect patients in hospitals or other healthcare facilities and are not present or incubating at the time of admission. They also include infections acquired by patients in the hospital or facility, but appearing after discharge, and occupational infections among staff. Many HAIs are caused by waterborne bacteria and viruses that can thrive in aging or complex plumbing systems often found in healthcare facilities.

The Affordable Care Act, passed in March 2010, puts in place comprehensive health insurance reforms that aim to lower costs and enhance quality of care. With its implementation, healthcare providers have substantial incentives to deliver better care or be forced to absorb the expenses associated with repeat medical procedures or complications like HAIs. As a consequence, hospitals and other healthcare facilities are proactively implementing strategies to reduce HAI potential. Our ultrafilters are designed to aid in infection control in the hospital and healthcare setting by treating facility water at the points of delivery, such as ice machines, sinks and showers.

In June 2017, the Center for Clinical Standards and Quality at the Centers for Medicare and Medicaid Services (“CMS”) announced the addition of requirements for facilities to develop policies and procedures that inhibit the growth and spread of legionella and other opportunistic pathogens in building water systems. Going forward, CMS surveyors will review policies, procedures, and reports documenting water management implementation results to verify that facilities are compliant with these requirements. We believe that these CMS regulations may have a positive impact on the sale of our HAI-inhibiting ultrafilters.

We currently have FDA 510(k) clearance on the following portfolio of medical device products for use in the hospital setting to aid in infection control:

The DSU-H is an in-line, 0.005 micron ultrafilter that provides dual-stage protection from water borne pathogens. The DSU H is primarily used to filter potable water feeding ice machines, sinks, and medical equipment, such as endoscope washers and surgical room humidifiers. The DSU-H has an up to 6 month product life when used in a hospital setting.

The SSU-H is an in-line, 0.005 micron ultrafilter that provides single-stage protection from water borne pathogens. The SSU-H is primarily used to filter potable water feeding sinks, showers and medical equipment. The SSU-H has an up to 3 month product life when used in a hospital setting.

The S100 is a point-of-use, 0.01 micron microfilter that provides protection from water borne pathogens. The S100 is primarily used to filter potable water feeding sinks and showers. The S100 has an up to 3 month product life when used in a hospital setting.

The HydraGuard™ and HydraGuard™ - Flush are 0.005 micron cartridge ultrafilters that provide single-stage protection from water borne pathogens. The HydraGuard™ ultrafilters are primarily used to filter potable water feeding ice machines and medical equipment, such as endoscope washers and surgical room humidifiers. The HydraGuard™ has an up to 6 month product life and the HydraGuard™ - Flush has an up to 12 month product life when used in a hospital setting.

We received FDA 510(k) clearance to market the HydraGuard™ in December 2016 and began shipping it in July 2017. We began shipping the HydraGuard™ - Flush in September 2017. The DSU-H, SSU-H, and S100 products were 510(k)-cleared in prior years.

The complete hospital infection control product line, including in-line, point-of-use, and cartridge filters, can be viewed on our website at <http://www.nephros.com/infection-control/>. We are not including the information on our website as a part of, nor incorporating it by reference, into this Quarterly Report on Form 10-Q.

*Dialysis Centers - Water/Bicarbonate.* To perform hemodialysis, all dialysis clinics have dedicated water purification systems to produce water and bicarbonate concentrate, two essential ingredients for making dialysate, the liquid that removes waste material from the blood. According to the American Journal of Kidney Diseases, there are approximately 6,300 dialysis clinics in the United States servicing approximately 430,000 patients annually. We estimate that there are over 100,000 hemodialysis machines in operation in the United States.

Medicare is the main payer for dialysis treatment in the United States. To be eligible for Medicare reimbursement, dialysis centers must meet the minimum standards for water and bicarbonate concentrate quality set by the Association for the Advancement of Medical Instrumentation (“AAMI”), the American National Standards Institute (“ANSI”) and the International Standards Organization (“ISO”). We anticipate that the stricter standards approved by these organizations in 2009 will be adopted by Medicare in the future.

We currently have FDA 510(k) clearance on the following portfolio of medical device products for use in the dialysis setting to aid in bacteria, virus, and endotoxin retention:

The DSU-D, SSU-D and SSUmini are in-line, 0.005 micron ultrafilters that provide protection from bacteria, viruses, and endotoxins. All of these products have an up to 12 month product life in the dialysis setting and are used to filter water following treatment with a reverse osmosis (“RO”) system and to filter bicarbonate concentrate. These ultrafilters are primarily used in the water lines and bicarbonate concentrate lines leading into dialysis machines and as a polish filter for portable RO machines.

The EndoPur is a 0.005 micron cartridge ultrafilter that provides single-stage protection from bacteria, viruses, and endotoxins. The EndoPur has an up to 12 month product life in the dialysis setting and is used to filter water following treatment with an RO system. More specifically, the EndoPur is used primarily to filter water in large RO systems designed to provide ultrapure water to an entire dialysis clinic. The EndoPur is available in 10”, 20”, and 30” configurations.

The EndoPur is a cartridge-based, “plug and play” market entry that requires no plumbing at installation or replacement. In March 2017, we received FDA 510(k) clearance to market the EndoPur filter. We began shipping the EndoPur 10” filter in July 2017 and the 20” and 30” versions in September 2017.

Commercial and Industrial Facilities. We currently market the following portfolio of proprietary products for use in the commercial, industrial, and food service settings:

The NanoGuard®-D is an in-line, 0.005 micron ultrafilter that provides dual-stage retention of any organic or inorganic particle larger than 15,000 Daltons. The NanoGuard®-D is primarily used to filter potable water feeding ice machines, sinks, and equipment that requires or benefits from ultrafiltered water, and filters up to 10,000 gallons of potable water, depending upon the particle load.

The NanoGuard®-S is an in-line, 0.005 micron ultrafilter that provides single-stage retention of any organic or inorganic particle larger than 15,000 Daltons. The NanoGuard®-S is primarily used to filter potable water feeding ice machines, sinks, showers and equipment that requires or benefits from ultrafiltered water, and filters up to 3,000 gallons of potable water, depending upon the particle load.

The NanoGuard®-E is a 0.005 micron ultrafilter cartridge that plugs into an Everpure® filter manifold and provides single-stage retention of any organic or inorganic particle larger than 15,000 Daltons. The NanoGuard®-E is primarily used to filter potable water feeding ice machines, beverage dispensers, and other equipment that requires or benefits from ultrafiltered water, and filters up to 10,000 gallons of potable water, depending upon the particle load.

The NanoGuard®-C is a 0.005 micron cartridge ultrafilter that fits with most 10”, 20”, 30” and 40” cartridge housings and provides single-stage retention of any organic or inorganic particle larger than 15,000 Daltons. The NanoGuard®-C is primarily used to filter potable water feeding ice machines and equipment that requires or benefits

from ultrafiltered water, and filters up to 10,000 gallons of potable water per 10” of length, depending upon the particle load.

The NanoGuard®-F is a 0.005 micron flushable cartridge ultrafilter, available in 10” or 20” sizes and provides single-stage retention of any organic or inorganic particle larger than 15,000 Daltons. The NanoGuard®-F is primarily used to filter potable water feeding ice machines, sinks and equipment that requires or benefits from ultrafiltered water. The NanoGuard®-F has an up to 12 month product life and can filter up to 2.5 gallons per minute per 10” length, depending upon the particle load.

In the fourth quarter of 2017, we released a lead filtration system that addresses both soluble and particulate lead in potable water, with the ability to treat up to 9,000 gallons of water between filter change-outs. This system is in the early stages of market roll-out.

*Military and Outdoor Recreation.* We developed our individual water treatment device (“IWTD”) in both in-line and point-of-use configurations. Our IWTD allows a soldier in the field to derive drinking water from any freshwater source. This enables the soldier to remain hydrated, to help maintain mission effectiveness and unit readiness, and to extend mission reach. Our IWTD has been validated by the military to meet the NSF Protocol P248 standard. It has also been approved by the U.S. Army Public Health Command and the U.S. Army Test and Evaluation Command for deployment.

In May 2015, we entered into a Sublicense Agreement with CamelBak Products, LLC (“CamelBak”). Under this Sublicense Agreement, we granted CamelBak an exclusive, non-transferable, worldwide (with the exception of Italy) sublicense and license, in each case solely to market, sell, distribute, import and export the IWTD. In exchange for the rights granted to CamelBak, CamelBak agreed, through December 31, 2022, to pay us a percentage of the gross profit on any sales made to a branch of the U.S. military, subject to certain exceptions, and to pay us a fixed per-unit fee for any other sales made. CamelBak is also required to meet or exceed certain minimum annual fees payable to us, and, if such fees are not met or exceeded, we may convert the exclusive sublicense to a non-exclusive sublicense with respect to non-U.S. military sales.

*Specialty Renal Products: HDF System*

Introduction to HDF

The current standard of care in the United States for patients with chronic renal failure is hemodialysis (“HD”), a process in which toxins are cleared via diffusion. Patients typically receive HD treatments at least 3 times weekly for 3-4 hours per treatment. HD is most effective in removing smaller, easily diffusible toxins. For patients with acute renal failure, the current standard of care in the United States is hemofiltration (“HF”), a process where toxins are cleared via convection. HF offers a much better removal of larger sized toxins when compared to HD. However, HF treatment is more challenging for patients, as it is performed on a daily basis, and typically takes 12-24 hours per treatment.

Hemodiafiltration (“HDF”) is an alternative dialysis modality that combines the benefits of HD and HF into a single therapy by clearing toxins using both diffusion and convection. Though not widely used in the United States, HDF is prevalent in Europe and is performed for a growing number of patients. Clinical experience and literature show the following clinical and patient benefits of HDF:

- Enhanced clearance of middle and large molecular weight toxins
- Improved survival - up to a 35% reduction in mortality risk
- Reduction in the occurrence of dialysis-related amyloidosis
- Reduction in inflammation
- Reduction in medication such as EPO and phosphate binders
- Improved patient quality of life
- Reduction in number of hospitalizations and overall length of stay

However, like HD, HDF can be resource-intensive and can require a significant amount of time to deliver one course of treatment.

Nephros HDF Background

Over the course of our history, we developed a medical device that enables a standard HD machine to perform HDF. We refer to our approach as an on-line mid-dilution hemodiafiltration (“mid-dilution HDF”) system. Our original solution included an OLpūr H2H Hemodiafiltration Module (“H2H Module”), a OLpūr MD 220 Hemodiafilter (“HDF Filter”) and a H2H Substitution Filter (“Dialysate Filter”).

Our H2H Module attaches to a standard HD machine to enable on-line HDF therapy. The HD machine controls and monitors the basic treatment functions, as it would normally when providing HD therapy. The H2H Module is a free-standing, movable device that is placed next to either side of an HD machine. The H2H Module connects to the clinic's water supply, drain, and electricity.

The H2H Module utilizes the HDF Filter and is very similar to a typical hollow fiber dialyzer assembled with a single hollow fiber bundle made with a high-flux (or high-permeability) membrane. The fiber bundle is separated into two discrete, but serially connected, blood paths. Dialysate flows in one direction that is counter-current to blood flow in Stage 1 and co-current to blood flow in Stage 2.

In addition to the HDF Filter, the H2H Module also utilizes a Dialysate Filter during patient treatment. The Dialysate Filter is a hollow fiber, ultrafilter device that consists of two sequential (redundant) ultrafiltration stages in a single housing. During on-line HDF with the H2H Module, fresh dialysate is redirected by the H2H Module's hydraulic (substitution) pump and passed through this dual-stage ultrafilter before being infused as substitution fluid into the extracorporeal circuit. Providing ultrapure dialysate is crucial for the success of on-line HDF treatment.

Our HDF system conformed with current ANSI/AAMI/ISO standards and was cleared by the FDA for the treatment of patients with chronic renal failure in 2012. To date, our HDF system is the only HDF system cleared by the FDA.

Over the last four years, DaVita Healthcare Partners, the Renal Research Institute (a research division of Fresenius Medical Care), and Vanderbilt University conducted post-market evaluations of our HDF system in their clinics. We gathered direct feedback from these evaluations to develop a better understanding of how our system best fits into the current clinical and economic ESRD treatment paradigm. The ultimate goal of the evaluations was to better understand the potential for HDF, in the U.S. clinical setting, to (a) improve the quality of life for the patient, (b) reduce overall expenditure compared to other dialysis modalities, (c) minimize the impact on nurse work flow at the clinic, and (d) demonstrate the pharmaco-economic benefit of the HDF technology to the U.S. healthcare system, as has been done in Europe with other HDF systems. The last evaluation was concluded at Vanderbilt in the first quarter of 2018. When practical, we will work with Vanderbilt to publish observational findings.



Specialty Renal Products, Inc.

Leveraging the learnings from our evaluations, we recently completed development of a 2<sup>nd</sup> generation HDF machine prototype. We believe that the design changes will enable our HDF machine to better align with clinical work-flow practices, to be highly reliable, to simplify the training required for proficiency, and to have a dramatically lower cost of goods. We have filed for patent protection on key features of our updated design.

We recently formed a new subsidiary, Specialty Renal Products, Inc. (“SRP”), to drive the development of this 2<sup>nd</sup> generation HDF system. A prototype of the new 2<sup>nd</sup> generation HDF system has been constructed. We intend to fund the HDF program primarily with funds directly raised into SRP, including a \$3 million Series A financing round completed in September, 2018. Pending FDA clearance, we believe we can return to the market with our HDF system in approximately 15 months.

**Critical Accounting Policies**

For the three- and nine-month periods ended September 30, 2018, in addition to the adoption of Accounting Standards Codification 606, Revenue from Contracts with Customers (see Note 9, “Recent Accounting Pronouncements,” of the Notes to our Unaudited Condensed Consolidated Interim Financial Statements contained in Item 1 of Part I of this Quarterly Report on Form 10-Q, which is incorporated herein by reference), below are the significant changes to our critical accounting policies as identified in our Annual Report on Form 10-K for the year ended December 31, 2017.

*Noncontrolling Interest*

We present the redeemable noncontrolling interest in SRP held by outside shareholders as mezzanine equity on the accompanying condensed consolidated interim balance sheet, as the noncontrolling interest is redeemable upon the occurrence of events that are not solely within the control of the Company.

*Segment Reporting*

We have two reportable segments, Water Filtration and Renal Products. The Water Filtration segment develops and sells high performance liquid purification filters, known as ultrafilters. The Renal Products segment is focused on the development of medical device products for patients with renal disease, including a 2<sup>nd</sup> generation hemodiafiltration

system, for the treatment of patients with ESRD.

Our chief operating decision maker evaluates the financial performance of our segments based upon segment net profit/loss. The accounting policies for our segments are the same as those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Estimates” contained in Item 7 of Part II and Note 2, “Summary of Significant Accounting Policies,” of the Notes to our Consolidated Financial Statements contained in Item 8 of Part II of our Annual Report on Form 10-K for the year ended December 31, 2017.

### **Recent Accounting Pronouncements**

We are subject to recently issued accounting standards, accounting guidance and disclosure requirements. For a description of these new accounting standards, see Note 9, “Recent Accounting Pronouncements,” of the Notes to our Unaudited Condensed Consolidated Interim Financial Statements contained in Item 1 of Part I of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

### **Results of Operations**

#### *Fluctuations in Operating Results*

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our annual results of operations will be impacted for the foreseeable future by several factors including the progress and timing of expenditures related to our research and development efforts, marketing expenses related to product launches, timing of regulatory approval of our various products and market acceptance of our products. Due to these fluctuations, we believe that the period to period comparisons of our operating results are not a good indication of our future performance.

**Three Months Ended September 30, 2018 Compared to the Three Months Ended September 30, 2017**

The following table sets forth our summarized, consolidated results of operations for the three months ended September 30, 2018 and 2017:

|   | Three Months Ended<br>September 30, |             | \$          | %    |    |
|---|-------------------------------------|-------------|-------------|------|----|
|   | 2018                                | 2017        |             |      |    |
| Total net revenues  | \$1,724,000                         | \$916,000   | \$ 808,000  | 88   | %  |
| Cost of goods sold  | 772,000                             | 384,000     | 388,000     | 101  | %  |
| Gross margin  | 952,000                             | 532,000     | 420,000     | 79   | %  |
| Gross margin  | 55                                  | % 58        | -           | (3)  | )% |
| Research and development expenses                             | 352,000                             | 237,000     | 115,000     | 49   | %  |
| Depreciation and amortization expense                         | 42,000                              | 60,000      | (18,000 )   | (30) | )% |
| Selling, general and administrative expenses                  | 1,069,000                           | 753,000     | 316,000     | 42   | %  |
| Loss from operations  | (511,000 )                          | (518,000)   | (7,000 )    | (1)  | )% |
| Interest expense  | (32,000 )                           | (88,000 )   | (56,000 )   | (64) | )% |
| Interest income   | 1,000                               | 1,000       | -           | -%   |    |
| Other expense   | (8,000 )                            | (27,000 )   | (19,000 )   | (70) | )% |
| Net loss  | (550,000 )                          | (632,000)   | (82,000 )   | (13) | )% |
| Less: Deemed dividend attributable to noncontrolling interest | (16,000 )                           | -           | 16,000      | 100  | %  |
| Net loss attributable to Nephros, Inc.                        | \$(566,000 )                        | \$(632,000) | \$(66,000 ) | (10) | )% |

**Water Filtration**

The following table sets forth results of operations for the Water Filtration segment for the three months ended September 30, 2018 and 2017:

|  | Three Months Ended<br>September 30, |      | \$ | % |  |
|--|-------------------------------------|------|----|---|--|
|  | 2018                                | 2017 |    |   |  |

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|  |              |             |              |      |    |     |    |
|--|--------------|-------------|--------------|------|----|-----|----|
| Total net revenues                           | \$ 1,724,000 | \$ 916,000  | \$ 808,000   | 88   | %  |     |    |
| Cost of goods sold                           | 772,000      | 384,000     | 388,000      | 101  | %  |     |    |
| Gross margin                                 | 952,000      | 532,000     | 420,000      | 79   | %  |     |    |
| Gross margin                                 | 55           | %           | 58           | %    | -  | (3) | )% |
| Research and development expenses            | 147,000      | 225,000     | (78,000 )    | (35) | )% |     |    |
| Depreciation and amortization expense        | 42,000       | 60,000      | (18,000 )    | (30) | )% |     |    |
| Selling, general and administrative expenses | 970,000      | 749,000     | 221,000      | 30   | %  |     |    |
| Loss from operations                         | \$(207,000 ) | \$(502,000) | \$(295,000 ) | (59) | )% |     |    |

*Net Revenues*

Total net revenues for the three months ended September 30, 2018 were approximately \$1,724,000 compared to approximately \$916,000 for the three months ended September 30, 2017. The increase of approximately \$808,000, or 88%, was driven by an increase in sales to new customers and expansion within existing customer accounts.

*Cost of Goods Sold*

Cost of goods sold was approximately \$772,000 for the three months ended September 30, 2018 compared to approximately \$384,000 for the three months ended September 30, 2017. The increase of approximately \$388,000, or 101%, was related to an increase in direct product costs in support of increased revenue. The increase exceeded the 88% increase in revenue largely due to an increase in 2018 of the ratio of product revenue to license, royalty and other revenues.

### *Gross Margin*

Gross margin was approximately 55% for the three months ended September 30, 2018 compared to approximately 58% for the three months ended September 30, 2017. The decrease of approximately 3% is primarily due to an increase in 2018 of the ratio of product revenue to license, royalty and other revenues.

### *Research and Development Expenses*

Research and development expenses were approximately \$147,000 and \$225,000 for the three months ended September 30, 2018 and September 30, 2017, respectively. This decrease of approximately \$78,000, or 35%, reflects lower expenditures on new filter development.

### *Depreciation and Amortization Expense*

Depreciation and amortization expense was approximately \$42,000 for the three months ended September 30, 2018 compared to approximately \$60,000 for the three months ended September 30, 2017. The decrease of approximately \$18,000, or 30%, is due to lower amortization expense for the three months ended September 30, 2018 as a result of an amendment to our License and Supply agreement with Medica in September 2017, which extended the term from December 31, 2022 to December 31, 2025.

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses were approximately \$970,000 for the three months ended September 30, 2018 compared to approximately \$749,000 for the three months ended September 30, 2017, representing an increase of \$221,000, or 30%. The increase was primarily due to an increase in personnel-related expenses of approximately \$68,000 due to increased headcount, an increase in stock-based compensation expenses of approximately \$12,000 due to increased headcount, an increase in professional service expenses of approximately \$76,000, and an increase in other expenses of approximately \$73,000.

### *Interest Expense*

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The table below summarizes interest expense for the three months ended September 30, 2018 and 2017:

|  |          |          | \$                | %                 |                 |
|--|----------|----------|-------------------|-------------------|-----------------|
|  | 2018     | 2017     | <b>Increase</b>   |                   | <b>Increase</b> |
|  |          |          | <b>(Decrease)</b> | <b>(Decrease)</b> |                 |
| Interest related to unsecured long-term note payable             | \$-      | \$33,000 | \$ (33,000 )      | (100 )            | )%              |
| Amortization of debt discount - unsecured long-term note payable | -        | 30,000   | (30,000 )         | (100 )            | )%              |
| Interest - outstanding payables due to a vendor                  | 1,000    | 7,000    | (6,000 )          | (86 )             | )%              |
| Interest related to secured note payable                         | 22,000   | -        | 22,000            | 100               | )%              |
| Interest on secured revolving credit facility                    | 9,000    | 18,000   | (9,000 )          | (50 )             | )%              |
| Total interest expense   | \$32,000 | \$88,000 | \$ (56,000 )      | (64 )             | )%              |

*Interest Income*

Interest income of approximately \$1,000 for each of the three-month periods ended September 30, 2018 and 2017 is as result of interest income recognized on the investment in lease, net.

*Other Income/Expense*

Other expense for the three months ended September 30, 2018 and 2017 was approximately \$8,000 and \$27,000, respectively. The decrease of 70% is primarily due to improvements in foreign currency exchange rates.

***Renal Products***

The following table sets forth results of operations for the Renal Products segment for the three months ended September 30, 2018 and 2017:

|  | Three Months Ended<br>September 30, |            | \$         | %          |   |
|--|-------------------------------------|------------|------------|------------|---|
|  | 2018                                | 2017       |            |            |   |
|  |                                     |            | (Decrease) | (Decrease) |   |
| Research and development expenses            | \$205,000                           | 12,000     | \$ 193,000 | 1608       | % |
| Selling, general and administrative expenses | 99,000                              | 4,000      | 95,000     | 2375       | % |
| Loss from operations                         | \$(304,000)                         | \$(16,000) | \$ 288,000 | 1800       | % |

***Research and Development Expenses***

Research and development expenses were approximately \$205,000 and \$12,000 for the three months ended September 30, 2018 and September 30, 2017, respectively, an increase of approximately \$193,000 due to increased investment in the 2<sup>nd</sup>-generation HDF product.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses were approximately \$99,000 and \$4,000 for the three months ended September 30, 2018 and September 30, 2017, respectively, an increase of approximately \$95,000 due to increased investment in the 2<sup>nd</sup>-generation HDF product.

***Nine Months Ended September 30, 2018 Compared to the Nine Months Ended September 30, 2017***

The following table sets forth our summarized, consolidated results of operations for the nine months ended September 30, 2018 and 2017:

|   | Nine Months Ended |               | \$          | %    |    |          |          |
|---|-------------------|---------------|-------------|------|----|----------|----------|
|   | September 30,     |               |             |      |    | Increase | Increase |
|   | 2018              | 2017          |             |      |    |          |          |
| Total net revenues  | \$4,075,000       | \$2,509,000   | \$1,566,000 | 62   | %  |          |          |
| Cost of goods sold  | 1,826,000         | 1,005,000     | 821,000     | 82   | %  |          |          |
| Gross margin  | 2,249,000         | 1,504,000     | 745,000     | 50   | %  |          |          |
| Gross margin  | 55                | % 60          | -           | (5)  | )% |          |          |
| Research and development expenses                             | 993,000           | 744,000       | 249,000     | 33   | %  |          |          |
| Depreciation and amortization expense                         | 123,000           | 178,000       | (55,000 )   | (31) | )% |          |          |
| Selling, general and administrative expenses                  | 3,420,000         | 2,405,000     | 1,015,000   | 42   | %  |          |          |
| Loss from operations  | (2,287,000)       | (1,823,000)   | 464,000     | 25   | %  |          |          |
| Loss on extinguishment of debt                                | (199,000 )        | -             | 199,000     | 100  | %  |          |          |
| Interest expense  | (146,000 )        | (218,000 )    | (72,000 )   | (33) | )% |          |          |
| Interest income   | 3,000             | 3,000         | -           | -%   |    |          |          |
| Other expense   | (32,000 )         | (60,000 )     | (28,000 )   | (47) | )% |          |          |
| Net loss  | (2,661,000)       | (2,098,000)   | (563,000 )  | 27   | %  |          |          |
| Less: Deemed dividend attributable to noncontrolling interest | (16,000 )         | -             | 16,000      | 100  | %  |          |          |
| Net loss attributable to Nephros, Inc.                        | \$(2,677,000)     | \$(2,098,000) | \$579,000   | 28   | %  |          |          |



**Water Filtration**

The following table sets forth results of operations for the Water Filtration segment for the nine months ended September 30, 2018 and 2017:

|  | Nine Months Ended<br>September 30, |               | \$          | %          |    |
|--|------------------------------------|---------------|-------------|------------|----|
|  | 2018                               | 2017          |             |            |    |
|  |                                    |               | (Decrease)  | (Decrease) |    |
| Total net revenues                           | \$4,075,000                        | \$2,509,000   | \$1,566,000 | 62         | %  |
| Cost of goods sold                           | 1,826,000                          | 1,005,000     | 821,000     | 82         | %  |
| Gross margin                                 | 2,249,000                          | 1,504,000     | 745,000     | 50         | %  |
| Gross margin                                 | 55                                 | % 60          |             | (5)        | )% |
| Research and development expenses            | 598,000                            | 732,000       | (134,000 )  | (18        | )% |
| Depreciation and amortization expense        | 123,000                            | 178,000       | (55,000 )   | (31        | )% |
| Selling, general and administrative expenses | 3,298,000                          | 2,401,000     | 897,000     | 37         | %  |
| Loss from operations                         | \$(1,770,000)                      | \$(1,807,000) | \$(37,000 ) | (2         | )% |

**Net Revenues**

Total net revenues for the nine months ended September 30, 2018 were approximately \$4,075,000 compared to approximately \$2,509,000 for the nine months ended September 30, 2017. The increase of approximately \$1,566,000, or 62%, was driven by an increase in sales to new customers and expansion within existing customer accounts.

**Cost of Goods Sold**

Cost of goods sold was approximately \$1,826,000 for the nine months ended September 30, 2018 compared to approximately \$1,005,000 for the nine months ended September 30, 2017. The increase of approximately \$821,000, or 82%, was due to approximately \$726,000 in increased direct product costs in support of increased revenue, approximately \$65,000 in inventory reserves for expiring items, and approximately \$30,000 in physical count inventory adjustments.

*Gross Margin*

Gross margin was approximately 55% for the nine months ended September 30, 2018, compared to approximately 60% for the nine months ended September 30, 2017. The decrease of approximately 5% was due to the higher cost of goods sold reported in the first quarter of 2018 and the lower ratio of product revenue to license, royalty and other revenues in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017.

*Research and Development Expenses*

Research and development expenses were approximately \$598,000 and \$732,000 for the nine months ended September 30, 2018 and September 30, 2017, respectively, an decrease of approximately \$134,000, or 18% due to lower expenditures on new filter development.

*Depreciation and Amortization Expense*

Depreciation and amortization expense was approximately \$123,000 for the nine months ended September 30, 2018 compared to approximately \$178,000 for the nine months ended September 30, 2017. The decrease of approximately \$55,000, or 31%, is due to lower amortization expense for the nine months ended September 30, 2018 as a result of an amendment to our License and Supply Agreement with Medica in September 2017, which extended the term from December 31, 2022 to December 31, 2025.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses were approximately \$3,298,000 for the nine months ended September 30, 2018 compared to approximately \$2,401,000 for the nine months ended September 30, 2017, representing an increase of \$897,000, or 37%. The increase was primarily due to an increase in personnel-related expenses of approximately \$509,000 due to increased headcount, an increase in stock-based compensation expenses of approximately \$111,000 due to increased headcount, an increase in marketing expenses of approximately \$85,000, an increase in office services and rent of approximately \$133,000, and an increase in other expenses of approximately \$57,000.

*Loss on Extinguishment of Debt*

During the nine months ended September 30, 2018, we recorded a loss on extinguishment of debt of approximately \$199,000 as a result of the repayment of our outstanding unsecured long-term note payable.

*Interest Expense*

The table below summarizes interest expense for the nine months ended September 30, 2018 and 2017:

|  |            |            | \$                | %                 |    |
|--|------------|------------|-------------------|-------------------|----|
|  | 2018       | 2017       | <b>Increase</b>   | <b>Increase</b>   |    |
|  |            |            | <b>(Decrease)</b> | <b>(Decrease)</b> |    |
| Interest related to unsecured long-term note payable             | \$ 30,000  | \$ 99,000  | \$ (69,000 )      | (70 )             | )% |
| Amortization of debt discount - unsecured long-term note payable | 34,000     | 84,000     | (50,000 )         | (60 )             | )% |
| Interest - outstanding payables due to a vendor                  | 13,000     | 17,000     | (4,000 )          | (24 )             | )% |
| Interest related to secured note payable                         | 51,000     | -          | 51,000            | 100               | )% |
| Interest on secured revolving credit facility                    | 18,000     | 18,000     | -                 | -                 | )% |
| Total interest expense   | \$ 146,000 | \$ 218,000 | \$ (72,000 )      | (33 )             | )% |

*Interest Income*

Interest income of approximately \$3,000 and \$3,000 for the nine months ended September 30, 2018 and 2017, respectively, is a result of interest income recognized on the investment in lease, net.

*Other Income/Expense*

Other expense for the nine months ended September 30, 2018 and 2017 was approximately \$32,000 and \$60,000, respectively. The decrease of 47% is primarily due to improvements in foreign currency exchange rates.

***Renal Products***

The following table sets forth results of operations for the Renal Products segment for the nine months ended September 30, 2018 and 2017:

|  | Nine Months Ended<br>September 30, |            | \$         | %          |   |
|--|------------------------------------|------------|------------|------------|---|
|  | 2018                               | 2017       |            |            |   |
|  |                                    |            | (Decrease) | (Decrease) |   |
| Research and development expenses            | \$395,000                          | \$12,000   | \$383,000  | 3192       | % |
| Selling, general and administrative expenses | 122,000                            | 4,000      | 118,000    | 2950       | % |
| Loss from operations                         | \$(517,000)                        | \$(16,000) | \$501,000  | 3131       | % |

***Research and Development***

Research and development expenses were approximately \$395,000 and \$12,000 for the nine months ended September 30, 2018 and September 30, 2017, respectively, an increase of approximately \$383,000 due to increased investment in the 2<sup>nd</sup> generation HDF product.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses were approximately \$122,000 and \$4,000 for the nine months ended September 30, 2018 and September 30, 2017, respectively, an increase of approximately \$118,000 due to increased investment in the 2<sup>nd</sup> generation HDF product.

## Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of September 30, 2018 and December 31, 2017 and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

| Liquidity and capital resources | September<br>30, 2018 | December<br>31, 2017 |
|---------------------------------|-----------------------|----------------------|
| Cash                            | \$ 5,322              | \$ 2,194             |
| Other current assets            | 3,054                 | 1,615                |
| Working capital surplus         | 6,936                 | 1,938                |
| Stockholders' equity            | 4,067                 | 1,950                |

We have sustained operating losses and expect such losses to continue over the next several quarters. Net losses from operations since inception have generated an accumulated deficit of approximately \$123,489,000 as of September 30, 2018. During the three months ended March 31, 2018, the Company issued and sold 1,900,000 shares of common stock to Lincoln Park for aggregate proceeds of \$854,000. On April 10, 2018, we completed a private placement transaction whereby we sold 6,540,669 shares of our common stock for aggregate proceeds of approximately \$2,943,000. On September 5, 2018, SRP completed a private placement transaction whereby SRP sold preferred shares equivalent to 37.5% of its outstanding equity interests for aggregate proceeds of \$3,000,000. The proceeds of this placement are restricted to SRP expenses and may not be used for the benefit of the Company or other affiliated entities, except to reimburse for expenses directly attributable to SRP. We believe that our cash will be sufficient to fund our current operating plan through at least the next twelve months from the date of issuance of the Unaudited Condensed Consolidated Interim Financial Statements contained in Item 1 of Part I of this Quarterly Report on Form 10-Q.

Our future liquidity sources and requirements will depend on many factors, including:

- the market acceptance of our products and our ability to effectively and efficiently produce and market our products;
- the continued progress in, and the costs of, clinical studies and other research and development programs;
- the costs involved in filing and enforcing patent claims and the status of competitive products; and
- the cost of litigation, including potential patent litigation and any other actual or threatened litigation.

We expect to put our current capital resources to the following uses:

- for the marketing and sales of our water-filtration products;

for the development of our 2<sup>nd</sup> generation HDF product; and  
for working capital purposes.

At September 30, 2018, we had cash totaling approximately \$5,322,000 and total assets of approximately \$8,433,000, excluding other intangible assets (related to the License and Supply Agreement with Medica) of approximately \$971,000.

Net cash used in operating activities was approximately \$3,134,000 for the nine months ended September 30, 2018 compared to approximately \$1,871,000 for the nine months ended September 30, 2017. Our net loss was approximately \$2,661,000 for the nine months ended September 30, 2018 compared to a net loss of approximately \$2,098,000 for the nine months ended September 30, 2017, an increase of approximately \$563,000.

The most significant items classified as cash used in operating activities, in addition to the increase in net loss, contributing to the increase of approximately \$1,263,000 are highlighted below:

our accounts receivable increased by approximately \$684,000 during the 2018 period compared to an increase of approximately \$341,000 during the 2017 period primarily as a result of increased revenue;  
our inventory increased by approximately \$850,000 during the 2018 period compared to an increase of approximately \$102,000 during the 2017 period primarily as a result of managing inventory levels to support increased sales volume;  
and  
our accounts payable decreased approximately \$309,000 during the 2018 period compared to a decrease of approximately \$166,000 during the 2017 period primarily as a result of improved management focus on payments.

The above changes are partially offset by:

our loss on extinguishment of debt of approximately \$199,000 during the 2018 period as a result of the repayment of our outstanding unsecured long-term note payable;

our accrued expenses increased approximately \$309,000 during the 2018 period compared to an increase of approximately \$105,000 during the 2017 period due to increases in personnel expenses as a result of increased revenue; and

our stock-based compensation was approximately \$588,000 during the 2018 period compared to approximately \$508,000 during the 2017 period, primarily due to an increase in grants of stock-based compensation as a result of increased headcount.

There was no cash used in investing activities for the nine months ended September 30, 2018 or 2017.

Net cash provided by financing activities of approximately \$6,269,000 for the nine months ended September 30, 2018 resulted from net proceeds from the issuance of our common stock of approximately \$3,778,000, contributions from the sale of preferred stock of SRP to a noncontrolling interest of approximately \$3,000,000, proceeds from the issuance of a secured note payable of approximately \$1,187,000 and proceeds from the exercise of warrants of approximately \$138,000, offset partially by net payments on our secured revolving credit facility of approximately \$548,000, payments on our secured note payable of approximately \$99,000 and payments of approximately \$1,187,000 on our unsecured long-term note payable.

Net cash provided by financing activities for the nine months ended September 30, 2017 was approximately \$1,742,000 resulting from the net proceeds from the issuance of common stock of approximately \$1,179,000 and net proceeds from our revolving credit facility of approximately \$563,000.

### **Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements as of September 30, 2018 or December 31, 2017.

### **Forward-Looking Statements**

Certain statements in this Quarterly Report on Form 10-Q 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, 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. 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 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 or any other statutes or regulations, 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 Quarterly Report on Form 10-Q, is set forth in our filings with the SEC, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and our other 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.



Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not required for smaller reporting companies.

Item 4. Controls and Procedures.

**Evaluation of Disclosure Controls and Procedures**

We maintain a system of disclosure controls and procedures, as defined in Rule 13a-15(e) or Rule 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which is designed to provide reasonable assurance that information required to be disclosed in our reports filed pursuant to the Exchange Act is accumulated and communicated to management in a timely manner. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Because there are inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud have been or will be detected.

At the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, regarding the effectiveness of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 6. Exhibits

**EXHIBIT INDEX**

| <b>Exhibit No.</b> | <b>Description of Exhibit</b>  |
|--------------------|--|
| 10.1               | <u>Series A Preferred Stock Purchase Agreement, dated September 5, 2018, among Specialty Renal Products, Inc. and the Purchasers identified therein. *</u>       |
| 10.2               | <u>Amended and Restated Certificate of Incorporation for Specialty Renal Products, Inc., dated September 5, 2018. *</u>  |
| 10.3               | <u>Investor Rights Agreement, dated September 5, 2018, among Specialty Renal Products, Inc. and the Purchasers identified therein. *</u>                         |
| 10.4               | <u>Voting Agreement, dated September 5, 2018, among Specialty Renal Products, Inc. and the Purchasers identified therein. *</u>                                  |
| 10.5               | <u>Right of First Refusal and Co-Sale Agreement, dated September 5, 2018, among Specialty Renal Products, Inc. and the Purchasers identified therein. *</u>      |
| 31.1               | <u>Certification by the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *</u>   |
| 31.2               | <u>Certification by the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *</u>   |
| 32.1               | <u>Certification by the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. **</u> |
| 32.2               | <u>Certification by the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. **</u> |
| 101                | Interactive Data File. *   |
| *                  | Filed herewith   |
| **                 | Furnished herewith.  |

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 thereunto duly authorized.

**NEPHROS, INC.**

Date: November 8, 2018 By: */s/ Daron Evans*

Name: Daron Evans

Title: President, Chief Executive Officer (Principal Executive Officer)

Date: November 8, 2018 By: */s/ Andrew Astor*

Name: Andrew Astor

Title: Chief Financial Officer (Principal Financial and Accounting Officer)

