

# Nephros, Inc. (OTCBB: NEPH), Target Price: \$1.65)

Based in River Edge, NJ, Nephros, Inc. (OTCBB: NEPH "Nephros") is a commercial stage medical device company, with innovative filtration products targeting large market opportunities including hospital infection control and advanced renal care. Nephros was founded by two healthcare professionals associated with Columbia University Medical Center / New York Presbyterian Hospital to develop a hemodiafiltration (HDF) device as an alternative to hemodialysis. Nephros has developed proprietary technology to accomplish this goal, and in addition to commercializing an HDF System, Nephros has also developed advanced filtration devices for a variety of applications where ultrapure filtration is of potential value.

# **Investment Highlights**

On March 17, 2017, Nephros reported full year 2017 results, with highlights as follows:

- Revenues grew by 19% in 2016 to reach \$2.3mn, versus \$1.9m in 2015
- Product revenues of 2.1mn rose by 17%, while License & Royalty revenue increased by 47% YoY from a small base.
- NEPH received 510(k) clearance for new 10" filters for HydraGuard™ for infection control and EndoPur™ for hemodialysis.
- > EPS narrowed to (0.06) for the year, versus (0.09) in 2015.
- Nephros management guided to growing product revenues by 100% in 2017 based on new products, and set a goal of reaching cash flow breakeven by mid-2017.

#### Solid 4Q16 results to end the year

Nephros ended 2016 with solid performance in 4Q. Despite having much of management's efforts focused on regulatory submissions and new product development / introductions, the company managed to grow its overall business by 19.3% during the year, with controlled operating expenses. Product revenues grew sharply in 4Q16, in particular, during which they rose by 40% sequentially. Growth was due to the launch of the new S100 point of use filters with rising demand for hospital infection control products. For the full year 2016, revenues came in \$2.3mn versus \$1.9mn in 2015.

#### Encouraging guidance on new products, targeting cash flow

Nephros CEO Daron Evans issued an encouraging outlook when the company released 2016 results. Evans stated that the company is now targeting positive cash flow within six months, as Nephros is expected to benefit from rising product revenues. Significant drivers are expected to be continued distribution of the S100, as well as the launch of HydraGuard<sup>™</sup> for infection control, which received FDA 510(k) clearance in December. Additionally, Nephros received regulatory clearance for the new 10" EndoPur<sup>™</sup> filter for use in hemodialysis in March, and is planning to launch this product in 2Q17.

# **Update** (March 28, 2017)

# Equity | Healthcare / Medical Instruments

### Price target unchanged at \$1.65

We are leaving our price target for Nephros unchanged at this time at \$1.65. We view Nephros as an intriguing high risk / high reward investment opportunity in the medical instruments industry with several potential catalysts in 2017 stemming from growth from new product launches and guidance for reaching cash flow breakeven in the next six months.

## Stock Details (3/21/17)

OTCBB:	NEPH
Sector / Industry	Healthcare /Medical Instruments
Price target	\$1.65
Recent share price	\$0.33
Shares o/s (mn)	50.1
Market cap (in \$mn)	17.5
52-week high/low	\$0.60 / \$0.24

Source: Thomson Reuters, SeeThruEquity Research

### Key Financial (\$mn, unless specified)

	FY14	FY15A	FY16A
Revenues	1.7	1.9	2.3
EBITDA	(2.5)	(3.2)	(1.8)
EBIT	(2.7)	(3.4)	(2.8)
Net Income	(7.4)	(3.1)	(2.0)
EPS (\$)	(0.31)	(0.09)	(0.07)

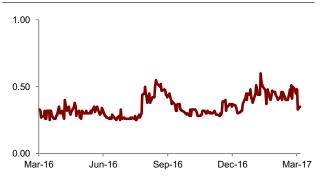
Source: SeeThruEquity Research

#### Key Ratios

	FY14	FY15A	FY16E
Gross margin (%)	68.6	54.5	55.8
Operating Margin (%)	(152.7)	(176.0)	(123.7)
EBITDA margin (%)	(140.3)	(165.1)	(113.8)
Net margin (%)	(421.7)	(158.8)	(130.7)
P/Revenue (x)	8.9	8.0	7.6
EV/Revenue (x)	9.3	8.4	7.0

Source: SeeThruEquity Research

#### Share Price Performance (\$, LTM)



# **QUARTERLY FINANCIAL SUMMARY**

igures in \$, unless specified	FY2016	FY 2015	FY 2014
Product	2,093	1,790	914
for growth	16.93%	95.84%	
License & Royalty	227	154	834
/oY growth	47.40%	-81.53%	
Fotal Revenue	2,320	1,944	1,748
/oY growth	19.34%	11.21%	-
Cost of Goods	1026	884	549
Gross Profit	1,294	1,060	1,199
Gross Margin	55.78%	54.53%	68.59%
Research& Development	1079	826	781
Depreciation & Amortization	230	212	217
Selling & Administrative	2,854	3,443	2,870
Dperating Expenses	4,163	4,481	3,868
/oY growth	-7.10%	15.85%	
Dperating Income	-2,869	-3,421	-2,669
Dperating Margin %	-123.66%	-175.98%	-152.69%
Other items, net	-163	333	-4,702
YoY growth	NM	NM	
Net income	-3,032	-3,088	-7,371
Foreign currency adjustments	4	1	1
Comprehensive income	-3,036	-3,089	-7,373
EPS, Basic	-0.06	-0.09	-0.31
Avg. Shares Outstanding EPS, Diluted	-0.06	-0.09	-0.31
Avg Shares Outstanding in period	48,583	34,781	23,817

Source: Company Form 10Q, SeeThruEquity Research

# ADDITIONAL NOTES

## Product sales drive 4Q16 as Nephros benefits from strong demand at year-end

- Nephros ended 2016 with solid 4Q results. Despite having much of management's efforts focused on regulatory submissions and new product development / introductions, the company managed to grow its overall business by 19.3% during the year, with controlled operating expenses. For the full year 2016, revenues came in \$2.3mn versus \$1.9mn in 2015.
- Loss Narrows: Nephros reported operating losses that narrowed to (\$2.9mn) in 2016 versus (\$3.4mn) in 2015. EPS also narrowed to (\$0.06) for the year, versus (\$0.09) in 2015, due primarily to a higher share count.
- Strength in product sales: Nephros management reported strength in product sales which represent the bulk of company revenues (\$2.1mn out of \$2.3mn in 2016 revenues), and rose by 17% in 2016 versus 2015. Product revenues grew sharply in 4Q16, in particular, rising by 40% sequentially. Growth was due to the launch of the new S100 point of use portfolio, and rising demand for hospital infection control products.
- **Positive Outlook:** Nephros expects continued growth in product sales. The company should benefit from a continuation of initial S100 sales, and is planning to launch recently approved new 10" filter products HydraGuard<sup>™</sup> and EndoPur<sup>™</sup> in 2Q17. Reflecting this, Nephros guided to 100% growth in its core product sales in 2017.
- Additionally, Nephros management highlighted a new product feature planned for introduction



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in 2H17. Specifically the company announced that it would be introducing a flushable system, which will increase product life by 3-5 times. The feature is expected to reduce the cost of ultrapure water below that of micropure water. Nephros management stated that it will be rolling out the flushable products into the hospital space in 3Q17, and then the food service space by the end of the year.

• Nephros expecting positive cash flow soon: We were encouraged that Nephros management stated that the company intends to reach cash flow profitability within 3-6 months. We have seen access to capital as a risk to the story, so would view Nephros becoming cash flow positive as a major company milestone. Nephros recently hired a new CFO, Andrew Astor, whose 30 years of relevant experience should help as they pursue this goal. We have include Astor's full bio at the conclusion of this report.



- **Balance Sheet Review:** Nephros ended 2016 with cash on hand of \$275,000. The company ended the quarter with \$1.3mn of current assets and shareholder's equity of \$0.7mn.
- **Private placement completed:** In March, prior to releasing 2016 results, Nephros successfully completed a \$1.2mn private placement. The company issued 4,059,994 shares at a purchase price of \$0.30, in an transaction led by Maxim Group LLC. As part of the offering, investors received a comparable number of warrants which convert at \$0.30 and are exercisable for a five year term.
- We were encouraged to see the company complete the transaction, as we see access to capital as a key area to watch for Nephros. Nephros had 50.1mn shares outstanding as of March 17, 2017, and we estimate there are 54.1mn following the private placement.

## Nephros receives clearance for EndoPur™ and HydraGuard™

- Nephros recently made significant progress on the regulatory front, receiving FDA clearance for two new 10" filter products: the HydraGuard<sup>™</sup> for infection control, and the EndoPur<sup>™</sup> endotoxin filter cartridge.
- Nephros received FDA clearance for HydraGuard<sup>™</sup> during December, and EndoPur<sup>™</sup> in March. The company is aiming to move forward with a commercial launch for these products in 2Q17.
- The EndoPur<sup>™</sup> endotoxin cartridge filter provides ultrafiltration of the water in a dialysis clinic's RO loop. The launch of EndoPur<sup>™</sup> will allow Nephros to provide its 5 nanometer pore-size endotoxin protection to all dialysis clinic RO systems, including large clinic-based and small portable ones. Nephros experienced a decline in dialysis product sales in 2016 as a result of delays related to the launch of this product, and we expect there may be pent up demand to support initial commercialization efforts.
- **Update on Hemodiafiltration:** Nephros also indicated that its program with Vanderbilt University began in early 2017. In the partnership, Vanderbilt is treating patients with NEPH's hemodiafiltration ("HDF") systems, and Nephros stated that it plans to support Vanderbilt in any efforts to publish prospective and observational data resulting from the treatment of patients with HDF.

#### Maintaining price target for Nephros

- We are maintaining our price target of \$1.65 for Nephros at this time. We view Nephros as an attractive high risk / high reward investment opportunity in the medical instruments industry.
- Nephros has several potential catalysts ahead over the next six months as the company has received FDA 510(k) clearance for two new products and prepares for commercial launch.
- Additionally, we would consider it a major accomplishment if the company is able to follow through on its growth plans while also achieving its goal of reaching cash flow positive within six months.

# Management Team

### Daron Evans – President & CEO

Mr. Evans joined the company as President and CEO in April 2015, and has served on Nephros' board of directors since 2013. He is a life sciences executive with over 20 years of financial leadership and operational experience. Mr. Evans was recently Managing Director of PoC Capital, LLC, and is a member of the board of Zumbro Discovery, Inc., an early stage company developing a novel therapy for resistant hypertension. From 2007 to 2013, Mr. Evans was Chief Financial Officer of Nile Therapeutics, Inc., a development-stage cardiovascular company that merged with Capricor Therapeutics, Inc. (NASDAQ:CAPR) in 2013. From 2004 to 2007, he held various project management and performance improvement roles at Vistakon Inc. and Scios, Inc., both divisions of Johnson & Johnson Corp. Mr. Evans was a co-founder of Applied Neuronal Network Dynamics, Inc. and served as its President from 2002 to 2004. From 1995 to 2002, Mr. Evans served in various roles at consulting firms Arthur D. Little and Booz Allen & Hamilton. Mr. Evans received his Bachelor of Science in Chemical Engineering from Rice University, his Master of Science in Biomedical Engineering from a joint program at the University of Texas at Arlington and Southwestern Medical School and his MBA from the Fuqua School of Business at Duke University.

### Andrew Astor – Chief Financial Officer

Andrew Astor is a technology and business executive with 30 years of financial and operating experience. Mr. Astor was most recently President and Chief Financial Officer at Open Source Consulting Group, a growth stage services firm. Previously, he was a Managing Director at Synechron, a global consulting organization, from 2013 to 2015. From 2009 to 2013, he served as Vice President at Asurion, a large, privately held insurance company. Mr. Astor was co-founder of the software company EnterpriseDB, and served as its CEO from 2004 to 2008. Mr. Astor was Vice President, Strategic Solutions at webMethods (ETR: SOW), a software firm, from 2002 to 2004. Mr. Astor was Vice President of Transactional Products at Dun & Bradstreet (NYSE: DNB) from 1998 to 2001. Prior to 1998, Mr. Astor held various roles at American Management Systems, SHL/MCI Systemhouse, and Ernst & Young. Mr. Astor received his Bachelor of Arts in Mathematics from Clark University, and his MBA from The Wharton School at the University of Pennsylvania.

### Gregory Collins, Ph.D - Vice President of R&D

Prior to Nephros, Dr. Collins was R&D Program Manager with National Medical Care (now Fresenius Medical Care). He also worked as a scientist for ITW MiniGrip and consultant to FoxS Labs, (Division of of Puritan-Bennet). Dr. Collins has 17 issued patents in the areas of hemodiafiltration and water purification and serves as scientific reviewer for NIH (SBIR) grant applications. Dr. Collins received his PhD in bio-engineering from the University of California, San Diego and his B.S. in chemical engineering from Arizona State University.

#### Michael Milman – Director of Product Development

Mr. Milman has over 15 years of experience bringing new products to market in electronics and medical devices industries. Mr. Milman focuses on the development and commercialization of medical and commercial products, and runs Nephros Product Development Program. Prior to Nephros, Mr. Milman held several positions at Stryker bringing new products through manufacturing to market, innovating coating applications, and research and development of custom implant products. Mr. Milman holds a B.S. in Mechanical Engineering from Lehigh University and several advanced engineering certifications.

#### Shane Sullivan – Director of North American Sales

Mr. Sullivan has spent nearly two decades in sales leadership roles in the healthcare, life science and biopharmaceutical industry. He brings industry experience, an extensive professional network and strong customer focus to our team at Nephros. Prior to joining Nephros, he led the sales team at Saxton Bradley with a focus on the healthcare and scientific market. Before Saxton Bradley, Mr. Sullivan was the Western Regional Sales Manager at Thermo Scientific (NYSE:TMO). While there, he lead the \$175 million laboratory furnishings and airflow products division to ten consecutive double digit increases in the Western Region. His extensive work within the architectural design, engineering, specifying, and contracting communities significantly contributed to their sales on a national level. Prior to Thermo, Mr. Sullivan worked at Applied Instruments, where he represented a variety of equipment manufacturers focused on solutions for the healthcare, life science and bio pharmaceutical research markets. At Applied Instruments, he helped grow their business, establish stronger roots for their

organization in the region and developed a strong understanding of the distribution market. Prior, at MDT Castle, he led the launch and direct sales efforts of their life science and pharmaceutical sterilization business. His sales efforts ultimately contributed to the merger that formed Getinge-Castle. Mr. Sullivan earned his undergraduate degree in Business Administration from the University of Southern California.

### Monet Carnahan, RN, BSN, CDN – Director of Dialysis Products

Ms. Carnahan joined the company as Director of Dialysis Products in August of 2015. She is a Registered Nurse with over 10 years of nursing experience in Nephrology and is a subject matter expert in chronic kidney disease, transplantation, vascular access, and end stage renal disease with both in-center and home therapy. Ms. Carnahan was previously the Program Manager of Renal Care Coordinators with Fresenius Medical Care (FMC). At FMC managed National Accounts and Employees across the United States, and worked with specific dialysis clinics to identify needs, develop and implement algorithms to improve patient outcomes. Ms. Carnahan has experience with critical care where she started her career at the Tennessee Valley Health Care System in Nashville, TN. Ms. Carnahan received her Nursing Degree from Motlow State. She was recently a member of a CMS Technical Expert Panel for Vascular Access, and currently reviews publications for ANNA journals, educational textbooks, and modules.

### Hollie Johnson – Director of Quality and Regulatory

Hollie Johnson is the Director of Quality and Regulatory, responsible for customer satisfaction, product quality and regulatory compliance. She has fifteen years' quality and regulatory experience in the medical device, scientific and combination product industries. Hollie has successfully implemented and managed ISO 13485 QMS, designed and managed global regulatory product market strategies, 510(k) and PMA product submissions for Osteotech, Inc. (purchased by Medtronic in 2010), TyRx, Inc. (purchased by Medtronic in 2014), Shukla Medical, Inc., and Swissray, Inc. Hollie is pursuing her Regulatory Affairs Certification through RAPS and is a lead ISO 13485 auditor.

# About Nephros, Inc.

Nephros is a commercial stage medical device company that develops and sells high performance liquid purification filters, as well as a hemodiafiltration system for the treatment of patients with End Stage Renal Disease. Its filters, which it calls ultrafilters, are used primarily in medical applications. Nephros ultrafilters are used by dialysis centers for the removal of biological contaminants from the water and bicarbonate concentrate feeding hemodialysis devices. Additionally, Nephros ultrafilters are used in hospitals and medical clinics as an aid in infection control by retaining bacteria (i.e. Legionella, Pseudomonas), virus and endotoxin from water used by patients.www.nephros.com.

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