March 1, 2017

OPKO Health Reports 2016 Financial and Operating Results

- **Consolidated revenue for the year ended December 31, 2016 increased to $1,221.7 million from $491.7 million for the comparable period of 2015. Consolidated revenue of $275.5 million for the three months ended December 31, 2016 was consistent with the comparable period of 2015 which was $276.2 million.**
- **For the year ended December 31, 2016, net loss was $25.1 million compared to net loss of $30.0 million for the comparable period of 2015. Net loss was $13.7 million for the three months ended December 31, 2016 compared to net income of $1.6 million for the comparable period of 2015. The 2015 period benefited from a $15 million milestone payment related to the U.S. launch of Varubi™ by TESARO**
- **U.S. commercial launch of *RAYALDEE* commenced late November; as of March 1, 2017, approximately 60% of U.S. patients are eligible for reimbursement**
- ***4Kscore* test utilization continues to grow; Level 1 CPT code and CMS pricing is in place, negotiations with payors continue.**
- **Phase 3 clinical trial for hGH-CTP in pediatric patients initiated; statistical outlier analyses for long acting hGH-CTP data for adult indication continues; preparations for BLA submission for adult indication underway.**
- **Clinical trials for Claros point-of-care (POC) PSA test commenced in January 2017; PMA filing anticipated in 1H 2017; Claros POC testosterone test clinical trials and 510(k) filing to follow in 2017.**
- **Initiation of three Phase 2 clinical trials anticipated in 2H 2017 and early 2018 for:**
  - *RAYALDEE* line extension for stage 5 CKD patients with secondary hyperparathyroidism (SHPT) undergoing dialysis
  - TT701, an orally administered selective androgen receptor modulator (SARM), in males with benign prostate hyperplasia (BPH)
  - TT401, a once-weekly oxyntomodulin dual GLP1/Glucagon agonist, for type II diabetes and obesity

MIAMI, March 01, 2017 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ:OPK)**, reports financial and operating results for the three months ended December 31, 2016.

Financial Highlights

- Consolidated revenues for the three months ended December 31, 2016 of $275.5 million were consistent with the comparable period of 2015 revenue of $276.2 million. The 2016 period benefited from increased revenue from services at BioReference of $12.8 million, which was offset by a non-recurring $15.0 million milestone payment that was received during the comparable period of 2015 related to Varubi™.

- Net loss for the three months ended December 31, 2016 was $13.7 million compared with net income of $1.6 million for the 2015 period. The three months ended December 31, 2016 included the launch related activities for *RAYALDEE,* including the 50 person commercial organization. Net (loss) income during the three month periods include significant non-recurring and non-cash activities:
  - During the three months ended December 31, 2015, revenue included a $15.0 million milestone payment related to the first commercial sale of Varubi™ by TESARO.
  - Other income and (expense) was $7.7 million and ($15.9) million in the 2016 and 2015 periods, respectively, primarily related to the change in fair value of derivative instruments. The change in fair value is principally related to an embedded derivative in OPKO's January 2013 convertible senior notes due in 2033. The 2015 period also included a ($7.3) million temporary impairment charge of an available for sale investment.

- Cash, cash equivalents and marketable securities were $168.7 million as of December 31, 2016.

Business Highlights

- **U.S. commercial launch of *RAYALDEE* began in late November:** *RAYALDEE* was launched with a highly specialized commercial team with deep experience in nephrology and specialty pharmaceuticals. Since the launch, substantial progress has been made obtaining formulary access for *RAYALDEE* with approximately 60% of U.S. patients already covered. Obtaining broad reimbursement coverage is critical to the adoption of *RAYALDEE*.
- ***4Kscore* test utilization continued to grow; Level 1 CPT code and CMS pricing is in place, negotiations with payors continue:** Level 1 CPT code and CMS pricing became effective on January 1, 2017, and the Company is working to secure coverage and favorable pricing with additional payors. During the quarter ended December 31, 2016, approximately 18,000 *4Kscore* tests were ordered which represents growth of more than 12% compared to the

quarter ended September 30, 2016. During 2016, the Company obtained positive coverage and pricing with a number of payors including a national healthcare plan. Novitas, the Company's Medicare administrator, continues to pay for a majority of *4Kscore* tests performed.

- **Phase 3 clinical trial for hGH-CTP in pediatric patients initiated; outlier analyses of data for adult study continues; preparations for BLA submission for the adult indication underway:** The phase 3 clinical trial for pediatric growth hormone deficient patients is underway. OPKO has begun a statistical outlier analysis of its Phase 3 trial data from the adult study, and OPKO and Pfizer have begun the preparation of a BLA.
- **Clinical trials for Claros point of care (POC) PSA test commenced in January 2017; PMA filing anticipated in 1H 2017; Claros POC testosterone test clinical trials and 510(k) filing to follow:** OPKO has commenced a multi-center clinical study of its POC diagnostic test for prostate specific antigen (PSA) utilizing its proprietary diagnostic platform. OPKO intends to submit its application to the U.S. Food and Drug Administration for approval of the assay in mid-2017. OPKO expects to begin an additional multi-center study of its POC testosterone test in 2017 followed by a 510(k) submission.
- **Initiation of three Phase 2 clinical trials anticipated in 2H 2017 and early 2018**
  - *RAYALDEE* line extension in dialysis patients with SHPT: OPKO is developing *RAYALDEE* for Stage 5 CKD patients with SHPT undergoing dialysis with its partner, Vifor Fresenius. The Company anticipates initiating a Phase 2 clinical trial during the second half of 2017.
  - TT701, an orally administered SARM: The Company plans to initiate a Phase 2b dose-ranging study in the second half of 2017 to evaluate the selective effects of TT701 to reduce prostate size and provide other therapeutic benefits such as increase in muscle mass and bone strength and decreased fat mass in men with BPH (enlarged prostate).
  - TT401, a once-weekly oxytomodulin dual GLP1/Glucagon agonist for diabetes and obesity: We plan to initiate a Phase 2b study in early 2018 involving a stepwise increase in dose to treat type II diabetes and obesity.

MANAGEMENT COMMENTARY:

"OPKO reached a number of important milestones during 2016," stated Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "We launched *RAYALDEE,* the first new medicine we have developed and launched ourselves. The commercial team is making great strides in the early days of the launch and has so far secured formulary access for 60% of all U.S. insured patients."

"Use of our innovative *4Kscore* test for predicting the probability of aggressive prostate cancer increased to nearly 18,000 tests ordered in the fourth quarter. We have now set the stage for continued, profitable growth at BioReference with a revenue cycle management program that is expected to improve financial results on an ongoing basis.

"We have a number of important initiatives ahead of us in 2017 and early 2018. We will complete the recently initiated clinical trial for our Claros POC diagnostic test for PSA and plan to file a PMA as quickly as possible upon completion. Along with our partner, Vifor Fresenius, we plan to initiate a Phase 2 trial in dialysis patients with SHPT. We also plan to initiate a Phase 2b trial for our SARM for the treatment of BPH, a condition that affects approximately 50 million men in the U.S., as well as a Phase 2 dose escalation study for TT401 to treat obesity and type II diabetes.

"We are diligently working to complete analysis of the data from our Phase 3 clinical trial for hGH-CTP in adults and are aggressively advancing our pediatric Phase 3 clinical trial for hGH-CTP," Dr. Frost concluded.

CONFERENCE CALL & WEBCAST INFORMATION:

OPKO's senior management will provide a business update and discuss the results in greater detail in a conference call and live audio webcast at 4:30 p.m. Eastern time today.

The conference call dial in information is listed below. To access the webcast, please log on to the OPKO website at www.opko.com.

WHEN: Wednesday, March 1, 2017, 4:30 p.m. Eastern time.
DOMESTIC DIAL-IN: (866) 634-2258
INTERNATIONAL DIAL-IN: (330) 863-3454
PASSCODE: 80392791
WEBCAST: http://investor.opko.com/events.cfm

For those unable to participate in the live conference call or webcast, a replay will be available beginning March 1, 2017 two hours after the close of the conference call. To access the replay, dial (855) 859-2056 or (404) 537-3406. The replay passcode is: 80392791. The replay can be accessed for a period of time on OPKO's website at http://investor.opko.com/events.cfm.

About OPKO Health, Inc.

OPKO Health is a diversified healthcare company that seeks to establish industry-leading positions in large, rapidly growing markets. Our diagnostics business includes Bio-Reference Laboratories, the nation's third-largest clinical laboratory with a core genetic testing business and a 400-person sales and marketing team to drive growth and leverage new products, including the 4Kscore® prostate cancer test and the Claros® 1 in-office immunoassay platform. Our pharmaceutical business features *RAYALDEE*, an FDA-approved treatment for SHPT in stage 3-4 CKD patients with vitamin D insufficiency (launched in November 2016), VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation launched by partner TESARO and IV formulation pending FDA approval), TT401, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists, and TT701, an androgen receptor modulator to treat men with BPH. Our biologics portfolio includes hGH-CTP, a once weekly human growth hormone injection (in phase 3 and partnered with Pfizer), and a long-acting Factor VIIa drug for hemophilia (in phase 2a). We also have production and distribution assets worldwide, multiple strategic investments and an active business development strategy. More information available at www.opko.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding expected financial performance, whether we will experience continued, profitable growth at Bio-Reference, whether our revenue cycle management program will improve financial results, our product development efforts and the expected benefits of our products, including whether our ongoing and future clinical trials will be successfully completed on a timely basis or at all and whether the data from any of our trials will support approval, validation and/or reimbursement for our products, the expected timing for launch of our products in development, whether the data for the hGH-CTP study in adults will support approval of a BLA, the expected timing of commencing and concluding our clinical trials, enrollment in clinical trials, and disclosure of results for the trials, the timing of our regulatory submissions, our ability to market and sell any of our products in development, expectations about developing RAYALDEE for dialysis patients, our ability to obtain broad reimbursement coverage for the 4Kscore test, increased adoption rates for the 4Kscore, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our Annual Reports on Form 10-K filed and to be filed with the Securities and Exchange Commission and in our other filings with the Securities and Exchange Commission, as well as integration challenges for Bio-Reference, EirGen, Transition, and other acquired businesses, the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, that the 4Kscore, RAYALDEE, Varubi™, hGH-CTP, TT-401, TT-701, and/or any of our compounds or diagnostic products under development may fail, may not achieve the expected results or effectiveness and may not generate data that would support the approval or marketing of products for the indications being studied or for other indications, that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

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OPKO Health, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in millions)

	As of December 31, 2016	As of December 31, 2015
Assets:		
Cash, cash equivalents and marketable securities	$ 168.7	$ 193.6
Other current assets	314.9	260.5
Total Current Assets	483.6	454.1
In-process Research and Development and Goodwill	1,349.3	1,535.6
Other assets	933.7	809.5
Total Assets	$ 2,766.6	$ 2,799.2
Liabilities and Equity:		
Current liabilities	$ 263.3	$ 251.9
2033 Senior Notes, net	43.7	49.0
Deferred tax liabilities	165.3	226.0
Other long-term liabilities, principally deferred revenue and contingent consideration	202.5	292.5
Total Liabilities	674.8	819.4
Equity	2,091.8	1,979.8
Total Liabilities and Equity	$ 2,766.6	$ 2,799.2

OPKO Health, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(in millions, except per share data)

	For the three months ended December 31,		For the years ended December 31,	
	2016	2015	2016	2015
Revenues				
Revenue from services	$ 234.6	$ 221.8	$ 1,012.1	$ 329.7
Revenue from products	20.2	21.1	83.5	80.1
Revenue from transfer of intellectual property	20.7	33.3	126.1	81.9
Total revenues	275.5	276.2	1,221.7	491.7
Costs and expenses				
Cost of revenues	159.3	143.1	611.5	235.2
Selling, general and administrative	120.5	102.9	490.9	196.6
Research and development	27.6	25.5	111.2	99.5
Contingent consideration	1.4	(1.4)	17.0	5.0
Amortization of intangible assets	17.1	14.0	64.4	28.0
Grant repayment	-	-	-	25.9
Total Costs and expenses	325.9	284.1	1,295.0	590.2
Operating (loss) income	(50.4)	(7.9)	(73.3)	(98.5)
Other income and (expense), net	7.7	(16.0)	(0.2)	(39.5)
(Loss) income before income taxes and investment losses	(42.7)	(23.9)	(73.5)	(138.0)
(Provision for) benefit from income taxes	31.5	26.5	56.1	113.7
(Loss) income before investment losses	(11.2)	2.6	(17.4)	(24.3)
Loss from investments in investees	(2.5)	(1.0)	(7.7)	(7.1)
Net (loss) income	(13.7)	1.6	(25.1)	(31.4)
Less: Net loss attributable to non-controlling interests	-	-	-	(1.4)
Net (loss) income attributable to common shareholders	$ (13.7)	$ 1.6	$ (25.1)	$ (30.0)
Basic income (loss) per share	$ (0.02)	$ 0.00	$ (0.05)	$ (0.06)

Diluted income (loss) per share	$ (0.04)	$ 0.00	$ (0.05)	$ (0.06)

Primary Logo

Source: OPKO Health Inc.

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