February 29, 2016

OPKO Announces Financial and Operating Results

- **Consolidated Revenue Increased to $276.2 Million From $25.5 Million for the Three Months Ended December 31, 2015, and Increased to $491.7 Million from $91.1 Million for the Year Ended December 31, 2015**
- **Clinical Utility Study Demonstrates 4Kscore® Test Reduces Number of Unnecessary Prostate Biopsies While Improving Risk Prediction for Aggressive Prostate Cancer**
- **4Kscore Blood Test to Identify Risk of Aggressive Prostate Cancer Assigned Level 1 CPT Code**
- **Rayaldee™ PDUFA Date Remains on Track For March 29, 2016**
- **Topline Phase 3 Results for hGH-CTP in Adults Expected 2H 2016; Pediatric Phase 3 Initiation Anticipated in 2H 2016**
- **First Patient Dosed in Phase 2a Clinical Trial of Long Acting Factor VIIa**
- **Phase 1 Clinical Trial for Long Acting Subcutaneous Oxyntomodulin for Obesity and Diabetes Expected to Commence in Q1**
- **VARUBI™ (rolapitant) Commercial Sales by TESARO Commenced in November 2015; OPKO is Eligible to Receive Up To an Additional $95 Million of Milestone Payments Plus Ongoing Double Digit Royalties**

MIAMI--(BUSINESS WIRE)-- **OPKO Health, Inc. (NYSE:OPK)** , a multinational biopharmaceutical and diagnostics company, today reported financial and operating results for the three months and year ended December 31, 2015.

Business Highlights

- **Clinical Utility Study Demonstrates 4Kscore Test Reduces Unnecessary Prostate Biopsies While Improving Risk Prediction for Aggressive Prostate Cancer:** The results of a 611 patient peer-reviewed study, "The 4Kscore® Test Reduces Prostate Biopsy Rates in Community and Academic Urology Practices", written by Badrinath Konety, MD, et al. (Reviews in Urology, January 2016), indicated that the 4Kscore test led to 65% fewer prostate biopsies being performed among participating patients and influenced approximately 89% of decisions about performing a prostate biopsy. A higher 4Kscore test result was significantly associated with a greater likelihood of having a prostate biopsy.
- **4Kscore Blood Test to Identify Risk of Aggressive Prostate Cancer Assigned a Level 1 CPT Code:** The American Medical Association (AMA) Current Procedural Terminology (CPT®) Editorial Panel granted a Category I CPT code which will be effective in January 2017 for OPKO's 4Kscore Test, the only blood test that accurately identifies an individual patient's risk for aggressive prostate cancer. A Category I CPT code is a designation reserved for established diagnostic tests, and will provide broader access to the 4Kscore Test to urologists and their patients across the United States.

- **Rayaldee PDUFA Date Remains on Track for March 29, 2016:** In late 2014, OPKO announced successful top-line results from both pivotal Phase 3 trials with Rayaldee. These trials were identical randomized, double-blind, placebo-controlled, multisite studies intended to establish the safety and efficacy of Rayaldee as a new treatment for secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency.
- **Topline Phase 3 Results for hGH-CTP in Adults Expected 2H 2016; Pediatric Phase 3 Initiation Anticipated in 2H 2016:** The Phase 3 trial in adults is designed to evaluate the safety and efficacy of hGH-CTP with a primary endpoint of superiority compared with placebo in decreasing fat mass in adults with GHD. The trial is a randomized, double-blind, placebo-controlled, multicenter, global study in adults with growth hormone deficiency (GHD). The study is divided into two treatment periods: a 26-week, double blind, placebo-controlled period, followed by a 26-week, open-label extension. A Phase 3 trial in pediatric patients is anticipated to commence in 2H 2016.
- **First Patient Dosed in Phase 2a Clinical Trial of Long Acting Factor VIIa for the Treatment of Hemophilia:** In February 2016, the first patient was dosed in OPKO's Phase 2a clinical trial of its long acting Factor VIIa, a dose escalation study to determine safety and explore efficacy endpoints of OPKO's long acting form of coagulation Factor VIIa (Factor VIIa-CTP) for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX. The study will enroll 24 patients in the United States.
- **Clinical Studies for Long Acting Oxyntomodulin for Obesity and Diabetes Expected to Begin:** OPKO expects to commence studies for its long acting subcutaneous oxyntomodulin for diabetes and obesity in Q1 2016.
- **VARUBI™(Rolapitant) was Approved by the FDA on September 2, 2015 and Commercial Launch Commenced in November 2015:** OPKO's partner, TESARO received FDA approval of oral VARUBI™, a neurokinin-1 (NK-1) receptor antagonist, in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic chemotherapy. TESARO commenced commercial sales in the U.S. in November 2015 and expects to submit its Marketing Authorization Application to the European Medicines Agency for oral VARUBI™ in Q2. VARUBI™ has been included in the NCCN Guidelines as a recommended option in combination with other antiemetic agents for patients receiving both high emetic risk intravenous chemotherapy (HEC) and moderate emetic risk intravenous chemotherapy (MEC). Category 1, the highest level category of evidence and consensus, was granted to VARUBI™ for both HEC and MEC chemotherapy. OPKO is eligible to receive up to $95 million in additional milestones and tiered, double-digit royalties.
- **Varubi™ (Rolapitant) IV Formulation NDA Submission.** TESARO expects to submit NDA for IV formulation of Varubi™ in Q1.

"We made great progress during 2015," stated Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "We have recently begun to expand the marketing and sales of our 4Kscore Test utilizing the commercial infrastructure of Bio-Reference, with very promising results. As we obtain broad reimbursement for the 4Kscore Test, we believe patients, providers and insurers will realize the benefits of this test in 2016 and beyond. We are now preparing for our launch of Rayaldee for treatment of SHPT in patients with stage 3 or 4 CKD later this year. Our commercial partner, TESARO, launched VARUBI™ late in 2015 and the launch is progressing as expected. Our collaboration with Pfizer is on track and

we expect to have topline data for our ongoing Phase 3 clinical trial for hGH-CTP in adults later this year and expect to initiate the pivotal clinical trial for the pediatric indication later this year. We continue to pursue other development programs as well and, earlier this month, initiated a clinical study utilizing our CTP platform technology for our long-acting Factor VIIa project. We expect to begin a Phase 1 clinical trial for long acting oxyntomodulin next month," Dr. Frost continued.

Financial Highlights

- Consolidated revenues increased to $276.2 million from $25.5 million for the three months ended December 31, 2015 compared to the 2014 period, and increased to $491.7 million from $91.1 million for the year ended December 31, 2015 as compared to 2014. The 2015 periods include revenue from Bio-Reference and EirGen beginning with their acquisitions in August and May 2015, respectively. Revenue for the three months and year ended December 31, 2015 also includes $17.7 million and $65.5 million, respectively, from OPKO's collaboration with Pfizer. The 2015 periods also include a $15.0 million milestone payment from TESARO related to the launch of VARUBI™ in November 2015.
- Net income for the three months ended December 31, 2015 was $1.6 million compared with a net loss of $53.0 million for the 2014 period and net losses for the year ended December 31, 2015 decreased to $30.0 million compared to $171.7 million for the 2014 period. In addition to the revenue related items, the 2015 three month and year periods include significant non-recurring and non-cash activities, including:
    - $26.5 million and $113.7 million of income tax benefit, respectively, reflecting the release of valuation allowances against all of OPKO's U.S.-based deferred tax assets as a result of the Bio-Reference acquisition in 2015;
    - $15.9 million gain related to the deconsolidation of OPKO's previously consolidated variable interest entity, SciVac, in the year ended December 31, 2015 as SciVac completed an initial public offering by merger with Levon Resources Ltd. in July 2015;
    - $25.9 million of non-recurring operating expense related to the repayment of a grant to the Office of the Chief Scientist in Israel related to the Pfizer transaction in the nine month period of 2015; and,
    - Other income and (expense) of ($15.9) million and ($39.5) million primarily related to the change in fair value of derivative instruments as well as a ($7.3) million temporary impairment charge of an available for sale investment in the three months and year ended December 31, 2015, respectively, compared with ($20.9) million and ($25.2) million in the 2014 periods. The change in fair value is principally related to an embedded derivative in our January 2013 convertible senior notes due in 2033.

- Cash, cash equivalents and marketable securities were $193.6 million as of December 31, 2015.
    - This reflects receipt of Pfizer upfront payments of $295.0 million, partially offset by a $94.7 million cash payment for the acquisition of EirGen (net of EirGen's cash on hand) and a one-time $25.9 million payment to the Office of the Chief Scientist in Israel related to the Pfizer transaction and cashed used by operations, principally related to our research and development expense.

CONFERENCE CALL & WEBCAST INFORMATION

WHEN: Monday, February 29, 2016, 4:30 p.m. Eastern time
DOMESTIC DIAL-IN: (866) 634-2258
INTERNATIONAL DIAL-IN: (330) 863-3454
PASSCODE: 56397388

WEBCAST: www.opko.com

For those unable to participate in the live conference call or webcast, a replay will be available beginning February 29, 2016 at 7:30 p.m. Eastern time. To access the replay, dial (855) 859-2056 or (404) 537-3406. The replay passcode is: 56397388. The replay can also be accessed for a period of time on OPKO's website at www.opko.com.

About OPKO Health, Inc.

OPKO Health, Inc. 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 420-person salesforce 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, a treatment for secondary hyperparathyroidism in stage 3-4 chronic kidney disease patients with vitamin D deficiency (March 29, 2016 PDUFA date) and VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation approved by FDA and pending launch by partner TESARO, IV formulation in Phase 3). Our biologics business 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 (entering Phase 2a). We also have production and distribution assets worldwide, multiple strategic investments and an active business development strategy. More information is 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 and revenue growth, the success of our acquisitions of Bio-Reference and EirGen, whether we have sufficient liquidity to fund development of our product candidates and operations, our product development efforts and the expected benefits of our products, including whether our ongoing and future clinical trials will be 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, including Rayaldee and hGH-CTP, the expected timing of our clinical trials, enrollment in clinical trials, and disclosure of results for the trials,

our ability to market and sell any of our products in development, including Rayaldee, the 4Kscore, and hGH-CTP, expectations about potential milestone payments from our partners, our ability to obtain broad reimbursement coverage for the 4Kscore test, increased adoption rates for the 4Kscore by Urologists in the U.S. and abroad, expectations about the timing of the NDA submission for an IV formulation of Varubi™ and European approvals for Varubi™, and the timing for approval of the NDA and launch for Rayaldee, 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 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, 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.

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

	As of	
	December 31, 2015	December 31, 2014
Assets:		
Cash and cash equivalents	$ 193.6	$ 96.9
Other current assets	260.5	46.0
Total Current Assets	454.1	142.9
In-process Research and Development and Goodwill	1,535.6	1,017.4

Other assets	809.9	107.4
Total Assets	$ 2,799.6	$ 1,267.7
Liabilities and Equity:		
Current liabilities	$ 251.9	$ 83.1
2033 Senior Notes, net	49.4	131.5
Deferred tax liabilities	226.0	167.2
Other long-term liabilities, principally deferred revenue and contingent consideration	292.5	50.1
Total Liabilities	819.8	431.9
Equity	1,979.8	835.8
Total Liabilities and Equity	$ 2,799.6	$ 1,267.7

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

	For the three months ended December 31,	
	2015	2014
Revenues	$ 276.2	$ 25.5
Costs and expenses	284.1	58.0
Operating loss	(7.9)	(32.5)
Other income and (expense), net	(15.9)	(20.9)
Income (loss) before income taxes and investment losses	(23.8)	(53.4)
Benefit from (provision for) income taxes	26.4	1.0
Income (loss) before investment losses	2.6	(52.4)
Loss from investments in investees	(1.0)	(1.1)
Net income (loss)	1.6	(53.5)
Less: Net loss attributable to non-controlling interests	-	(0.5)
Net income (loss) attributable to common shareholders	$ 1.6	$ (53.0)
Basic income (loss) per share	$ 0.00	$ (0.12)
Diluted income (loss) per share	$ 0.00	$ (0.12)

	For the years ended December 31,	
	2015	2014

Revenues	$ 491.7	$ 91.1
Costs and expenses	590.2	236.9
Operating loss	(98.5)	(145.8)
Other income and (expense), net	(39.5)	(25.2)
Loss before income taxes and investment losses	(138.0)	(171.0)
Benefit from (provision for) income taxes	113.7	(0.0)
Loss before investment losses	(24.3)	(171.0)
Loss from investments in investees	(7.1)	(3.6)
Net loss	(31.4)	(174.6)
Less: Net loss attributable to non-controlling interests	(1.4)	(3.0)
Net loss attributable to common shareholders	$ (30.0)	$ (171.6)
Basic and diluted loss per share	$ (0.06)	$ (0.41)

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