November 9, 2015

OPKO Announces Third Quarter Financial and Operating Results

- **Consolidated Revenue Increased to $143.0 Million From $19.8 million for the Three Months Ended September 30, 2015, and Increased to $215.5 Million from $65.6 Million for the Nine Months Ended September 30, 2015**
- **Closed Acquisition of Bio-Reference Laboratories on August 20, 2015**
- **Announced Genomics Collaboration with Vanderbilt University School of Medicine**
- **4Kscore® Blood Test to Identify Risk of Aggressive Prostate Cancer Included in the National Comprehensive Cancer Network Guidelines for Cancer Early Detection**
- **Rayaldee™ New Drug Application (NDA) Accepted by FDA; Expected PDUFA Date is March 29, 2016**
- **Completed Enrollment in hGH-CTP Phase 3 Trial in Growth Hormone Deficient Adults**
- **Presented Positive 12-month Clinical Data on hGH-CTP Phase 2 Trial in Growth Hormone Deficient Children**
- **Reported New Preclinical Data Supporting Subcutaneous Administration for Long-Acting Factor VIIa-CTP for Hemophilia; Phase 2a Clinical Trial of Long Acting IV Form Expected to Commence in Q4 2015**
- **Phase 1 Clinical Trial for Long-Acting Subcutaneous Oxyntomodulin for Obesity and Diabetes Expected to Commence in Q1 2016**
- **VARUBI™ (rolapitant) Approved by the FDA; Commercial Sales Expected to Commence this Month by TESARO with OPKO Eligible to Receive Up To an Additional $110 Million of Milestone Payments Plus Ongoing Royalties**

MIAMI--(BUSINESS WIRE)-- **OPKO Health, Inc. (NYSE:OPK)**, a multinational biopharmaceutical and diagnostics company, today reported financial and operating results for the three and nine months ended September 30, 2015.

Business Highlights

- **Completed the Acquisition of Bio-Reference Laboratories on August 20, 2015:** Bio-Reference Laboratories is the third largest full-service clinical laboratory in the United States and is known for its innovative technological solutions and pioneering leadership in the areas of genomics and genetic sequencing. Through GeneDx, Bio-Reference Laboratories' genetic sequencing laboratory, and GenPath Diagnostics, its Oncology and Women's Health business units, Bio-Reference Laboratories has accumulated a vast array of genetic and genomic data that OPKO will make available to industry and academic scientists to enhance their drug discovery and clinical trial programs. Since closing, OPKO has begun to leverage the national marketing, sales and distribution resources of Bio-Reference Laboratories to enhance sales of OPKO's 4Kscore® test, a blood test that provides a personalized risk score for aggressive prostate cancer, and plans to further leverage the Bio-Reference capabilities with OPKO's other diagnostic products under development.
- **4Kscore® Recommended in National Comprehensive Cancer Network Guidelines for Prostate Cancer Early Detection:** The National Comprehensive Cancer Network (NCCN) included 4Kscore® as a recommended test in their 2015 Guidelines for Prostate Cancer Early Detection. The panel making this recommendation concluded that the 4Kscore®, as a blood test with greater specificity over the PSA test, is indicated for use prior to a first prostate biopsy, or after a negative biopsy, to assist patients and physicians in further defining the probability of high-grade cancer.
- **Rayaldee™ PDUFA Date is 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.
- **Completed Enrollment in Ongoing Phase 3 Trial in Growth Hormone Deficient Adults:** The trial 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 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 period. The study is expected to conclude in the second half of 2016; with positive results, a regulatory submission to the FDA will follow study completion.
- **IND for Long-Acting Factor VIIa-CTP for Hemophilia Filed and Accepted:** In March 2015, the FDA

accepted OPKO's IND application to initiate a Phase 2a trial for its long-acting intravenous coagulation Factor VIIa-CTP to treat hemophilia. Clinical trials are expected to commence during Q4 2015.

- **Clinical Studies for Long-Acting Oxyntomodulin for Obesity and Diabetes Expected to Begin During 2016:** 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 is Expected to Commence this Month:** 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 expects to commence commercial sales in the U.S. this month. 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. Following commercialization, OPKO is eligible to receive up to $110 million in additional milestones and tiered, double-digit royalties.

"OPKO has already achieved numerous important milestones during 2015," said Phillip Frost, M.D., Chairman and CEO. "We believe that the Pfizer transaction for hGH-CTP and the acquisitions of EirGen and Bio-Reference Laboratories have had a positive impact on our financial operations and will provide significant revenue opportunities and an expanded commercial platform for us going forward. The addition of our 4Kscore® Test to the NCCN guidelines was an important step toward obtaining reimbursement from healthcare payors, a key factor for obtaining broad access to men for the test. Our NDA filing for Rayaldee™ continues to advance through the FDA drug approval process and we have high expectations for our new treatment option for patients with stage 3 or 4 chronic kidney disease and secondary hyperparathyroidism. Our clinical development programs for Factor VIIa-CTP and oxyntomodulin, each with great commercial potential, are advancing on plan and we expect to initiate human trials for both products in the near future," continued Dr. Frost.

Financial Highlights

- Consolidated revenues increased to $143.0 million from $19.8 million for the three months ended September 30, 2015 compared to three months ended September 30, 2014, and increased to $215.5 million from $65.6 million for the nine months ended September 30, 2015 as compared to the 2014 period. The 2015 periods include revenue from Bio-Reference and EirGen beginning with their acquisitions in August and May 2015, respectively. Revenue for the three and nine months ended September 30, 2015 also includes $17.7 million and $47.8 million, respectively, from OPKO's collaboration with Pfizer.
- Net income for the three months ended September 30, 2015 was $128.2 million compared with net loss of $48.7 for the 2014 period and net losses for the nine months ended September 30, 2015 decreased to $31.6 million compared and $118.7 million for the 2014 period. The 2015 three and nine month periods include significant non-recurring and/or non-cash activities, including:
    - $93.0 million and $87.2 million of income tax benefit 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 the three and nine month periods of 2015, respectively;
    - 17.3 million gain related to the deconsolidation of OPKO's previously consolidated variable interest entity, SciVac, in the three month period of 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 $32.2 million and ($34.1) million related to the change in fair value of derivative instruments in the three and nine months of 2015, respectively, compared with $3.3 million and $3.8 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 $212.1 million as of September 30, 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.

CONFERENCE CALL & WEBCAST INFORMATION:

WHEN: Monday, November 9, 2015, 4:30 p.m. ET

DOMESTIC & CANADA DIAL-IN: (866) 634-2258

INTERNATIONAL DIAL-IN: (330) 863-3454

LIVE WEBCAST LINK: http://edge.media-server.com/m/p/j2oc63ro

For those unable to participate in the conference call or webcast, a replay will be available beginning November 9, 2015 at 7:30 p.m. ET until November 15, 2015 at 11:59 p.m. ET. To access the replay, dial (855) 859-2056 or (404) 537-3406. The replay passcode is 66021053.

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, the timing for approval of the NDA for Rayaldee, our ability to manufacture products at EirGen and achieve expected synergies, 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	
	September 30, 2015	December 31, 2014
Assets:		
Cash and cash equivalents	$ 212.1	$ 96.9
Other current assets	305.3	46.0
Total Current Assets	517.4	142.9
In-process Research and Development and Goodwill	1,574.0	1,017.4
Other assets	924.5	107.4
Total Assets	$ 3,015.9	$ 1,267.7
Liabilities and Equity:		
Current liabilities	$ 357.6	$ 83.1
2033 Senior Notes, net	44.2	131.5
Deferred tax liabilities	408.2	167.2
Other long-term liabilities, principally deferred revenue and contingent consideration	236.5	50.1
Total Liabilities	1,046.5	431.9
Equity	1,969.4	835.8
Total Liabilities and Equity	$ 3,015.9	$ 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	
	September 30,	
	2015	2014
Revenues	$ 143.0	$ 19.8
Costs and expenses	151.3	68.0
Operating loss	(8.3)	(48.2)
Other income and (expense), net	47.0	(1.5)
Income (loss) before income taxes and investment losses	38.7	(49.7)
Benefit from (provision for) income taxes	93.0	(0.3)
Income (loss) before investment losses	131.7	(50.0)
Loss from investments in investees	(3.5)	(0.0)
Net income (loss)	128.2	(50.0)
Less: Net loss attributable to non-controlling interests	-	(1.3)
Net income (loss) attributable to common shareholders	$ 128.2	$ (48.7)
Basic income (loss) per share	$ 0.26	$ (0.11)

Diluted income (loss) per share	$ 0.25	$ (0.11)

	For the nine months ended September 30,	
	2015	2014
Revenues	$ 215.5	$ 65.6
Costs and expenses	306.0	179.0
Operating loss	(90.5)	(113.4)
Other income and (expense), net	(23.6)	(4.3)
Loss before income taxes and investment losses	(114.1)	(117.7)
Benefit from (provision for) income taxes	87.2	(1.0)
Loss before investment losses	(26.9)	(118.7)
Loss from investments in investees	(6.1)	(2.5)
Net loss	(33.0)	(121.2)
Less: Net loss attributable to non-controlling interests	(1.4)	(2.5)
Net loss attributable to common shareholders	$ (31.6)	$ (118.7)
Basic and diluted loss per share	$ (0.07)	$ (0.28)

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