August 8, 2016

OPKO Health Reports Improved Financial and Operating Results

- **Net income was $15.5 million and $3.6 million for the three and six months ended June 30, 2016 compared to net losses of $42.8 million and $159.9 million for the comparable periods of 2015**
- **Consolidated revenue increased to $357.1 million from $42.4 million and to $648.1 million from $72.5 million for the three and six months ended June 30, 2016 compared to the 2015 periods**
- **Entered into collaboration and license agreement with Vifor Fresenius Medical Care Renal Pharma (VFMCRP) for OPKO's *RAYALDEE*®. OPKO to receive up to $282 million in upfront and milestone payments, and tiered double digit royalties; Vifor Fresenius also acquired an option for rights to the U.S. dialysis market for a new dosage form of *RAYALDEE* which provides for payment to OPKO of up to $555 million in additional milestone payments plus double digit royalties if exercised**

- **The U.S. Food and Drug Administration (FDA) approved*RAYALDEE*; launch anticipated in Q4 2016**
- **Signed agreement to acquire Transition Therapeutics; closing expected in Q3 2016**
- ***4Kscore* test utilization continues to grow; reimbursement negotiations underway**

MIAMI--(BUSINESS WIRE)-- **OPKO Health, Inc. (NYSE:OPK)**, reports financial and operating results for the three and six months ended June 30, 2016.

Financial Highlights

- Consolidated revenues for the three months ended June 30, 2016 increased to $357.1 million from $42.4 million for the three months ended June 30, 2015. The 2016 period includes revenue from BioReference Laboratories and EirGen which were acquired in August and May 2015, respectively. In addition, the 2016 period includes $50.0 million of revenue related to our license of *RAYALDEE* to VFMCRP.
- Net income for the three months ended June 30, 2016 was $15.5 million compared with net loss of $42.8 million for the 2015 period. Net income (loss) during the three month periods include significant non-recurring and non-cash activities, including:
  - Upfront payment for the license of *RAYALDEE* to VFMCRP of $50.0 million; and
  - Other income and (expense) was $5.1 million and ($16.8) 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.

- Cash, cash equivalents and marketable securities were $171.6 million as of June 30, 2016.

Business Highlights

- **VFMCRP and OPKO Health Enter into License and Option Agreement for OPKO's *RAYALDEE*:** OPKO entered into an agreement with VFMCRP for the development and commercialization of *RAYALDEE* in Europe, Canada, Mexico, Australia, South Korea and certain other international markets for the treatment of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) and vitamin D insufficiency. Under the terms of the agreement, OPKO received an upfront payment of $50 million, and will receive up to $232 million in regulatory and sales based milestones. In addition, VFMCRP will pay OPKO tiered, double digit royalties on sales of the product. OPKO and VFMCRP will also collaborate to develop and commercialize a new dosage form of *RAYALDEE* for the treatment of SHPT in dialysis patients. OPKO granted VFMCRP an option to acquire rights to this dosage form for the US market; if exercised, OPKO will receive up to $555 million in additional milestones and double digit royalties.
- ***RAYALDEE* Approved in June 2016:** The FDA approved *RAYALDEE* extended release capsules for the treatment of secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. *RAYALDEE* is a patented extended release product containing 30 mcg of a prohormone called calcifediol (25-hydroxyvitamin D3).
- **Transition Therapeutics:** The acquisition of Transition Therapeutics Inc. (NASDAQ: TTHI, TSX: TTH), a Toronto based biotechnology company, is expected to close during the third quarter of 2016. Transition Therapeutics has two drugs in mid-stage clinical development; TT401, a long acting GLP-1/glucagon dual agonist for the treatment of type 2 diabetes and obesity; and TT701, an orally administered selective androgen

receptor modulator (SARM) being developed for the treatment of certain features of androgen deficiency without androgenic effects on the prostate gland.

- ***4Kscore* test utilization continues to grow; reimbursement coverage negotiations continued:** Reimbursement of the *4Kscore* test is progressing; pricing agreements are already in place with several payors, and the Company is working to obtain a positive coverage decision by its local Medicare administrator. Through June 30, 2016, over 5,000 clinicians have utilized the test and in the month of June, alone, over 5,300 *4Kscore* tests were performed.

"Our improved financial performance this quarter was fueled by continued growth in our diagnostics business through increases in patient volume at BioReference Laboratories and its GeneDx unit, as well as continued growth in the utilization of our innovative *4Kscore* test for predicting the probability of aggressive prostate cancer," stated Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "We were pleased with the FDA's decision to approve *RAYALDEE* before its PDUFA date, and we are building an impressive commercial team to make this important medicine available to the large number of chronic kidney disease patients suffering from SHPT. Other drug development programs are progressing well and we anticipate having topline data from our phase 3 clinical trial for long acting human growth hormone in adults later this year. We also anticipate clinical data late this year or early next year for our long acting Factor VIIa-CTP, as well as clinical data for our Phase 1 clinical trial for long acting oxyntomodulin. We look forward to the closing of the Transition Therapeutics acquisition and adding Transition's important products to our robust late stage drug pipeline," continued Dr. Frost.

CONFERENCE CALL & WEBCAST INFORMATION:

OPKO's senior management will provide a business update and discuss 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: Monday, August 8, 2016, 4:30 p.m. ET
DOMESTIC DIAL-IN: (866) 634-2258
INTERNATIONAL DIAL-IN: (330) 863-3454
PASSCODE: 56394307

For those unable to participate in the conference call or webcast, a replay will be available beginning August 8, 2016 at 7:30 p.m. ET for a period of time. To access the replay, dial (855) 859-2056 or (404) 537-3406. The replay passcode is: 56394307.

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 sales force 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, and VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation launched by partner Tesaro and IV formulation PDUFA is January 2017). Our biologics business includes hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), a long-acting Factor VIIa drug for hemophilia (in Phase 2a) and a long acting oxyntomodulin for diabetes and obesity (in Phase 1). 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, 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, the timing of completion for our 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 and royalties from our partners, our ability to obtain broad reimbursement coverage for the 4Kscore test, increased adoption rates for the 4Kscore by Urologists, our ability to increase the number of 4Kscore tests performed, and expectations about the Transition acquisition, including the closing date, 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, 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	
	June 30, 2016	December 31, 2015
Assets:		
Cash, cash equivalents and marketable securities	$ 171.6	$ 193.6
Other current assets	334.0	260.5
Total Current Assets	505.6	454.1
In-process Research and Development and Goodwill	1,297.1	1,535.6
Other assets	971.3	809.5
Total Assets	$ 2,774.0	$ 2,799.2
Liabilities and Equity:		
Current liabilities	$ 281.2	$ 251.9
2033 Senior Notes, net	45.2	49.0
Deferred tax liabilities	207.6	226.0
Other long-term liabilities, principally deferred revenue and contingent consideration	224.4	292.5
Total Liabilities	758.4	819.4
Equity	2,015.6	1,979.8
Total Liabilities and Equity	$ 2,774.0	$ 2,799.2

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

	For the three months ended June 30,		For the six months ended June 30,	
	2016	2015	2016	2015
Revenues				
Revenue from services	$ 266.0	$ 1.9	$ 518.5	$ 4.0
Revenue from products	22.8	22.8	42.7	38.3
Revenue from transfer of intellectual property	68.3	17.7	86.9	30.2
Total revenues	357.1	42.4	648.1	72.5
Costs and expenses				
Cost of revenues	153.4	14.4	301.0	24.7
Selling, general and administrative	117.5	20.9	245.5	38.4
Research and development	31.3	29.6	59.1	55.1
Contingent consideration	10.8	(0.3)	12.5	4.8
Amortization of intangible assets	15.8	3.2	29.2	5.9
Grant repayment	-	-	-	25.9
Total Costs and expenses	328.8	67.8	647.3	154.8
Operating income (loss)	28.3	(25.4)	0.8	(82.3)
Other income and (expense), net	5.1	(16.8)	2.5	(70.6)
Income (loss) before income taxes and investment losses	33.4	(42.2)	3.3	(152.9)
(Provision for) benefit from income taxes	(15.9)	(0.3)	4.6	(5.8)
Income (loss) before investment losses	17.5	(42.5)	7.9	(158.7)
Loss from investments in investees	(2.0)	(0.8)	(4.3)	(2.6)
Net income (loss)	15.5	(43.3)	3.6	(161.3)
Less: Net loss attributable to non-controlling interests	-	(0.5)	-	(1.4)
Net income (loss) attributable to common shareholders	$ 15.5	$ (42.8)	$ 3.6	$ (159.9)
Basic income (loss) per share	$ 0.03	$ (0.09)	$ 0.01	$ (0.35)
Diluted income (loss) per share	$ 0.02	$ (0.09)	$ 0.00	$ (0.35)

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