August 8, 2017

OPKO Health Reports Second Quarter 2017 Business and Financial Results

Conference call begins at 4:30 p.m. Eastern time today

MIAMI, Aug. 08, 2017 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (NASDAQ:OPK) ("OPKO" or "the Company"), reports business and financial results for the three and six months ended June 30, 2017.

Business Highlights

• Sales force expansion for *RAYALDEE* underway. OPKO has made substantial progress in obtaining formulary access for *RAYALDEE*, with more than 68% of potential patient lives now covered under insurance plans. With the more extensive insurance coverage available, OPKO is continuing to expand its field-based sales force to 70 representatives from the original 35.
• Phase 2a trial for intravenously administered Factor VII-CTP and Phase 1 trial for subcutaneously administered Factor VII-CTP ongoing. These long-acting forms of Factor VII utilizing OPKO's CTP technology are expected to better support prophylaxis, provide easier administration and decrease dosing frequency for hemophilia patients.
• Enrollment for global pediatric Phase 3 hGH-CTP clinical trial continues and a Japanese pediatric registration trial for hGH-CTP is now underway.
• Clinical trials of Claros point-of-care (POC) prostate specific antigen (PSA) test completed and Premarket Approval (PMA) filing anticipated this fall. Analytic and clinical validation studies of OPKO's proprietary POC diagnostic test for PSA have been completed; PMA application to the FDA is planned for 4Q 2017. OPKO expects to begin an additional multicenter study of its POC testosterone test in late 2017 or early 2018, followed by a 510(k) submission to FDA.
• Initiation of five Phase 2 clinical trials anticipated in 2H 2017 and early 2018

- *RAYALDEE* line extension in dialysis patients with SHPT: Together with its partner, Vifor Fresenius, OPKO is developing *RAYALDEE* for Stage 5 chronic kidney disease (CKD) patients with secondary hyperparathyroidism (SHPT) undergoing dialysis and anticipates initiating a Phase 2 trial during 4Q 2017.
- OPK88004, orally administered selective androgen receptor modulator (SARM): OPKO plans to initiate a Phase 2b dose ranging study in 4Q 2017 to evaluate its use to treat men with benign prostate hyperplasia (BPH or enlarged prostate). It is expected to improve symptoms of BPH by reducing prostate size and, on the basis of data from a previous trial in 350 men, increase muscle mass and bone strength and decrease fat mass. BPH affects approximately 50 million men in the U.S.
- OPK88003, once weekly oxyntomodulin dual GLP1-Glucagon agonist for type 2 diabetes and obesity: In a 420-patient type 2 diabetes trial, OPK8804 reduced HbA1c levels similar to those achieved with exenatide extended release (Ex ER). The drug also showed a statistically significant improvement in weight loss, cholesterol and triglycerides compared to once-weekly Ex ER. The drug has a good safety profile and is expected to enter a Phase 2b dose-escalation study in early 2018.
- OPK88002, NK-1 antagonist to treat pruritus (severe itching) in Stage 5 CKD patients undergoing dialysis: Approximately 50% of renal dialysis patients experience difficult-to-control pruritus. An Investigational New Drug application was approved for a Phase 2a trial of OPK88002 and OPKO expects to initiate this study later this year.
- OPK88001, an oligonucleotide based AntagoNAT for the treatment of Dravet Syndrome: OPK88001 has received orphan drug designation in the U.S. and Europe. OPKO plans to file an IND for a Phase 2 clinical trial in 2H 2017 and plans to initiate that study by the end of the year. Currently, there is no globally approved treatment for Dravet Syndrome. AntagoNAT, anti-Natural Antisense Transcripts, is an in-house developed OPKO platform technology in which single strand oligonucleotide molecules are designed to interfere with regulatory gene expression in order to enhance production of endogenous functional proteins.

• BioReference Laboratories is well positioned to accelerate revenue growth and expand operating margins through the second half of 2017 and 2018.

- Continued investment in new systems provides better financial data and more information about customers, products and sales.

- New leadership team introducing new programs that are expected to benefit all aspects of the business.
- GeneDx, BioReference's genetic testing unit, continues to actively expand its innovative tests and services offerings and to further develop its relationships with health care providers and systems.
  - Expanded relationship with the University of California Health System to offer genetic, genomic and molecular testing services.
  - Implemented a unique clinician-focused test ordering portal to provide better management and tracking of data.

Financial Highlights

- Revenue for the three months ending June 30, 2017 was $314.2 million, which included a $10.0 million milestone payment from TESARO related to the commercial launch of VARUBY® in Europe. This compares with revenue of $357.1 million for the comparable 2016 period, which included a $50 million payment related to a *RAYALDEE* license to Vifor Fresenius.
- During the three months ended June 30, 2017, operating expenses included significant investment in the activities supporting the commercial launch of *RAYALDEE®,* as well as continued investment in the Company's pharmaceutical pipeline.
- For the three months ending June 30, 2017, net loss was $17.5 million compared with net income of $15.5 million for the comparable 2016 period, which benefited from a $50 million payment for *RAYALDEE* from Vifor Fresenius.
- Cash, cash equivalents and marketable securities were $130.5 million as of June 30, 2017.

Conference Call and 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: Tuesday, August 8, 2017, 4:30 p.m. Eastern time.
DOMESTIC DIAL-IN: (866) 634-2258
INTERNATIONAL DIAL-IN: (330) 863-3454
PASSCODE: 65755948
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 August 8, 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: 65755948. 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), OPK88003, 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 OPK88004, an androgen receptor modulator for androgen deficiency indications. 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 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 and expectations regarding the market for and sales of our products, whether 4Kscore test utilization will continue to grow, 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 submission or approval, validation and/or reimbursement for our products, the expected timing for launch of our products in development, whether the data for hGH-CTP 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, expectations regarding revenue growth and operating margins for BioReference for the remainder of 2017 and 2018, 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, OPKO88003, OPK88004, 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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Tables to Follow

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

	As of June 30, 2017	As of December 31, 2016
Assets:		
Cash, cash equivalents and marketable securities	$ 130.5	$ 168.7
Other current assets	342.0	314.9
Total Current Assets	472.5	483.6
In-process Research and Development and Goodwill	1,358.0	1,349.3
Other assets	938.2	933.7
Total Assets	$ 2,768.7	$ 2,766.6
Liabilities and Equity:		
Current liabilities	$ 283.1	$ 263.3
2033 Senior Notes, net	34.8	43.7
Deferred tax liabilities	142.2	165.3
Other long-term liabilities, principally deferred revenue and contingent consideration	201.8	202.5

Total Liabilities	661.9	674.8
Equity	2,106.8	2,091.8
Total Liabilities and Equity	$ 2,768.7	$ 2,766.6

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

	For the three months ended June 30,		For the six months ended June 30,	
	2017	2016	2017	2016
Revenues				
Revenue from services	$ 256.7	$ 266.0	$ 512.0	$ 518.5
Revenue from products	29.0	22.8	51.2	42.7
Revenue from transfer of intellectual property	28.5	68.3	47.1	86.9
Total revenues	314.2	357.1	610.3	648.1
Costs and expenses				
Cost of revenues	157.4	153.4	312.2	301.0
Selling, general and administrative	128.3	117.5	265.0	245.5
Research and development	32.6	31.3	58.6	59.1
Contingent consideration	4.4	10.8	6.7	12.5
Amortization of intangible assets	18.0	15.8	35.9	29.2
Total Costs and expenses	340.7	328.8	678.4	647.3
Operating income (loss)	(26.5)	28.3	(68.1)	0.8
Other income and (expense), net	3.6	5.1	9.4	2.5
Income (loss) before income taxes and investment losses	(22.9)	33.4	(58.7)	3.3
(Provision for) benefit from income taxes	11.0	(15.9)	17.9	4.6
Income (loss) before investment losses	(11.9)	17.5	(40.8)	7.9
Loss from investments in investees	(5.6)	(2.0)	(7.7)	(4.3)
Net income (loss)	$ (17.5)	$ 15.5	$ (48.5)	$ 3.6
Earnings (loss) per share:				
Earnings (loss) per share, basic	$ (0.03)	$ 0.03	$ (0.09)	$ 0.01
Earnings (loss) per share, diluted	$ (0.04)	$ 0.02	$ (0.10)	$ 0.00
Weighted average common shares outstanding, basic	559,347,540	547,558,800	558,892,375	546,691,117
Weighted average common shares outstanding, diluted	564,163,808	557,040,435	563,617,274	556,735,862

Source: OPKO Health Inc.