

OPKO Health Reports First Quarter 2018 Financial Results

Conference Call begins today at 4:30 p.m. Eastern Time

MIAMI, May 08, 2018 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (NASDAQ:OPK) reports financial results and business highlights for the three months ended March 31, 2018.

Financial Highlights

- Consolidated revenues for the three months ended March 31, 2018 were \$254.9 million compared with \$266.4 million for the comparable period of 2017.
 - Revenue from services were \$211.3 million for the three months ended March 31, 2018 compared with \$228.6 million for the comparable 2017 period. While not directly comparable, this represents a marked improvement from the most recently completed quarter ended December 31, 2017.
 - Revenue from products included \$3.7 million of revenue from *RAYALDEE* during the first quarter of 2018. Revenues from *RAYALDEE* were deferred during the initial launch period so there is no prior-year comparison.
- During the three months ended March 31, 2018, operating expenses included investment in commercial activities supporting the launch of *RAYALDEE* of \$7.3 million and continued investment in our pharmaceutical pipeline, with R&D expense increasing \$6.3 million to \$32.9 million compared with \$26.6 million for the 2017 period.
- Net loss of \$43.1 million or \$0.08 per share during the three months ended March 31, 2018 compares with a net loss of \$34.5 million or \$0.06 per share for the comparable period of 2017.
- Cash, cash equivalents and marketable securities were \$99.9 million as of March 31, 2018.

“We are pleased to report steady sequential-quarter growth for *RAYALDEE* and 4Kscore, as well as improvement in our lab business from Q4 of last year,” said Phillip Frost, Chairman and Chief Executive Officer of OPKO Health. “The improved first quarter results were in line with our expectations, starting 2018 positively coming off challenging fourth quarter 2017 results. These factors, taken together, reflect progress across the breadth of our commercial and laboratory services.”

Business Highlights

- ***RAYALDEE* total prescriptions reported by IMS for Q1 2018 increased 730% compared with Q1 2017 and 38% compared with Q4 2017:** As of May 1, 2018, more than 79% of patients had access to *RAYALDEE* under their insurance plans.
- **4Kscore utilization in Q1 2018 increased 13% compared with Q1 2017.** Five abstracts of studies further demonstrating the utility of the 4Kscore test in the management of prostate cancer are to be presented at the American Urological Association meeting May 18-21.
- **Appointed Geoff Monk as General Manager, BioReference Laboratories:** Mr. Monk is well prepared to lead BRL with more than 20 years of management experience in the diagnostic laboratory business. Mr. Monk was previously Managing Director of the New York and New Jersey unit of Quest Diagnostics.
- **Advanced the Phase 2b trial for our SARM (selective androgen receptor modulator) to treat benign prostatic hyperplasia (BPH):** Enrollment is ongoing in this dose-ranging study for our orally administered SARM. This medicine is expected to improve the 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 body fat. BPH affects approximately 50 million men in the U.S.
- **Initiated a Phase 2b clinical trial for OPK88003, our once-weekly oxyntomodulin dual GLP1-Glucagon agonist to treat type 2 diabetes and obesity:** In a previous Phase 2 trial in 420 overweight patients with type

2 diabetes, the drug was shown to be safe and effective. The current trial is to study a new dosing schedule to achieve even greater weight loss.

- **Premarket Approval (PMA) application for Claros[®] point-of-care PSA test under review by FDA** OPKO has submitted a PMA for a PSA test utilizing the Claros 1 immunoassay analyzer, a novel diagnostic instrument that can provide rapid, quantitative blood test results in 10 minutes in the physician's office with only a finger stick drop of whole blood. A second product utilizing the Claros platform to measure testosterone is advancing toward a 510(k) submission to the FDA later this year.
- **Global and Japanese Phase 3 registration trials for hGH-CTP in pediatric growth hormone deficient children are continuing to enroll patients:** The global pediatric study compares a single weekly administration with daily injections of a currently marketed growth hormone product. The global and Japanese pediatric studies utilize the pen device and formulation that will be launched commercially upon approval. The pediatric segment represents more than 80% of the market for treatment of hGH deficiency.
- **Initiation of three additional Phase 2 clinical trials are anticipated in 2018**
 - **RAYALDEE line extension in dialysis patients with secondary hyperparathyroidism (SHPT)** Together with our partners, Vifor Fresenius and Japan Tobacco, OPKO is developing RAYALDEE for Stage 5 chronic kidney disease (CKD) patients with SHPT undergoing dialysis and anticipates initiating a global Phase 2 trial during Q3 of this year.
 - **OPKO's NK-1 antagonist to treat pruritus (itching) in Stage 5 CKD patients undergoing dialysis** An Investigational New Drug application was submitted to the FDA and plans are being finalized to begin a single-dose Phase 2a trial in dialysis patients to treat severe itching. Approximately 50% of renal dialysis patients experience pruritus.
 - **OPKO's AntagoNAT oligonucleotide OPK88001 to treat Dravet's syndrome** Three clinical research centers in the United States are expected to participate in this first-in-human trial of OPKO's AntagoNAT to treat Dravet's syndrome.

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 and webcast information is as follows:

WHEN:	Tuesday, May 8, 2018 at 4:30 p.m. Eastern time.
DOMESTIC DIAL-IN:	866-634-2258
INTERNATIONAL DIAL-IN:	330-863-3454
PASSCODE:	5976529
WEBCAST:	http://investor.opko.com/events

For those unable to participate in the live conference call or webcast, a replay will be available beginning May 8, 2018 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: 5976529. The replay can be accessed for a period of time on OPKO's website at <http://investor.opko.com/events>.

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 BioReference 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 secondary hyperparathyroidism in stage 3 and 4 chronic kidney disease patients with vitamin D insufficiency (launched in November 2016), 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, OPK88004, a SARM (Selective Androgen Receptor Modulator) for treating BPH (Benign Prostatic Hypertrophy), OPK88002, an NK-1 antagonist to treat pruritus (itching) in dialysis patients, and OPK88001, a proprietary oligonucleotide to treat Dravet syndrome. In addition, the Company is advancing its CTP technology, which includes a long-acting hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer). OPKO also has 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 expectations regarding the market for and sales of our products, whether 4Kscore test utilization and prescriptions for RAYALDEE will continue to increase, our product development efforts and the expected benefits of our products, including whether our ongoing and future clinical trials will be successfully enrolled or 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, whether OPK88004 will improve the symptoms of BPH by reducing prostate size and increase muscle mass and bone strength and decrease body fat, the expected timing for launch of our products in development, the expected timing of commencing and concluding our clinical trials, including studies for OPK88001, OPK88002, OPK88003, and OPK88004, expected enrollment in clinical trials, the timing of our regulatory submissions, our ability to market and sell any of our products in development, and expectations about developing RAYALDEE for dialysis patients, 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, liquidity issues and 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, hGH-CTP, OPK88003, 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 (in millions)

	As of	
	March 31, 2018	December 31, 2017
Assets:		
Cash, cash equivalents and marketable securities	\$ 99.9	\$ 91.5
Other current assets	249.4	257.4
Total Current Assets	349.3	348.9

In-process Research and Development and Goodwill	1,366.3	1,364.4
Other assets	863.3	876.7
Total Assets	<u>\$ 2,578.9</u>	<u>\$ 2,590.0</u>
Liabilities and Equity:		
Current liabilities	\$ 288.4	\$ 316.5
2033 Senior Notes and 5% Convertible Notes	84.9	29.2
Deferred tax liabilities	148.7	148.7
Other long-term liabilities, principally deferred revenue, contingent consideration and lines of credit	233.6	240.0
Total Liabilities	<u>755.6</u>	<u>734.4</u>
Equity	1,823.3	1,855.6
Total Liabilities and Equity	<u>\$ 2,578.9</u>	<u>\$ 2,590.0</u>

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

	For the three months ended March 31,	
	2018	2017
Revenues		
Revenue from services	\$ 211.3	\$ 228.6
Revenue from products	27.9	22.2
Revenue from transfer of intellectual property	15.7	15.6
Total revenues	<u>254.9</u>	<u>266.4</u>
Costs and expenses		
Cost of revenues	154.1	154.8
Selling, general and administrative	91.5	109.9
Research and development	32.9	26.6
Contingent consideration	1.7	2.4
Amortization of intangible assets	17.3	17.9
Total Costs and expenses	<u>297.5</u>	<u>311.6</u>
Operating loss	<u>(42.6)</u>	<u>(45.2)</u>
Other income and (expense), net	1.0	5.9
Loss before income taxes and investment losses	<u>(41.6)</u>	<u>(39.3)</u>
Income tax benefit (provision)	1.0	6.9
Loss before investment losses	<u>(40.6)</u>	<u>(32.4)</u>
Loss from investments in investees	<u>(2.5)</u>	<u>(2.1)</u>
Net loss	<u>\$ (43.1)</u>	<u>\$ (34.5)</u>
Basic and diluted loss per share	<u>\$ (0.08)</u>	<u>\$ (0.06)</u>



Source: OPKO Health, Inc.