

August 7, 2018



# OPKO Health Reports Second Quarter 2018 Financial Results

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

MIAMI, Aug. 07, 2018 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (NASDAQ:OPK) reports financial results and business highlights for the three months ended June 30, 2018.

## Financial Highlights

- Net loss for the quarter decreased by 63% to \$6.2 million or \$0.01 a share on revenues of \$263.7 million during the three months ended June 30, 2018, compared to net loss of \$16.9 million or \$0.03 per share on revenues of \$292.6 million for the comparable period of 2017.
- Revenues from products during the three months ended June 30, 2018 include \$4.8 million from *RAYALDEE* and revenues from services were \$216.1 million for the 2018 period compared with \$233.9 million for the corresponding 2017 period.
- Revenue and net loss for the three months ended June 30, 2017 benefited from a non-recurring \$10 million milestone payment for VARUBI while net loss for the three months ended June 30, 2018 benefited from the reduction of contingent consideration expense of \$15.4 million attributable to changes in assumptions regarding the timing of milestone payments.
- During the three months ended June 30, 2018, costs of revenue and selling, general and administrative expenses decreased by approximately 9%, or \$26.0 million, compared to the 2017 period. Research and Development expenses were \$29.2 million compared to \$33.1 million for the corresponding 2017 period.

## Business Highlights

- **RAYALDEE total prescriptions reported by IMS for Q2 2018 increased 467% compared with Q2 2017 and 36% compared with Q1 2018:** As of August 1, 2018, more than 83% of patients have access to *RAYALDEE* under their insurance plans. Fresenius Medical Care Renal Pharma (Vifor Fresenius) received approval from Health Canada to market *RAYALDEE* in Canada for the treatment of secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency.
- **4Kscore utilization in Q2 2018 increased 10% compared with Q2 2017.** Utilization of the 4Kscore continues to improve with nearly 20,500 4Kscore tests performed during the three months ended June 30, 2018 compared to 18,600 tests performed during the second quarter of 2017.

- **Geoff Monk Appointed as General Manager, BioReference Laboratories:** Mr. Monk has more than 20 years of management experience in the diagnostic laboratory business and 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 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.
- **Completed the enrollment of a Global Phase 3 study of somatrogen (hGH-CTP) in Growth Hormone Deficient Children:** The somatrogen Phase 3 trial is a randomized, open-label, active-controlled study taking place in over 30 countries. This study enrolled approximately 225 treatment naïve children with growth hormone deficiency (GHD) who were randomized 1:1 into two arms: once-weekly somatrogen vs once-daily Genotropin®. The primary endpoint of the trial is height velocity at 52 weeks. Secondary endpoints are safety and pharmacodynamic endpoints.
- **Japanese Phase 3 registration trial of somatrogen in growth hormone deficient children continues to enroll patients:** The global and Japanese pediatric studies utilize the multiple dose pen device that will be launched commercially upon approval.
- **Completed the enrollment of a Phase 2b clinical trial for 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.
- **Initiation of two additional Phase 2 clinical trials anticipated in 2018**
  - **RAYALDEE in dialysis patients with SHPT:** Together with our partners, Vifor Fresenius and Japan Tobacco, OPKO is developing RAYALDEE for Stage 5 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 a single-dose Phase 2a trial is commencing. Pruritus is often a problem for renal dialysis patients.

## 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:**

DOMESTIC Tuesday, August 7, 2018 at

DIAL-IN: 4:30 p.m. Eastern time.

INTERNATIONAL (866) 634-2258

DIAL-IN: (330) 863-3454

PASSCODE: 9243717

WEBCAST: [investor.opko.com/events](http://investor.opko.com/events)

For those unable to participate in the live conference call or webcast, a replay will be available beginning August 7, 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: 9243717. 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. In diagnostics, its BioReference Laboratories is the nation's third largest clinical laboratory; GeneDx is a rapidly growing genetic testing business; the 4Kscore® prostate cancer test is used to confirm an elevated PSA to help decide about next steps such as prostate biopsy; Claros® 1 is a point of care diagnostics platform with PSA and testosterone as the most advanced in development. In our pharmaceutical pipeline, RAYALDEE is our first pharmaceutical product to be marketed. OPK88003, a once weekly oxyntomodulin for type 2 diabetes and obesity in Phase 2 clinical trials, is among a new class of GLP-1 – glucagon receptor dual agonists. OPK88004, a SARM (Selective Androgen Receptor Modulator) for treating BPH (Benign Prostatic Hypertrophy), urinary incontinence, and other conditions, is in clinical trials. The Company's most advanced product utilizing its CTP technology, a once weekly human growth hormone for injection, is in Phase 3 trials, and is partnered with Pfizer. OPKO has research, development, production and distribution facilities abroad. More information is available at [www.opko.com](http://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, 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, whether OP88003 will be*

*shown to be safe and effective and achieve even greater weight loss, the expected timing for launch of our products in development, the expected timing of commencing and concluding our clinical trials, 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 the success of our relationship with Pfizer and our other partners, 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.*

## **CONTACTS:**

### **Investors**

LHA Investor Relations  
Miriam W. Miller, 212-838-3777  
[MMiller@lhai.com](mailto:MMiller@lhai.com)

or

Bruce Voss, 310-691-7100  
[bvoss@lhai.com](mailto:bvoss@lhai.com)

## **—Tables to Follow—**

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

As of

|                                                                                                         | June 30,<br>2018  | December<br>31,<br>2017 |
|---------------------------------------------------------------------------------------------------------|-------------------|-------------------------|
| Assets:                                                                                                 |                   |                         |
| Cash, cash equivalents and marketable securities                                                        | \$ 80.4           | \$ 91.5                 |
| Other current assets                                                                                    | 241.2             | 257.4                   |
| Total Current Assets                                                                                    | 321.6             | 348.9                   |
| In-process Research and Development and Goodwill                                                        | 1,359.9           | 1,364.4                 |
| Other assets                                                                                            | 849.4             | 876.7                   |
| Total Assets                                                                                            | <u>\$ 2,530.9</u> | <u>\$ 2,590.0</u>       |
| Liabilities and Equity:                                                                                 |                   |                         |
| Current liabilities                                                                                     | \$ 276.5          | \$ 316.5                |
| 2033 Senior Notes and 5% Convertible Notes                                                              | 86.2              | 29.2                    |
| Deferred tax liabilities                                                                                | 148.3             | 148.7                   |
| Other long-term liabilities, principally deferred revenue, contingent consideration and lines of credit | 209.4             | 240.0                   |
| Total Liabilities                                                                                       | 720.4             | 734.4                   |
| Equity                                                                                                  | 1,810.5           | 1,855.6                 |
| Total Liabilities and Equity                                                                            | <u>\$ 2,530.9</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<br>ended June 30, |          | For the six months ended<br>June 30, |          |
|------------------------------------------------|----------------------------------------|----------|--------------------------------------|----------|
|                                                | 2018                                   | 2017     | 2018                                 | 2017     |
| Revenues                                       |                                        |          |                                      |          |
| Revenue from services                          | \$ 216.1                               | \$ 233.9 | \$ 427.4                             | \$ 462.5 |
| Revenue from products                          | 28.5                                   | 29.0     | 56.4                                 | 51.2     |
| Revenue from transfer of intellectual property | 19.1                                   | 29.7     | 34.8                                 | 45.3     |
| Total revenues                                 | 263.7                                  | 292.6    | 518.6                                | 559.0    |
| Costs and expenses                             |                                        |          |                                      |          |
| Cost of revenues                               | 150.1                                  | 157.4    | 304.1                                | 312.2    |
| Selling, general and administrative            | 87.7                                   | 105.5    | 179.2                                | 215.5    |
| Research and development                       | 29.2                                   | 33.1     | 62.1                                 | 59.7     |
| Contingent consideration                       | (15.4 )                                | 4.4      | (13.6 )                              | 6.7      |

|                                                         |            |            |            |            |
|---------------------------------------------------------|------------|------------|------------|------------|
| Amortization of intangible assets                       | 17.2       | 18.0       | 34.5       | 35.9       |
| Total Costs and expenses                                | 268.8      | 318.4      | 566.3      | 630.0      |
| Operating loss                                          | (5.1 )     | (25.8 )    | (47.7 )    | (71.0 )    |
| Other income and (expense), net                         | 8.1        | 3.5        | 9.2        | 9.4        |
| Income (loss) before income taxes and investment losses | 3.0        | (22.3 )    | (38.5 )    | (61.6 )    |
| Income tax benefit (provision)                          | (2.0 )     | 11.0       | (1.1 )     | 17.9       |
| Income (loss) before investment losses                  | 1.0        | (11.3 )    | (39.6 )    | (43.7 )    |
| Loss from investments in investees                      | (7.2 )     | (5.6 )     | (9.7 )     | (7.7 )     |
| Net loss                                                | \$ (6.2 )  | \$ (16.9 ) | \$ (49.3 ) | \$ (51.4 ) |
| Basic loss per share                                    | \$ (0.01 ) | \$ (0.03 ) | \$ (0.09 ) | \$ (0.09 ) |
| Diluted loss per share                                  | \$ (0.01 ) | \$ (0.04 ) | \$ (0.09 ) | \$ (0.11 ) |



Source: OPKO Health, Inc.