August 9, 2013

OPKO Announces Second Quarter 2013 Operating and Financial Highlights

- **Revenue More Than Doubles to $23.8 million for the Second Quarter 2013; Nearly Triples to $55.2 million for the First Half of 2013**
- **Citicoline Products Approved in Spain**
- **More than 50% enrollment in Phase 3 Trial for *Rayaldy*™**
- **Acquisition of PROLOR Biotech Expected to be Completed in Third Quarter 2013**
- **Top-Line Phase 3 Trial Results for Rolapitant Expected to be Announced by TESARO in Second Half of 2013**
- **Preparing U.S. Commercial Launch of *4Kscore*™**
- **Cash and Marketable Securities at $169.1 million as of June 30, 2013**

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE: OPK), a multi-national biopharmaceutical and diagnostics company, today reported operating and financial highlights for the second quarter of 2013.

Second Quarter 2013 Financial Highlights

- Consolidated revenues more than doubled to $23.8 million during the three months ended June 30, 2013, from $10.2 million in the prior year period and nearly tripled to $55.2 million for the six months ended June 30, 2013, from $19.0 million in the prior year period. Revenue for the six months ended June 30, 2013, includes $12.5 million of revenue resulting from a strategic partnership in the field of RNA interference with RXi Pharmaceuticals Corporation.
- Net loss for the three months ended June 30, 2013, was $ 3.4 million, compared to a net loss of $10.8 million for the 2012 period. Net loss for the three months ended June 30, 2013, includes the impact of:
    - $9.9 million non-cash benefit related to the change in fair value of embedded derivatives which are part of our January 2013 convertible senior notes due in 2033 (the “2033 Senior Notes”). This non-cash benefit resulted principally from the decrease in the closing market price of our common stock as of June 30, 2013, as compared to the previous quarter end; and
    - $8.5 million related to other income from the sale of available for sale securities.
- Net loss for the six months ended June 30, 2013, was $38.0 million, compared to a net loss of $20.0 million for the 2012 period. Net loss for the six months ended June 30, 2013, includes the impact of:
    - $14.9 million in net non-cash charges related to the change in fair value of embedded derivatives which are part of our 2033 Senior Notes, principally as a result of the increase in the closing market price of our common stock as of June 30, 2013, as compared to the date of issuance of such notes; and
    - $10.8 million related to other income from the sale of available for sale securities.

- Cash, cash equivalents and marketable securities were $169.1 million as of June 30, 2013.

Business Highlights

- Our Spanish subsidiary, Pharmadiet, S.L.U., received regulatory approval for commercialization of its oral and injectable formulations of citicoline to treat memory disorders and behavior related to stroke, head injury, chronic disease, as well as degenerative brain disorders.
- The two Phase 3 trials of *Rayaldy*™**,** our vitamin D prohormone to treat patients with secondary hyperparathyroidism with stage 3 or 4 chronic kidney disease and vitamin D insufficiency, are progressing on schedule. We anticipate top-line data from this pivotal program in mid-2014.
- Our acquisition of PROLOR Biotech, Inc. (NYSE MKT: PBTH), a biopharmaceutical company focused on developing longer-acting proprietary forms of presently marketed therapeutic proteins and peptides, is expected to close during the third quarter of 2013. PROLOR has reported that its long-acting version of human growth hormone, hGH-CTP, can reduce the dosing frequency from one injection per day to a single weekly injection. A Phase 2 trial in children with GHD is currently ongoing, and a Phase 3 trial in adults with GHD was initiated in June 2013. PROLOR also recently announced results from preclinical studies of its long-acting clotting factor VIIa (Factor VIIa-CTP), a next-generation investigational therapy in advanced preclinical development for the potential treatment of hemophilia. The data indicate that Factor VIIa-CTP can be administered by subcutaneous (SC) injection in contrast to presently used products which must be given intravenously; this would facilitate its prophylactic at home use.
- Enrollment, now surpassing 90%, continues by our licensee, TESARO, Inc. in each of three Phase 3 trials of Rolapitant for the prevention of chemotherapy induced nausea and vomiting. TESARO anticipates that top-line data from this pivotal program will be announced by year end. TESARO also presented results from a pharmacokinetic study of Rolapitant at the recent Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) International Symposium in Berlin. These data support concomitant administration of Rolapitant with other pharmaceutical products that are metabolized by the liver microsomal enzyme CYP3A4, without a requirement for dose adjustment of the co-administered product.
- The U.S. commercial launch of the OPKO 4Kscore™ prostate cancer test as a laboratory developed test will be through our CLIA-certified laboratory based in Nashville, TN.

“We continue to build and strengthen the foundation for a sound profitable business,” said Phillip Frost, M.D., OPKO’s Chairman and Chief Executive Officer. “We are pleased that Pharmadiet, our Spanish subsidiary, has received regulatory approval for our oral and injectable formulations of citicoline, and we are beginning the process for marketing them in Spain as well as through our Latin American units. These products will be sold by prescription to improve memory in certain patients,” continued Dr. Frost. “We are also very proud of the pipeline of new products in various stages of development in OPKO and soon to be acquired PROLOR. They can provide the basis for an important health care company.”

About OPKO Health, Inc.

We are a multi-national biopharmaceutical and diagnostics company that seeks to establish

industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies.

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, continued revenue growth and our ability to build a profitable business, our product development efforts, including whether the Phase 3 clinical trials for Rayaldy™, PROLOR's hGH-CTP product, rolapitant, or any of our products in development will be completed on a timely basis or at all, the expected timing for launch of our products in development, including the 4kscore™, 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 Rayaldy™, citicoline, the 4KScore™, and PROLOR's hGH-CTP product, the timing of and anticipated closing of our acquisition of PROLOR, 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 filings with the Securities and Exchange Commission, as well as 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 Rayaldy™, rolapitant, PROLOR's hGH-CTP product, and/or any of our compounds or diagnostic products under development, including our 4KScore™ test, 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, and that we may not be able to successfully complete the acquisition of PROLOR. 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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Source: OPKO Health, Inc.