May 9, 2013

OPKO Announces First Quarter 2013 Operating and Financial Highlights

- **Consolidated Revenue Nearly Triples to $31.4 million**
- **Net Cash Position at $181.6 million as of March 31, 2013**
- **Phase 3 Trial for CTAP 101 Capsules for Treatment of Secondary Hyperparathyroidism (SHPT) Continuing on Schedule, Top Line Results Expected mid-2014**
- **Entered Into Definitive Agreement to Acquire PROLOR Biotech, Enhancing OPKO's Pipeline of Significant Products, Which Will Include Four Phase 3 Products**
- **Top-Line Phase 3 Trial Results for Rolapitant Expected to be Announced by TESARO in Second Half of 2013**
- **Acquired Interest in Growing Russian Pharmaceutical Company**
- **Entered Into Strategic Pooling of Assets with RXi Pharmaceuticals**
- **Preparing for 4Kscore™ Commercial Launch**

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

"Consistent with our growth strategy, progress across most business fronts accelerated during the first quarter of 2013," said Phillip Frost, OPKO's Chairman and Chief Executive Officer. "We are pleased with the advances of our operating businesses, as well as the progress made in the development of our CTAP101 Capsules and 4Kscore™ prostate diagnostic test. Our solid financial position, coupled with anticipated revenue growth, will facilitate progress of our product pipeline, soon to include PROLOR's once a week human growth-hormone."

Business Highlights

- Our CTAP101 Capsules, a vitamin D prohormone to treat SHPT in patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency, is being evaluated in three ongoing Phase 3 trials, the third of which was started during the first quarter of 2013. The trials are on schedule and later this month subject enrollment is expected to surpass 50% in the most advanced trial. A new patent covering CTAP101 Capsules was granted by the U.S. Patent and Trademark Office (the "USPTO"), and a pending patent application was allowed.
- We entered into a definitive merger agreement to acquire PROLOR Biotech, Inc. (NYSE MKT: PBTH), a biopharmaceutical company focused on developing and commercializing longer-acting proprietary versions of already approved therapeutic proteins and peptides. PROLOR's long-acting version of human growth hormone, hGH-CTP, has successfully completed four clinical trials, including a Phase 2 trial in adults with growth hormone deficiency (GHD). PROLOR has reported that the trials

showed that hGH-CTP has the potential to reduce the required dosing frequency of human growth hormone from the current standard of 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 is planned to begin in the second quarter of 2013. Recombinant human growth hormone (hGH) is used for the long-term treatment of children and adults with GHD due to inadequate secretion of endogenous growth hormone. hGH-CTP has been awarded orphan drug designation in the U.S. and Europe for both adults and children with GHD. PROLOR recently announced that it received a notice of allowance from the USPTO for a patent application covering PROLOR's long-acting CTP-enhanced coagulation factors for the treatment of hemophilia: Factor VIIa-CTP, Factor VII-CTP and Factor IX-CTP. The allowed claims cover both product composition and treatment methods. PROLOR also recently announced that it received a notice of allowance from the USPTO for a new patent application covering hGH-CTP. Upon issuance, the new patent will provide PROLOR with additional intellectual property protection that covers methods for decreasing body fat in humans through the use of hGH-CTP therapy.

- Enrollment continues by our licensee, TESARO, Inc. in each of three Phase 3 trials of rolapitant for the prevention of chemotherapy induced nausea and vomiting. This global trial program is being conducted at more than 200 sites across 25 countries. Top line Phase 3 trial results are expected to be announced by TESARO during the second half of 2013.
- We acquired an approximate ten percent stake in OAO Pharmsynthez (MICEX: LIFE), a growing, fully-integrated Russian pharmaceutical company and the only life science company listed on the Moscow Stock Exchange. OPKO will partner with Pharmsynthez to develop and market several OPKO products for sale in Russia and certain other Eastern European countries.
- We announced a strategic partnership in the field of RNA interference with RXi Pharmaceuticals Corporation ("RXi"), received 50 million shares of RXi common stock and will receive milestone payments from RXi up to an aggregate of $50 million per product tied to the successful development and commercialization of products utilizing the acquired OPKO intellectual property. In addition, upon commercialization of these products RXi would make royalty payments to OPKO.
- Development work toward the U.S. commercial launch of the OPKO 4Kscore™ prostate cancer test as a laboratory developed test through our CLIA-certified laboratory based in Nashville, TN, remains on track for a 2013 launch.

First Quarter 2013 Financial Highlights

- Cash and cash equivalents were $181.6 million as of March 31, 2013.
- Consolidated revenues nearly tripled to $31.4 million during the three months ended March 31, 2013 from $8.8 million in the prior year period, including $12.5 million of revenue related to the RXi transaction.
- Net loss for the three months ended March 31, 2013, exclusive of a $24.8 million non-cash charge related to the change in fair value of embedded derivatives which are part of our January 2013 convertible senior notes due in 2033, was $ 9.8 million, compared to a net loss of $9.2 million for the comparable 2012 period. Net loss for the three months ended March 31, 2013, including the $24.8 million non-cash charge related to the change in fair value of embedded derivatives which are part of our January 2013 convertible senior notes due in 2033, was $34.6 million.

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 other commercial opportunities during the remainder of 2013, our product development efforts, including whether the Phase 3 clinical trials for CTAP101 Capsules, 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, the timing of and anticipated closing of our acquisition of PROLOR, the issuance of a new patent to PROLOR, and whether we will receive milestone payments and royalties from TESARO and RXi, 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 CTAP101 Capsules, 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.