UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 11, 2014

OPKO Health, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-33528**	**75-2402409**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4400 Biscayne Blvd
Miami, Florida 33137
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (305) 575-4100

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On August 11, 2014, OPKO Health, Inc., a Delaware corporation (the "Company") issued a press release announcing operating and financial highlights for the quarter ended June 30, 2014. A copy of the press release is attached hereto as Exhibit 99.1.

The information included herein and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 ("Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 7.01. Regulation FD Disclosure.

On August 11, 2014, the Company issued a press release announcing top-line results from the first pivotal Phase 3 trial of Rayaldee™, a new treatment for secondary hyperparathyroidism in patients with stage 3 or 4 chronic kidney disease and vitamin D insufficiency. A copy of the press release announcing these results is attached to this Current Report on Form 8-K as Exhibit 99.2 and incorporated herein by reference.

In addition, on August 12, 2014, the Company will hold a conference call and webcast to review the data and to discuss operating and financial highlights from the second quarter 2014.

The information contained in Item 7.01 to this Current Report on Form 8-K and Exhibits 99.1 and 99.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing by the Company under the Act, unless expressly stated otherwise.

ITEM 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release of the Company dated August 11, 2014.
99.2	Press Release of the Company dated August 11, 2014.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OPKO Health, Inc.

Date: August 12, 2014

By /s/ Adam Logal
Name: Adam Logal
Title: Senior Vice President,
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of the Company dated August 11, 2014.
99.2	Press Release of the Company dated August 11, 2014.

Exhibit 99.1

OPKO Announces Second Quarter Operating and Financial Results

- **Rayaldee™ Meets Primary Endpoints in First Pivotal Phase 3 Trial; Top Line Data From 2nd Pivotal Phase 3 Trial to be Available September 2014; NDA Submission on Track for Q4 2014**
- **IND Submitted for Rayaldee as Adjunctive Cancer Therapy**
- **Positive Pediatric Phase 2 Data Reported for hGH-CTP Once Weekly Human Growth Hormone**
- **Long Acting Factor VIIa-CTP For Hemophilia Receives Three Orphan Drug Designations in Europe**
- **U.S. Marketing Commenced for 4Kscore™ Blood Test to Diagnose Aggressive Prostate Cancer**
- **Rolapitant™ Meets all Primary and Secondary Endpoints in Final Phase 3 Trial; On Schedule for mid-September NDA Filing**
- **Inspiro Next Generation Inhaler Acquisition Completed**
- **Cash and Cash Equivalents Total $134.0 Million Providing Adequate Liquidity To Fund Development Programs**

MIAMI—August 11, 2014— OPKO Health, Inc. (NYSE:OPK), a multi-national biopharmaceutical and diagnostics company, today reported operating and financial results for its second quarter ended June 30, 2014.

Business Highlights

- **Rayaldee Meets Primary Endpoints in First Pivotal Phase 3 Trial; NDA Submission on Track for Q4 2014:** OPKO announced successful top-line results from the first pivotal Phase 3 trial of Rayaldee. This trial is one of two identical randomized, double-blind, placebo-controlled, multi-site studies intended to establish the safety and efficacy of Rayaldee as a new treatment for secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency. OPKO to announce top line results from the second Phase 3 trial in September 2014 and is on track to submit a New Drug Application (NDA) with the United States (U.S.) Food and Drug Administration (FDA) in the fourth quarter of 2014.
- **Submission of IND for Rayaldee as Adjunctive Cancer Therapy:** OPKO submitted an Investigational New Drug (IND) Application to the FDA to evaluate Rayaldee as an adjunctive therapy, the first of other possible uses, for the prevention of skeletal-related events (SREs) in patients with bone metastases undergoing anti-resorptive therapy. The clinical trial will commence later in 2014.
- **Positive Pediatric Phase 2 Data Reported for hGH-CTP:** OPKO announced positive 6 month results from its Phase 2 study evaluating the safety and efficacy of hGH-CTP, a long-acting form of human growth hormone, to treat growth hormone deficiency in children. All three hGH-CTP once-weekly doses resulted in strong catch-up growth during the six month treatment period,

with annualized increases in height of more than 12 cm. The results indicated excellent dose dependent pharmacokinetic (PK) and pharmacodynamic (PD) profiles. No serious adverse events were reported.

- **Factor VIIa-CTP Received Positive Opinion For Three Orphan Drug Designations in Europe:** The European Committee for Orphan Medicinal Products (COMP) gave a positive opinion to recommend approval of orphan drug designations for OPKO's long-acting version of clotting Factor VIIa (Factor VIIa-CTP) to treat bleeding episodes in patients with hemophilia A or B who have inhibitors to Factor VIII, Factor IX or congenital Factor VII deficiency. Factor VII-CTP previously was granted orphan status in the U.S. The European designations may provide OPKO the opportunity to have marketing exclusivity for periods of up to 10 years.

- **Adoption of 4Kscore Test is Growing:** OPKO completed a validation study and launched the 4Kscore Test in the U.S. through its CLIA accredited OPKO Lab in late March 2014. Since launch, its adoption by Urologists has steadily increased. OPKO expects to launch the 4Kscore Test in Europe through its Spanish subsidiary in September 2014 and elsewhere shortly thereafter. OPKO is working to obtain reimbursement for the 4Kscore Test by payers. The 4Kscore Test makes the prostate biopsy decision process more rational. In the U.S. approximately 1 million biopsies are performed annually with 80% indicating no cancer or only low grade cancer. With the knowledge of the risk (probability) of having high grade cancer provided by the 4Kscore Test, prostate biopsies are more likely to be performed only in men at higher risk. OPKO presented data from its U.S. clinical validation study in a plenary session at the American Urological Association (AUA) in Orlando, FL. The talk, "The 4Kscore Test as a Predictor of High-Grade Prostate Cancer on Biopsy," was also selected for a plenary presentation at the Spanish National Congress of Urology in June, and will be presented at the 83rd Annual Meeting of the New England Section of the AUA in October 2014 in Newport, RI.

- **Rolapitant Meets all Primary and Secondary Endpoints in Final Phase 3 Trial; On Schedule for a mid-September NDA Filing:** OPKO's partner, TESARO, announced positive results from the third and final Phase 3 trial of Rolapitant, a neurokinin-1 (NK-1) receptor antagonist for the prevention of chemotherapy-induced nausea and vomiting (CINV). The oral formulation of Rolapitant is on track for an NDA filing by mid-September; the intravenous (IV) formulation is expected to be available to patients one year after the oral formulation.

- **Inspiro Acquisition Completed:** OPKO acquired Inspiro Medical Ltd., an Israeli medical device company with a new platform to deliver inhaled drugs. Inspiro's Inspiromatic™ is a "smart", easy-to-use dry powder inhaler with important advantages over existing devices.

"In the second quarter, we continued to make strides in converting our advanced pipeline of diagnostic and pharmaceutical products into commercial successes," said Phillip Frost, M.D., Chairman and CEO. "The 4Kscore Test is being increasingly adopted by Urologists because of its utility for identifying patients at the greatest risk of having high-grade prostate cancer and clinical trials of Rayaldee, hGH-CTP and Rolapitant have all provided the anticipated evidence of safety and efficacy. We look forward to making these important products available as rapidly as possible to patients who will benefit from their use."

Financial Highlights

At June 30, 2014, OPKO had cash and cash equivalents of $134.0 million providing OPKO with adequate liquidity to continue the development of its product candidates. In addition, OPKO strengthened its balance sheet by retiring $70.4 million of its convertible senior notes due in 2033 through a privately negotiated transaction. During the six months ended June 30, 2014, OPKO continued to invest in its research and development programs, utilizing $44.5 million of cash from operations to advance its projects including clinical trials for Rayaldee and hGH-CTP and the clinical validation study for 4Kscore Test which was completed in March 2014.

Pharmaceutical product revenue for the three months ended June 30, 2014 increased approximately 15% to $21.4 million compared to $18.6 million for the 2013 period. This increase was principally the result of increased revenue from OPKO's active pharmaceutical ingredient business at FineTech as well as increased pharmaceutical product revenue at OPKO Spain and OPKO Mexico. Total revenue for the three months ended June 30, 2014 was $23.5 million compared to $23.8 million for the 2013 period. Total revenue for the three months ended June 30, 2013 included non-recurring revenue of $2.0 million related to OPKO's transactions with Pharmsynthez.

Net loss for the three months ended June 30, 2014 was $25.5 million, compared to $3.4 million in the comparable period of 2013. The increase in net loss was significantly impacted by an $8.5 million gain related to the successful exit of a strategic investment in the three months ended June 30, 2013. Net loss for the three months ended June 30, 2014 included $10.1 million of non-recurring expense related to the write-off of acquired in-process research and development expense related to the Inspiro acquisition. OPKO continued to increase its investment in research and development activities during the three months ended June 30, 2014 related to its ongoing Phase 3 programs for Rayaldee and hGH-CTP. As a result, OPKO's spending on research and development increased $6.7 million to $16.2 million for the three months ended June 30, 2014 from $9.6 million for the three months ended June 30, 2013.

For the six months ended June 30, 2014, pharmaceutical product revenue increased approximately 21% to $41.2 million compared to $34.1 million for the 2013 period. The increase in pharmaceutical product revenue was principally the result of increased revenue from FineTech, OPKO Spain and OPKO Mexico. Total revenue for the six months ended June 30, 2014 was $45.8 million compared to $55.2 million for the 2013 period. Total revenue for the three months ended June 30, 2013 included non-cash, non-recurring revenue of $12.5 million related to OPKO's transaction with RXi, which was partially offset by increased product revenue.

Net loss for the six months ended June 30, 2014 was $70.0 million compared to $38.0 million for the first six months of 2013. OPKO continued to increase its investment in research and development activities related to its ongoing Phase 3 programs for Rayaldee and hGH-CTP as well as costs associated with the clinical validation study for the 4Kscore. As a result, OPKO's spending on research and development increased $17.8 million to $37.2 million for the six months ended June 30, 2014 from $19.5 million for the six months ended June 30, 2013. In addition, net loss for the six months ended June 30, 2014 included a non-recurring in-process research and development expense of $10.1 million

due to a write-off of in-process research and development expense in connection with the acquisition of Inspiro. The six month period ended June 30, 2013 also included $12.5 million of non-cash income related to the RXi transaction and a $10.8 million gain realized from the successful exit of a strategic investment. These reductions were partially offset during the six months ended June 30, 2014 by our increased pharmaceutical product revenue of $7.1 million and a decrease in non-cash expense of $11.4 million from the change in fair value of embedded derivatives principally related to the retirement of our Senior 2033 Notes.

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, whether we have sufficient liquidity to fund our research and development and operations, our product development effort and the expected benefits of our products, including whether the Phase 3 clinical trials for Rayaldee, hGH-CTP, and Rolapitant will be completed on a timely basis or at all and whether the data will support approval, validation and/or reimbursement for our products, the expected timing for launch of our products in development, including Rayaldee and hGH-CTP, 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 Rayaldee, the 4Kscore, and hGH-CTP, our ability to launch sales of the 4Kscore Test in Spain and through our other subsidiaries, increased adoption rates for the 4Kscore by Urologists, the timing for submission of an NDA by us for Rayaldee and by TESARO for Rolapitant, whether the 4Kscore will provide substantial benefits to patients and doctors by informing them of the risk of a patient having a high-grade cancer and clarify the decision making process, whether the 4Kscore will reduce unnecessary biopsies, 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 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, Rolapitant, hGH-CTP, 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.

OPKO Health, Inc.

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

	As of June 30, 2014	As of December 31, 2013
Assets:		
Cash and cash equivalents	$ 134.0	$ 185.8
Other current assets	49.0	56.9
Total Current Assets	183.0	242.7
In-process Research and Development and Goodwill	1,019.3	1,019.7
Other assets	124.8	129.1
Total Assets	$1,327.1	$ 1,391.5
Liabilities, Series D Preferred Stock and Equity:		
Current liabilities	$ 79.4	$ 91.8
2033 Senior Notes, net	116.4	211.9
Other long-term liabilities	218.5	214.8
Total Liabilities	414.3	518.5
Series D Preferred Stock and Equity	912.8	873.0
Total Liabilities, Series D Preferred Stock and Equity	$1,327.1	$ 1,391.5

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

	For the three months ended June 30,	
	2014	2013
Revenues	$ 23.5	$ 23.8
Costs and expenses	58.4	41.8
Operating loss	(34.9)	(18.0)
Other income and (expense), net	9.3	16.9
Loss before income taxes and investment losses	(25.6)	(1.1)
Benefit from (provision for) income taxes	(0.1)	(0.9)
Loss before investment losses	(25.7)	(2.0)
Loss from investments in investees	(0.4)	(2.4)
Net loss	(26.1)	(4.4)
Less: Net loss attributable to non-controlling interests	(0.6)	(1.0)
Preferred stock dividend	—	—
Net loss attributable to common shareholders	$ (25.5)	$ (3.4)
Basic and diluted loss per share	$ (0.06)	$ (0.01)

	For the six months ended June 30,	
	2014	2013
Revenues	$ 45.8	$ 55.2
Costs and expenses	111.0	80.0
Operating loss	(65.2)	(24.8)
Other income and (expense), net	(2.8)	(7.1)
Loss before income taxes and investment losses	(68.0)	(31.9)
Benefit from (provision for) income taxes	(0.7)	(1.0)
Loss before investment losses	(68.7)	(32.9)
Loss from investments in investees	(2.4)	(6.2)
Net loss	(71.1)	(39.1)
Less: Net loss attributable to non-controlling interests	(1.1)	(1.5)
Preferred stock dividend	—	(0.4)
Net loss attributable to common shareholders	$ (70.0)	$ (38.0)
Basic and diluted loss per share	$ (0.17)	$ (0.12)

Exhibit 99.2

Rayaldee™ Phase 3 Trial Meets Primary Endpoints

- Top-line Data from Second Identical Pivotal Phase 3 Trial Expected in September 2014
- New Drug Application (NDA) Submission to the U.S. FDA on Track for End of 2014

MIAMI— August 11, 2014 — OPKO Health, Inc. (NYSE: OPK), announced successful top-line results from the first pivotal phase 3 trial of Rayaldee. This trial is one of two identical randomized, double-blind, placebo-controlled, multi-site studies intended to establish the safety and efficacy of Rayaldee as a new treatment for secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency. Both trials are the subject of a Special Protocol Assessment (SPA) established with the United States (U.S.) Food and Drug Administration (FDA) in August 2012.

“Top-line data from this study demonstrate that Rayaldee effectively controls secondary hyperparathyroidism in patients with stage 3 or 4 chronic kidney disease by correcting vitamin D insufficiency,” stated Joel Z. Melnick, MD, Vice President of Clinical Research and Development for OPKO’s Renal Division. “Rayaldee was equally effective in both disease stages, indicating that this new therapy is appropriate even for patients with minimal functioning kidney mass.”

This trial involved 213 adult patients recruited from 39 sites throughout the U.S. Patients were stratified by CKD stage and randomized in a 2:1 fashion to receive six months of treatment with either Rayaldee or placebo. On enrollment, all patients exhibited vitamin D insufficiency which was corrected in 96% of patients treated with Rayaldee.

The completed trial successfully met all primary efficacy and safety endpoints. The primary efficacy endpoint was a responder analysis in which “responder” was defined as any treated subject who demonstrated an average 30% decrease in plasma parathyroid hormone (PTH) from pre-treatment baseline during the last six weeks of the treatment period. A significantly higher response rate ($p<0.001$) was observed with Rayaldee which steadily increased with treatment duration. The response rate with Rayaldee was similar in CKD stages 3 and 4. Safety and tolerability data were comparable in both treatment groups.

“Rayaldee is designed to fill a void in the treatment armamentarium of nephrologists and endocrinologists who care for pre-dialysis chronic kidney disease patients,” commented Dr. Charles W. Bishop, CEO of OPKO’s Renal Division. “Controlled trials have shown that over-the-counter and prescription vitamin D supplements are ineffective in treating SHPT in these patients and are, at best, unreliable in correcting vitamin D insufficiency. On the other hand, vitamin D hormone drugs can effectively treat SHPT but, due to high potency, often oversuppress PTH, increasing the risk of adynamic bone disease and vascular calcification. These hormone drugs are entirely ineffective in treating vitamin D insufficiency, the underlying cause of SHPT in most pre-dialysis patients. Rayaldee addresses a long-standing unmet need to safely control SHPT by reliably correcting vitamin D insufficiency.”

“Physicians will embrace a product that does what we want, namely, treat vitamin D insufficiency and gradually correct elevated PTH, without safety concerns,” stated David A. Bushinsky, MD, Chief, Nephrology Division, University of Rochester Medical Center. “Data from this first pivotal trial indicate that Rayaldee may be such a product, and I look forward to confirmation from the second identical trial.”

Top-line data from the second, identical pivotal phase 3 trial are expected to be available in September 2014.

Patients completing the two pivotal trials are being treated, at their election, for an additional 6 months with Rayaldee during an ongoing open-label extension study. Enrollment in this extension study surpassed the targeted level of 270 patients by May 2014 and 141 patients have completed participation.

“Rayaldee is the lead candidate in a growing portfolio of products that OPKO is developing in its Renal Division for global commercialization,” explained Dr. Phillip Frost, Chairman and CEO of OPKO Health. “Rayaldee provides an excellent solution to the problem of secondary hyperparathyroidism associated with vitamin D insufficiency for more than 4 million CKD patients in the U.S. and many more elsewhere.”

A New Drug Application (NDA) submission to the U.S. FDA is on track for the end of 2014.

About Rayaldee™

Rayaldee is a first-in-class oral vitamin D prohormone treatment being developed for SHPT in patients with stage 3 or 4 CKD and vitamin D insufficiency. It has a proprietary modified-release formulation designed to gradually and reliably raise serum total 25-hydroxyvitamin D (prohormone) concentrations to targeted levels (at least 30 ng/mL) while avoiding upregulation of CYP24, a cytochrome P-450 enzyme that reduces the PTH-lowering potency of current vitamin D supplements. Activation of calcifediol, the active ingredient in Rayaldee, by the kidney is tightly regulated, preventing excessive elevation of serum calcium and related side effects which limit the value of current vitamin D hormone therapies by promoting vascular and renal calcification. Rayaldee is expected to address the approximately 4 million patients in the U.S., and many more elsewhere, with stage 3 or 4 CKD, SHPT and vitamin D insufficiency.

About Chronic Kidney Disease

CKD is a condition characterized by a progressive decline in kidney function. The kidney is normally responsible for excreting waste and excess water from the body, and for regulating various hormones. CKD is classified in five different stages — mild (stage 1) to severe (stage 5) disease — as measured by the kidney’s glomerular filtration rate. According to the National Kidney Foundation, CKD afflicts over 26 million people in the U.S., including more than eight million patients with moderate (stages 3 or 4) and severe (stage 5) forms of CKD. In stage 5 CKD, kidney function is minimal to absent and patients require regular dialysis or a kidney transplant for survival.

About Vitamin D Insufficiency

Vitamin D insufficiency is a condition in which the body has low vitamin D stores, characterized by inadequate blood levels of vitamin D prohormone, known as 25-hydroxyvitamin D. An estimated 70-90% of CKD patients have vitamin D insufficiency, which can lead to SHPT and resultant debilitating bone diseases. Vitamin D insufficiency has been associated with increased mortality in CKD.

About Secondary Hyperparathyroidism (SHPT)

SHPT is a condition commonly associated with CKD in which the parathyroid glands secrete excessive amounts of PTH. SHPT arises as a result of vitamin D insufficiency or impaired kidney function that prevents sufficient production of vitamin D hormone to properly regulate calcium and phosphorus metabolism, and PTH secretion. Prolonged elevation of blood PTH causes excessive calcium and phosphorus to be released from bone, leading to elevated serum calcium and phosphorus, softening of the bones (osteomalacia) and calcification of vascular and renal tissues. SHPT affects 40-60% of patients with moderate CKD and approximately 90% of patients with severe CKD. Vitamin D therapy for SHPT is associated with reduced mortality in CKD patients.

About Special Protocol Assessment

The Special Protocol Assessment (SPA) provided a mechanism for the FDA and OPKO to reach agreement on the design, size, execution and analysis of the two pivotal phase 3 trials with Rayaldee. The FDA agreed that the design and planned analysis of these studies adequately addressed the objectives necessary to support an NDA submission.

About OPKO

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry leading positions in large, rapidly growing markets by leveraging its discovery, development and commercialization expertise and 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), regarding product development efforts and other non-historical facts about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects, including statements regarding our ability to successfully launch and commercialize proprietary renal disease products, expectations about Rayaldee™, its market potential, that it will address the approximately 4 million CKD stage 3 and 4 patients in the U.S. and many more elsewhere, with SHPT and vitamin D insufficiency, that Rayaldee™ will treat vitamin D insufficiency and gradually correct elevated PTH, without safety concerns, and that we will be able to successfully develop, obtain approval for and launch sales of Rayaldee™. 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 risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, including the risks that the phase 3 clinical trials for Rayaldee™ may not be successful or achieve the expected results or effectiveness, and may not generate data that would support the approval or marketing of this product for the indications being studied, that others may develop products which are superior to Rayaldee™, and that Rayaldee™ may not have advantages or prove to be superior over presently marketed products, including the currently used high monthly doses of prescription vitamin D2, activated vitamin D hormone and over-the-counter vitamin D supplements . 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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