UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): June 21, 2016

OPKO Health, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-33528	75-2402409
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. 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

Not Applicable

Former name or former address, if changed since last report

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:

[ ] 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))

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Item 7.01 Regulation FD Disclosure.

On June 21, 2016, OPKO Health, Inc., a Delaware corporation (the "Company"), issued a press release announcing that the U.S. Food and Drug Administration approved the Company's New Drug Application for RAYALDEE® (calcifediol) for the treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease and serum total 25-hydroxyvitamin D levels less than 30 ng/mL.

A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company dated June 21, 2016

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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.

June 21, 2016

By: Adam Logal

Name: Adam Logal
Title: Senior Vice President-Chief Financial Officer

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Exhibit No.	Description
99.1	Press Release of the Company dated June 21, 2016

FDA Approves New Drug Application for RAYALDEE® to Treat Secondary Hyperparathyroidism Associated with Vitamin D Insufficiency in Stage 3-4 Chronic Kidney Disease

Approval Based Upon Two Randomized, Double Blind, Placebo Controlled Trials and an Open Label Extension Study
There are Approximately 9 Million Patients in the U.S. with SHPT, Stage 3 or 4 CKD and Vitamin D Insufficiency; Large Potential U.S. Market

U.S. Launch Planned for 2H 2016

MIAMI (June 21, 2016) – OPKO Health, Inc. (NYSE: OPK) announced that the U.S. Food and Drug Administration (FDA) has approved RAYALDEE® (calcifediol) extended release capsules for the treatment of secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. RAYALDEE is a patented extended release product containing 30 mcg of a prohormone called calcifediol (25-hydroxyvitamin D_3).

"FDA's approval of RAYALDEE represents an important milestone for OPKO," noted Dr. Phillip Frost, CEO and Chairman of OPKO. "RAYALDEE is the first product to receive FDA approval for this important indication and is one of OPKO's many pharmaceutical products being developed for significant medical problems which will benefit from new treatment options."

Results from two 26 week placebo controlled, double blind phase 3 trials demonstrated that a larger proportion of stage 3 or 4 CKD patients with SHPT and vitamin D insufficiency achieved 30% reductions in plasma intact parathyroid hormone (iPTH) when treated with RAYALDEE than with placebo. Vitamin D insufficiency was corrected in more than 80% of the patients receiving RAYALDEE compared with less than 7% of subjects receiving placebo. Mean serum calcium and phosphorus levels increased by 0.1 mg/dL during RAYALDEE treatment compared to placebo treatment, but these changes were deemed clinically irrelevant. No differences in RAYALDEE's efficacy or safety were observed between patients with stage 3 CKD or stage 4 CKD.

"RAYALDEE fills a large void in the current treatment options for SHPT in predialysis patients," commented Dr. Charles W. Bishop, CEO of OPKO's Renal Division. "The current standard of care is high dose vitamin D supplementation, an approach for treating SHPT that is neither FDA approved nor demonstrated to be safe and effective in this population. SHPT is a progressive disease that becomes increasingly debilitating and difficult to treat, necessitating timely and effective treatment."

"RAYALDEE is an important new option for treating SHPT in patients with stage 3 or 4 CKD and vitamin D insufficiency," stated Kevin J. Martin, Director of Research, Division of Nephrology at Saint Louis University School of Medicine. "The great majority of SHPT cases in this patient population are associated with vitamin D insufficiency, a problem that RAYALDEE can correct."

About RAYALDEE

RAYALDEE (calcifediol) extended release capsules are approved by the U.S. Food and Drug Administration (FDA) for the treatment of SHPT in adult patients with stage 3 or 4 CKD and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. RAYALDEE has a patented formulation designed to raise serum total 25-hydroxyvitamin D (prohormone) concentrations to targeted levels (at least 30 ng/mL) and to reduce elevated iPTH. OPKO expects to launch RAYALDEE in the U.S. through its dedicated renal sales force in the second half of 2016. RAYALDEE is not indicated in patients with stage 5 chronic kidney disease or end-stage renal disease on dialysis. The full prescribing information for RAYALDEE will be available at www.opkorenal.com.

Potential side effects of RAYALDEE include hypercalcemia (elevated serum calcium), which can also lead to digitalis toxicity, and adynamic bone disease with subsequent increased risk of fractures if intact PTH levels are suppressed by RAYALDEE to abnormally low levels. Severe hypercalcemia may require emergency attention; symptoms of hypercalcemia may include feeling tired, difficulty thinking clearly, loss of appetite, nausea, vomiting, constipation, increased thirst, increased urination, and weight loss. Digitalis toxicity can be potentiated by hypercalcemia of any cause. Excessive administration of RAYALDEE can cause hypercalciuria, hypercalcemia, hyperphosphatemia, or oversuppression of intact PTH. Common symptoms of vitamin D overdosage may include constipation, decreased appetite, dehydration, fatigue, irritability, muscle weakness, or vomiting. Patients concomitantly taking cytochrome P450 inhibitors, thiazides, cholestyramine, phenobarbital or other anticonvulsants may require dose adjustments and more frequent monitoring.

The most common adverse reactions in clinical trials (3% and more frequent than placebo) were anemia, nasopharyngitis, increased blood creatinine, dyspnea, cough, congestive heart failure and constipation.

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 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 20 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. Rayaldee is only indicated for treating SHPT in patients with stage 3 or stage 4 CKD.

About Secondary Hyperparathyroidism (SHPT)

SHPT is a condition commonly associated with CKD in which the parathyroid glands secrete excessive amounts of parathyroid hormone (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.

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 25D. 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 OPKO Health, Inc.

OPKO Health, Inc. is a diversified healthcare company that seeks to establish industry leading positions in large, rapidly growing markets. Our diagnostics business includes Bio-Reference Laboratories, the nation's third largest clinical laboratory with a core genetic testing business and a 420-person sales force 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 SHPT in stage 3-4 CKD patients with vitamin D insufficiency, and VARUBI™ for chemotherapy induced nausea and vomiting (oral formulation launched by partner Tesaro and IV formulation PDUFA date: January 2017). Our biologics business includes hGH-CTP, a once weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), and a long acting Factor VIIa drug for hemophilia (Phase 2a). We also have production and distribution assets worldwide, multiple strategic investments and an active business development strategy. More information is available at www.opko.com.

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 RAYALDEE, our ability to successfully launch and commercialize RAYALDEE and our other products under development *, expectations about RAYALDEE* and its market size and potential*, that RAYALDEE will effectively control SHPT in patients with stage 3 or 4 CKD by correcting vitamin D insufficiency, that RAYALDEE fills a large void in the current treatment options for SHPT in predialysis patients, whether RAYALDEE will be highly effective in correcting vitamin D insufficiency, and that we will be able to successfully launch sales of RAYALDEE in the second half of 2016. 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 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 D_2, 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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