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): March 30, 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 8.01. Other Matters.

On March 30, 2016, OPKO Health, Inc., a Delaware corporation (the "Company"), issued a press release announcing that the U.S. Food and Drug Administration ("FDA") issued a Complete Response Letter ("CRL") to the Company's New Drug Application for RAYALDEE®.

The FDA indicated in the CRL that observations of deficiencies at OPKO's third-party contract manufacturer were issued on March 25, 2016 as a result of an FDA field inspection initiated on March 14, 2016. The observations were not specific to RAYALDEE manufacturing. The CRL did not cite any safety, efficacy or labeling issues with regard to RAYALDEE, nor did it request any additional studies to be conducted prior to FDA approval.

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 March 30, 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.

March 30, 2016

By: Adam Logal

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

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Exhibit Index

Exhibit No.	Description
99.1	Press Release of the Company dated March 30, 2016

Exhibit 99.1

OPKO Receives Complete Response Letter from FDA for RAYALDEE ® New Drug Application

Sole issue relates to third-party manufacturing observations
No new clinical studies requested
No safety or efficacy issues identified
Management to host conference call today at 8:30 a.m. Eastern time

MIAMI (March 30, 2016) – OPKO Health, Inc. (NYSE: OPK)announces that the U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) to the Company's New Drug Application (NDA) for RAYALDEE® (calcifediol) as a treatment for secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency.

The FDA indicated in the CRL that observations of deficiencies at OPKO's third-party contract manufacturer were issued on March 25, 2016 as a result of an FDA field inspection initiated on March 14, 2016. The observations were not specific to RAYALDEE manufacturing. The CRL did not cite any safety, efficacy or labeling issues with regard to RAYALDEE, nor did it request any additional studies to be conducted prior to FDA approval.

The Company's third-party manufacturer has committed to respond promptly to the FDA's observations to ensure early resolution.

In the CRL, FDA has re-confirmed the acceptance of the proprietary name RAYALDEE. The FDA also reached agreement with OPKO for an approvable package insert and all container labeling.

"OPKO is committed to bringing RAYALDEE to patients who will benefit from its intended use and will work closely with the FDA and our third-party manufacturer to ensure that the inspection observations are promptly and fully addressed," noted Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "We will continue to build our commercial sales organization in preparation for the earliest possible RAYALDEE launch."

CONFERENCE CALL & WEBCAST INFORMATION

WHEN: Wednesday, March 30, 2016 at 8:30 a.m. Eastern time
DOMESTIC DIAL-IN: (866) 634-2258
INTERNATIONAL DIAL-IN: (330) 863-3454
PASSCODE: 81841862
WEBCAST: www.opko.com

For those unable to participate in the live conference call or webcast, a replay will be available beginning March 30, 2016 at 11:30 a.m. Eastern time for a period of time. To access the replay, dial (855) 859-2056 or (404) 537-3406. The replay passcode is: 81841862. The replay can also be accessed for a period of time on OPKO's website at www.opko.com.

About RAYALDEE

RAYALDEE (calcifediol) extended-release capsules are being developed 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 proprietary formulation designed to raise serum total 25-hydroxyvitamin D (prohormone) concentrations to targeted levels (at least 30 ng/mL) and to reduce elevated iPTH.

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.

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, a treatment for SHPT in stage 3-4 CKD patients with vitamin D insufficiency, and VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation approved by FDA and launched by partner Tesaro, IV formulation in Phase 3). 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 (in 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 obtain regulatory approval for and launch RAYALDEE, expectations about RAYALDEE, that RAYALDEE will effectively control secondary hyperparathyroidism in patients with stage 3 or 4 chronic kidney disease by correcting vitamin D insufficiency, the expected market potential for RAYALDEE, whether adequate responses to the FDA observations will be timely submitted for early resolution, whether we will successfully build out our commercial sales organization, and our expected approval and launch dates for 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 our third party manufacturer may not be able to resolve the deficiencies noted by the FDA in a timely matter or at all, that the FDA could identify additional issues that affect our ability to obtain regulatory approval, that the phase 3 clinical trials for RAYALDEE may not have generated data that would support the approval or marketing of this product for the indications being pursued, 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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