

Opko Health, Inc.
Form 8-K
March 30, 2016

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

(State or other jurisdiction
of incorporation)

001-33528

(Commission
File Number)

75-2402409

(I.R.S. Employer
Identification No.)

4400 Biscayne Blvd., Miami, Florida

(Address of principal executive offices)

33137

(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