

Opko Health, Inc.
Form 8-K
June 21, 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):

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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| <u>Exhibit No.</u> | <u>Description</u> |
|---------------------------|--|
| 99.1 | Press Release of the Company dated June 21, 2016 |