

Opko Health, Inc.
Form 8-K
October 12, 2017

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): October 12, 2017

OPKO Health, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other

Jurisdiction of

Incorporation)

001-33528
(Commission

File Number)

4400 Biscayne Blvd

75-2402409
(IRS Employer

Identification No.)

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Miami, Florida 33137

(Address of Principal Executive Offices) (Zip Code)

(305) 575-4100

Registrant's telephone number, including area code

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 (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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01. Entry into a Material Definitive Agreement.

On October 12, 2017, EirGen Pharma Limited (*EirGen*), an entity formed under the laws of Ireland and a subsidiary of OPKO Health, Inc., a Delaware corporation (*OPKO*), and Japan Tobacco Inc., an entity formed under the laws of Japan (*JT*), entered into a Development and License Agreement (the *Agreement*) granting JT the exclusive rights for the development and commercialization of extended release calcifediol (the *Product*) in Japan (the *Territory*). Extended release calcifediol is marketed in the United States under the tradename RAYALDEE® by OPKO. The license grant to JT covers the therapeutic and preventative use of the Product for (i) secondary hyperparathyroidism (SHPT) in non-dialysis and dialysis patients with chronic kidney disease, (ii) rickets, and (iii) osteomalacia (the *Initial Indications*), as well as such additional indications as may be added to the scope of the license subject to the terms of the Agreement (the *Additional Indications*), and together with the Initial Indications, the *Field*).

OPKO will receive an initial upfront payment of \$6 million. OPKO will receive another \$6 million upon the initiation of OPKO's planned phase 2 study for RAYALDEE in dialysis patients in the U.S. OPKO is also eligible to receive up to an additional aggregate amount of \$31 million upon the achievement of certain regulatory and development milestones by JT for the Product in the Territory, and \$75 million upon the achievement of certain sales based milestones by JT in the Territory. OPKO will also receive tiered, double digit royalty payments at rates ranging from low double digits to mid-teens on net product sales within the Territory and in the Field.

As part of the arrangement, JT and OPKO agree to form a joint steering committee responsible for overseeing activities under the Agreement, and a joint development committee responsible for overseeing the development and regulatory approval of the Products in the Field in the Territory. JT will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for the Product in Japan and for all commercial activities pertaining to the Product in Japan, except for certain preclinical expenses which OPKO has agreed to reimburse JT up to a capped amount.

Unless earlier terminated, the Agreement will remain in effect until such time as all royalty payment terms and extended payment terms have expired, and JT shall have no further payment obligations to OPKO under the terms of the Agreement. JT's royalty obligations expire on the later of (i) expiration of the last to expire valid patent claim covering the Product sold in Japan, (ii) expiration of all regulatory and data exclusivity applicable to the Product in Japan, and (iii) if the indication first approved for the first Product is SHPT, ten (10) years after such Product's first commercial sale in Japan, and four (4) years from the first commercial sale for any subsequent Product in Japan. In addition to termination rights for material breach and bankruptcy, JT is permitted to terminate the Agreement after a specified notice period.

OPKO has guaranteed the performance of certain of EirGen's obligations under the Agreement.

A copy of the press release announcing the Agreement is attached hereto as Exhibit 99.1 and incorporated by reference herein.

The foregoing description is a summary only and is qualified in its entirety by reference to the Agreement, which will be filed as an exhibit to OPKO's Annual Report on Form 10-K for the period ending December 31, 2017.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit No. | Description |
|------------------------|----------------------------------------------|
| 99.1 | Press Release of OPKO dated October 12, 2017 |

Exhibit Index

| Exhibit No. | Description |
|------------------------|-----------------------------------------------------|
| 99.1 | <u>Press Release of OPKO dated October 12, 2017</u> |

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: October 12, 2017

By /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President,

Chief Financial Officer