Opko Health, Inc.
Form 8-K
May 09, 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): May 8, 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**
		(Zip Code)

(Address of principal executive offices)

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))

Item 1.01 Entry into a Material Definitive Agreement.

Development and License Agreement between EirGen Pharma Limited and Vifor Fresenius Medical Care Pharma Ltd

On May 8, 2016, EirGen Pharma Limited (EirGen), an entity formed under the laws of Ireland and a subsidiary of OPKO Health, Inc., a Delaware corporation (OPKO), and Vifor Fresenius Medical Care Pharma Ltd, an entity formed under the laws of Switzerland (VFMCRP), entered into a Development and License Agreement (the Agreement) for the development and marketing of RAYALDEE® (the Product) worldwide, except for (i) the United States, (ii) any country in Central America or South America (excluding Mexico), (iii) Russia, (iv) China, (v) Japan, (vi) Ukraine, (vii) Belorussia, (viii) Azerbaijan, (ix) Kazakhstan, and (x) Taiwan (the Territory). The license to VFMCRP potentially covers all therapeutic and prophylactic uses of the Product in humans (the Field), provided that initially the license is for the use of the Product for the treatment or prevention of secondary hyperparathyroidism related to patients with stage 3 or 4 chronic kidney disease and vitamin D insufficiency/deficiency (the Initial Indication).

Under the terms of the Agreement, EirGen granted to VFMCRP an exclusive license in the Territory in the Field to use certain EirGen patents and technology to make, have made, use, sell, offer for sale, and import Products and to develop, commercialize, have commercialized, and otherwise exploit the Product. EirGen will receive an initial payment of $50 million within ten (10) business days after the effective date of the Agreement. EirGen is also eligible to receive up to an additional aggregate amount of $232 million upon the achievement of certain regulatory and sales-based milestones and will receive tiered, double digit royalty payments upon the commencement of sales of the Product within the Territory and in the Field.

As part of the arrangement, the companies will share responsibility for the conduct of trials specified within an agreed-upon development plan, with each company leading certain activities within the plan. EirGen will lead the manufacturing activities within and outside the Territory and the commercialization activities outside the Territory and outside the Field in the Territory and VFMCRP will lead the commercialization activities in the Territory and the Field. Development activities under the collaboration will be managed through a shared governance structure with both companies having equal representation on a joint steering committee. For the initial development plan agreed to by the companies, the companies have agreed to certain cost sharing arrangements. VFMCRP will be responsible for all other development costs that VFMCRP considers necessary to develop the Product for the use of the Product for the Initial Indication in the Territory in the Field except as otherwise provided in the Agreement.

The Agreement will remain in effect with respect to the Product in each country of the Territory, on a country by country basis, until the date on which VFMCRP shall have no further payment obligations to EirGen under the terms of the Agreement, unless earlier terminated pursuant to the Agreement. VFMCRP s royalty obligations expire on a country-by-country and product-by-product basis on the later of (i) expiration of the last to expire valid claim covering the Product sold in such country, (ii) expiration of all regulatory and data exclusivity applicable to the Product in the country of sale, and (c) ten (10) years after the Product first commercial sale in such country. In addition to termination rights for material breach and bankruptcy, VFMCRP is permitted to terminate the Agreement in its entirety, or with respect to one or more countries in the Territory, after a specified notice period provided that VFMCRP shall not have the right to terminate the Agreement with respect to certain major countries without terminating the entire Agreement. If the Agreement is terminated by EirGen or VFMCRP, provision has been made for transition of product and product responsibilities to EirGen.

In connection with the Agreement, the parties entered into a letter agreement (the Letter Agreement) pursuant to which EirGen granted to VFMCRP an exclusive option (the Option) to acquire an exclusive license under certain EirGen patents and technology to use, import, offer for sale, sell, distribute and commercialize Product in the United States solely for treatment of secondary hyperparathyroidism in dialysis patients with chronic kidney disease patients and vitamin D insufficiency (the Dialysis Indication). Upon exercise of the Option, VFMCRP will reimburse EirGen for all of the development costs incurred by EirGen with respect to the Product for the Dialysis Indication in the

United States. VFMCRP would also pay EirGen up to an additional aggregate amount of $555 million upon the achievement of certain milestones and would be obligated to pay certain double digit royalties on VFMCRP s sales in the United States for the Dialysis Indication.

The Option is exercisable until the earlier of (i) the date that EirGen submits a new drug application or supplemental new drug application or their then equivalents to the U.S. Food and Drug Administration for the Product for the Dialysis Indication in the United States, (ii) the parties mutually agree to discontinue development of Product for the Dialysis Indication, or (iii) VFMCRP provides notice to OPKO that it has elected not to exercise the Option.

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

A copy of the press release announcing the Agreement and Letter 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 and the Letter Agreement, which will be filed as an exhibit to OPKO s Quarterly Report on Form 10-Q for the period ending June 30, 2016.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release of OPKO dated May 9, 2016

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.

May 9, 2016

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

EXHIBIT INDEX

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