Opko Health, Inc.
Form 8-K
December 15, 2014

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): December 13, 2014

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 1.01 Entry into a Material Definitive Agreement.

On December 13, 2014, OPKO Health, Inc. (OPKO), OPKO Ireland Ltd. (OPKO Ireland , and together with OPKO, the Company), and Pfizer, Inc. (Pfizer) entered into a Development, Commercialization License Agreement (the Agreement) for the Company s long-acting human growth hormone product (hGH-CTP) for the treatment of growth hormone deficiency (GHD).

Under the terms of the Agreement, the Company granted to Pfizer an exclusive license under applicable patents, patent applications, and know-how owned by OPKO to develop, commercialize, and manufacture hGH-CTP. The Company will receive an initial payment of $295 million within fifteen (15) days of closing, a portion of which will be used by OPKO to fund research and development expenses. OPKO is also eligible to receive up to an additional $275 million upon the achievement of certain regulatory milestones.

Under the Agreement, the Company is eligible to receive tiered, double digit royalty payments upon commencement of sales of hGH-CTP for adult GHD. Upon the approval and launch of hGH-CTP for pediatric GHD in certain major markets, the Agreement will convert into a regional tiered profit sharing arrangement covering sales of hGH-CTP and Pfizer s Genotropin® for all indications in the applicable region.

As part of the strategic collaboration, the companies will share responsibility for the conduct of trials specified within an agreed-upon global development plan, with each company leading certain activities within the plan. OPKO will lead the clinical activities and Pfizer will lead the manufacturing activities covered by the global development plan. Development activities under the global collaboration will be managed through a shared governance structure with both companies having equal representation on a joint steering committee. For the initial global development plan agreed to by the companies, OPKO will fund their development activities subject to an agreed upon cap. Costs in excess of the cap will be allocated between the parties in accordance with the Agreement. Pfizer will be responsible for all development costs for additional markets and indications that are not part of the development plan, as well as all post-marketing studies and commercialization activities.

The Agreement will remain in effect until the last sale of the Licensed Product, unless earlier terminated as permitted under the Agreement. In addition to termination rights for material breach and bankruptcy, Pfizer is permitted to terminate the Agreement in its entirety, or with respect to one or more world regions, without cause after a specified notice period. If the Agreement is terminated by OPKO for Pfizer s uncured material breach, or by Pfizer without cause, provision has been made for transition of product and product responsibilities to OPKO for the terminated regions, as well as continued supply of product by Pfizer or transfer of supply to OPKO in order to support continued development and commercialization of product.

The transaction is subject to clearance by the U.S. antitrust authorities under the Hart-Scott-Rodino Act and is expected to become final as soon as such clearance has occurred.

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 the Company s Annual Report on Form 10-K for the year ending December 31, 2014.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company dated December 15, 2014

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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.

December 15, 2014

By: Adam Logal

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

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