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**
(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))

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

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

Exhibit 99.1

Media Information

Date 9 May 2016

Contact VFMCRP: Beatrix Benz, Head Global Communications
OPKO: Steven Rubin, EVP, Administration

Subject Vifor Fresenius Medical Care Renal Pharma acquires marketing rights to RAYALDEE ®

Vifor Fresenius Medical Care Renal Pharma and OPKO Health Enter into Agreement for OPKO's RAYALDEE®

- **Vifor Fresenius Medical Care Renal Pharma obtains rights to commercialize RAYALDEE® in Europe, Canada and certain other international markets**
- **OPKO to receive up to USD 282 million in upfront and milestone payments, plus tiered double-digit royalties**
- **OPKO and Vifor Fresenius Medical Care Renal Pharma to jointly develop RAYALDEE® for dialysis patients**

St. Gallen, Switzerland, and Miami, FL – Vifor Fresenius Medical Care Renal Pharma (VFMCRP), a common company of Galenica and Fresenius Medical Care, and OPKO Health (NYSE: OPK), have entered into a collaboration and license agreement for the development and commercialization of RAYALDEE® in Europe, Canada, Mexico, Australia, South Korea and certain other international markets for the treatment of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) and vitamin D insufficiency. Under the terms of the agreement, the parties will also collaborate to develop and commercialize RAYALDEE® for the treatment of SHPT in dialysis patients, and OPKO has granted VFMCRP an option to acquire rights to the US market for treatment of dialysis patients.

"Vifor Fresenius Medical Care Renal Pharma is a leader in chronic kidney disease and we believe they are the ideal partner to bring RAYALDEE® to patients across Europe and other territories," said Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "We believe further developing RAYALDEE® for dialysis patients is an important additional step in the care of chronic kidney disease patients," Dr. Frost continued.

"Managing bone and mineral disorders in CKD patients remains a challenge for physicians despite the treatment options already available to them. The clinical data for RAYALDEE® show promising safety and efficacy and we strongly believe that once approved, RAYALDEE® will become a cornerstone therapy to better address this key co-morbidity and improve the well-being of chronic kidney disease patients," said Stefan Schulze, Chief Executive Officer of VFMCRP.

SHPT is a common disorder in CKD patients triggered by vitamin D insufficiency, which can cause reduced vitamin D hormone production, decreased intestinal absorption of dietary calcium, increased secretion of parathyroid hormone (PTH), and metabolic bone disease. Using current treatment options, most patients underachieve control of both vitamin D insufficiency and SHPT, leading to a range of bone and mineral disorders.

RAYALDEE® is an oral vitamin D prohormone treatment in a modified release capsule being developed by OPKO. VFMCRP has entered into an exclusive license agreement with OPKO to co-develop and commercialize RAYALDEE® in leading markets around the world, including Europe (except Russia), Canada, Mexico, Australia and South Korea. OPKO retains all rights in the US, Latin America (excluding Mexico), Russia, China, Taiwan and Japan. The two companies will also collaborate to prepare the Marketing Authorization Application (MAA) submission to the European Medicines Agency (EMA).

Vifor Fresenius Medical Care Renal Pharma Ltd.
Rechenstrasse 37 • P.O. Box • CH-9001 St. Gallen

Under the agreement, VFMCRP will make an upfront payment to OPKO of USD 50 million, plus up to an additional USD 52 million in regulatory and launch milestones, and USD 180 million in sales-based milestones. In addition, VFMCRP will pay OPKO tiered, double-digit royalties on sales of the product. In the event VFMCRP exercises its option for rights to the US dialysis market, VFMCRP will pay OPKO additional commercial-based milestones, as well as double-digit royalties.

OPKO submitted a New Drug Application (NDA) for RAYALDEE® to the US Food and Drug Administration (FDA) in 2015 for the treatment of SHPT in patients with stage 3 or 4 CKD and vitamin D insufficiency. On 29 March 2016, the FDA indicated in a Complete Response Letter (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 labelling issues with regard to RAYALDEE®, nor did it request that additional studies be conducted prior to FDA approval. OPKO subsequently resubmitted its NDA to the FDA, and the FDA accepted OPKO's resubmission on April 22, 2016. The new Prescription Drug User Fee Act (PDUFA) date is October 22, 2016.

The NDA is supported by data from three randomized, double-blind, placebo-controlled studies and one open label extension study conducted in the targeted patient population at 105 US sites.

These studies met all primary efficacy and safety endpoints, confirming the anticipated product profile of RAYALDEE's ability to correct vitamin D insufficiency and treat SHPT without meaningfully increasing serum calcium or phosphorus levels.

For further information, please contact:

Vifor Fresenius Medical Care Renal Pharma, Media Relations:
Beatrix Benz, Head of Global Communications & Public Affairs
Tel.: +41 58 851 80 16
E-mail: media@viforpharma.com

OPKO Health, Inc.:
Investor relations:
Tara Mackay: +1 305-575-4100

Media—Rooney & Associates
Terry Rooney: +1 212-223-0689; trooney@rooneyco.com
Marion Janic: +1 212-223-4017; mjanic@rooneyco.com

Investors – LHA
Anne Marie Fields: +1 212-838-3777; afields@lhai.com
Bruce Voss, +1 310-691-7100; bvoss@lhai.com

RAYALDEE® *(calcifediol) extended-release capsules are being developed for the treatment of SHPT in adult patients with stage 3 or 4 CKD and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. RAYALDEE® has a proprietary formulation designed to raise serum total 25-hydroxyvitamin D (prohormone) concentrations to targeted levels (at least 30 ng/mL) and to reduce elevated iPTH (intact parathyroid hormone).*

Chronic Kidney Disease *(CKD) is a condition characterized by a progressive decline in kidney function. The kidney is normally responsible for excreting waste and excess water from the body, and for regulating various hormones. CKD is classified in five stages – mild (stage 1) to severe (stage 5) disease – as measured by the kidney's glomerular filtration rate. According to the National Kidney Foundation, CKD afflicts over 26 million people in the US, including more than 20 million patients with moderate (stages 3 or 4) and severe (stage 5) forms of CKD. In stage 5 CKD, kidney function is minimal to absent and patients require regular dialysis or a kidney transplant for survival.*

Vitamin D Insufficiency *is a condition in which the body has low vitamin D stores, characterized by inadequate blood levels of vitamin D prohormone, known as 25D. An estimated 70-90% of CKD patients have vitamin D insufficiency, which can lead to SHPT and resultant debilitating bone diseases. Vitamin D insufficiency has been associated with increased mortality in CKD.*

Secondary Hyperparathyroidism (SHPT) *is a condition commonly associated with CKD in which the parathyroid glands secrete excessive amounts of parathyroid hormone (PTH). SHPT arises as a result of vitamin D insufficiency or impaired kidney function that prevents sufficient production of vitamin D hormone to properly regulate calcium and phosphorus metabolism, and PTH secretion.*

Prolonged elevation of blood PTH causes excessive calcium and phosphorus to be released from bone, leading to elevated serum calcium and phosphorus, softening of the bones (osteomalacia) and calcification of vascular and renal tissues. SHPT affects 40-60% of patients with moderate CKD and approximately 90% of patients with advanced CKD.

Vifor Fresenius Medical Care Renal Pharma Ltd.*, a common company of Galenica and Fresenius Medical Care, develops and commercialises innovative and high quality therapies to improve the life of patients suffering from CKD worldwide. The company was founded at the end of 2010 and is owned 55% by Galenica and 45% by Fresenius Medical Care.*

OPKO Health, Inc. *is a diversified healthcare company that seeks to establish industry-leading positions in large, rapidly growing markets. OPKO's diagnostics business includes BioReference Laboratories, the third-largest clinical laboratory in the US with a core genetic testing business and a 420-person sales force to drive growth and leverage new products, including the 4Kscore® prostate cancer test and the Claros®1 in office immunoassay platform. OPKO's pharmaceutical business features RAYALDEE, a treatment for SHPT in stage 3-4 CKD patients with vitamin D insufficiency, and VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation approved by FDA and launched by partner Tesaro, IV formulation in Phase 3). OPKO's biologics business includes hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), and a long-acting Factor VIIa drug for hemophilia (in Phase 2a). OPKO also has production and distribution assets worldwide, multiple strategic investments and an active business development strategy. More information is available at* www.opko.com.

Safe Harbor Statement

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), regarding product development efforts and other non-historical facts about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects, including statements regarding expectations about RAYALDEE and the success of the collaboration and licensing agreement, whether the parties will obtain regulatory approval for, launch or successfully commercialize RAYALDEE, whether the parties will successfully develop RAYALDEE for the treatment of SHPT in dialysis patients, that RAYALDEE will effectively control SHPT in patients with stage 3 or 4 CKD by correcting vitamin D insufficiency, that RAYALDEE will improve the well-being of CKD patients, whether payment milestones and royalty obligations will ever be triggered, and the expected market for RAYALDEE. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in OPKO's filings with the Securities and Exchange Commission, as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, including the risks that the phase 3 clinical trials for RAYALDEE may not have generated data that would support the approval or marketing of this product for the indications being studied, that others may develop products which are superior to RAYALDEE, and that RAYALDEE may not have advantages or prove to be superior over presently marketed products, including the currently used high monthly doses of prescription vitamin D_2, activated vitamin D hormone and over-the-counter vitamin D supplements. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.