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	**001-33528**	**75-2402409**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4400 Biscayne Blvd
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

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99.1	Press Release of OPKO dated October 12, 2017

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

Exhibit 99.1

OPKO Health Enters into Exclusive Agreement with Japan Tobacco to Develop and Commercialize RAYALDEE® in Japan

OPKO to receive up to $118 million in upfront and milestone payments, plus tiered double-digit royalties on product sales

MIAMI (October 12, 2017) – OPKO Health, Inc. (NASDAQ: OPK) announced that its subsidiary EirGen Pharma has entered into an exclusive agreement with Japan Tobacco Inc. (JT) for the development and commercialization in Japan of RAYALDEE® for the treatment of secondary hyperparathyroidism (SHPT) in non-dialysis and dialysis patients with chronic kidney disease (CKD).

Under the terms of the agreement, JT will make an upfront payment to OPKO of $6 million with another $6 million payment to be made upon initiation of OPKO's planned phase 2 study of RAYALDEE in U.S. dialysis patients. In addition, OPKO will be eligible to receive up to an additional $31 million in development and regulatory milestones and $75 million in sales based milestones. JT will also pay OPKO tiered, double digit royalties on net product sales. JT will be responsible for all regulatory approvals and commercial activities pertaining to RAYALDEE in Japan. According to JT, an estimated 13.3 million people in Japan have CKD and more than 300,000 are undergoing dialysis, with both patient populations increasing due to the aging population.

"JT, together with its subsidiary Torii Pharmaceuticals, has a strong and growing franchise in hemodialysis and renal diseases, which makes JT an ideal partner to bring RAYALDEE to physicians and patients in Japan," said Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "We believe JT and Torii's innovative marketing activities and their established network with Japanese nephrologists will accelerate adoption of RAYALDEE in this key market. We are confident this collaboration will substantially expand access to the important clinical benefits of RAYALDEE for Japanese patients with CKD."

RAYALDEE is an extended-release prohormone of calcitriol, the active form of vitamin D_3 that is the first and only such therapy approved by the U.S. Food and Drug Administration (FDA) that both raises serum 25-hydroxyvitamin D and lowers blood levels of intact parathyroid hormone. RAYALDEE is indicated for the treatment of SHPT in adults with stage 3 or 4 CKD and vitamin D insufficiency. It is not indicated in patients with stage 5 CKD or end stage renal disease on dialysis.

OPKO Health launched RAYALDEE in the U.S. in November 2016.

About OPKO Health, Inc.

OPKO Health is a diversified healthcare company that seeks to establish industry leading positions in large, rapidly growing markets. Our diagnostics business includes BioReference Laboratories, the nation's third largest clinical laboratory with a core genetic testing business and a 400 person sales and marketing team to drive growth and leverage new products, including the 4Kscore® prostate cancer test and the Claros® 1 in office immunoassay platform. Our pharmaceutical business features RAYALDEE, an FDA approved treatment for SHPT in stage 3-4 CKD patients with vitamin D insufficiency (launched in November 2016), VARUBI® for chemotherapy induced nausea and vomiting (oral formulation launched by partner TESARO and IV formulation pending FDA approval), OPK88003, a once weekly oxyntomodulin for type 2 diabetes and obesity that is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists, and OPK88004, a selective androgen receptor modulator being developed for benign prostatic hyperplasia and other urologic and metabolic conditions. Our 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. We also have 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, and products, financial condition, strategies or prospects, including statements regarding expectations about RAYALDEE and the success of the collaboration and licensing agreement with Japan Tobacco, whether Japan Tobacco will successfully develop, obtain regulatory approval for, launch or commercialize RAYALDEE in Japan, whether the parties will successfully develop RAYALDEE for the treatment of SHPT in dialysis patients, whether we will be successful in accelerating adoption of RAYALDEE in Japan, 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 products and treatments, including the risks 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.

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