
**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): June 18, 2021

OPKO Health, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-33528

(Commission
File Number)

75-2402409

(IRS 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	OPK	NASDAQ Global Select Market

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

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 June 18, 2021 (the “*Effective Date*”), EirGen Pharma Limited, an entity formed under the laws of Ireland and a subsidiary of OPKO Health, Inc., a Delaware corporation (“*OPKO*”), and NICOYA Macau Limited (“*Nicoya*”), a Macau corporation and an affiliate of NICOYA Therapeutics, entered into a Development and License Agreement (the “*Agreement*”) granting Nicoya the exclusive rights for the development and commercialization of extended release calcifediol (the “*Product*”) in Greater China, which includes mainland China, Hong Kong, Macau, and Taiwan (collectively, the “*Territory*”). Extended release calcifediol is marketed in the United States under the tradename *Royaldee*® by OPKO. The license grant to Nicoya covers the therapeutic and preventative use of the Product for secondary hyperparathyroidism (“*SHPT*”) in non-dialysis (“*ND*”) and hemodialysis chronic kidney disease patients (the “*Field*”).

OPKO will receive an initial upfront payment of \$5 million and is eligible to receive an additional \$5 million upon the first to occur of (A) the initiation of a phase 3 clinical trial for *Royaldee* for the prevention or treatment of SHPT in ND patients in the Territory or (B) the first anniversary of the Effective Date. OPKO is also eligible to receive up to an additional aggregate amount of \$115 million upon the achievement of certain regulatory and development milestones by Nicoya for the Product in the Territory. OPKO will also receive tiered, double digit royalty payments at rates in the low double digits on net product sales within the Territory and in the Field.

As part of the arrangement, Nicoya and OPKO agree to form a joint steering committee responsible for overseeing activities under the Agreement, including the development and regulatory approval of the Products in the Field in the Territory. Nicoya will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for the Product in the Territory and for all commercial activities pertaining to the Product in the Territory.

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

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 Quarterly Report on Form 10-Q for the period ending June 30, 2021.

ITEM 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company dated June 21, 2021
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document

Exhibit Index

Exhibit No.	Description
99.1	Press Release of the Company dated June 21, 2021

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.

By: /s/ Steven D. Rubin

Name: Steven D. Rubin

Title: Executive Vice President-Administration

Date: June 21, 2021



OPKO Health to Develop and Commercialize RAYALDEE® in Greater China with Nicoya Therapeutics

MIAMI (June 21, 2021) – OPKO Health, Inc. (NASDAQ: OPK) today announced that its subsidiary EirGen Pharma has entered into an agreement with Nicoya Macau Limited, an affiliate of Nicoya Therapeutics (Nicoya), for the development and commercialization in Greater China (mainland China, Hong Kong, Macau and Taiwan) of RAYALDEE® for the treatment of secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD). Nicoya is a leading biotechnology company incubated by 6 Dimensions Capital and its successor fund 120 Capital and other co-investors, and is focusing on the Greater China nephrology market.

Nicoya will make an upfront payment to OPKO of \$5 million and an additional \$5 million payment will be made during the first 12 months of the agreement or upon Nicoya achieving a certain predetermined development milestone. In addition, OPKO will be eligible to receive up to \$115 million upon the achievement of certain development, regulatory and sales-based milestones. Nicoya will also pay OPKO tiered, double-digit royalties on product sales. Nicoya will be responsible for regulatory approvals and commercial activities pertaining to RAYALDEE in their territory.

"We are delighted to work with Nicoya to expand the market for RAYALDEE by establishing a framework for access by physicians and patients across Greater China," said Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "China represents a significant market opportunity with an estimated 19 million people suffering from stage 3 or 4 CKD. Given Nicoya's expertise and established network, we are confident this collaboration will provide an effective strategy for RAYALDEE to penetrate this significant and growing market."

"We recognize the unique value RAYALDEE can bring to CKD patients and want to work together with OPKO to bring this innovative solution to patients in Greater China with unmet medical need related to their kidney health. The OPKO portfolio and strategic focus is fully aligned with Nicoya's vision to become the leading nephrology platform company in Greater China. We are truly excited about this opportunity," said Gan Ding, CEO of Nicoya Therapeutics.

RAYALDEE is an extended-release formulation of calcifediol, a prohormone of calcitriol, the active form of vitamin D₃. The product is the only medicine approved by the U.S. Food and Drug Administration that sufficiently raises serum total 25-hydroxyvitamin D to effectively lower blood levels of intact parathyroid hormone. RAYALDEE, approved to treat SHPT in adults with stage 3 or 4 CKD and vitamin D insufficiency, was launched in the U.S. in November 2016.

About Nicoya Therapeutics

Nicoya Therapeutics group is a renal-focused biopharma company based in China. Led by a market-leading management team, Nicoya has capabilities spanning from research and development to clinical trial execution to marketing and sales of in-licensed and wholly owned products. Nicoya Therapeutics is

incubated by 6 Dimensions Capital and its successor fund 120 Capital, a group of cross-border leading investment funds in the healthcare industry. Other co-investors in Nicoya include Mubadala Investment Company and Beijing Guokonghuayao Investment. Among 6 Dimensions Capital's incubated platform companies in China are Innovent (HKEX:1801), CStone Pharmaceuticals (HKEX: 2616), Ocumension (HKEX:1477, The leading China ophthalmology platform) and Cutia Therapeutics (China's leading dermatology platform).

About OPKO Health

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development, and commercialization expertise and novel and proprietary technologies. For more information, visit www.opko.com.

Cautionary Statement Regarding Forward Looking Statements

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding product development efforts as well as other non-historical statements about our expectations, products, beliefs or intentions regarding our business, financial condition, strategies or prospects including statements regarding expectations about RAYALDEE and the success of the collaboration and licensing agreement with Nicoya, whether Nicoya will successfully develop, obtain regulatory approval for, launch or commercialize RAYALDEE in China, Hong Kong, Macau and Taiwan 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 China, Hong Kong, Macau and Taiwan 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 our Annual Reports on Form 10-K filed and to be filed with the Securities and Exchange Commission and under the heading "Risk Factors" in our other 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 D₂, 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.

Contacts:

LHA Investor Relations

Yvonne Briggs, 310-691-7100

ybriggs@lhai.com

or

Bruce Voss, 310-691-7100

bvoss@lhai.com

###