
**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): May 12, 2020

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 May 12, 2020, OPKO Health, Inc. (“OPKO”) entered into an amendment (the “Amendment”) to that certain Development, Commercialization License Agreement, dated December 13, 2014 (the “Original License Agreement”), by and among OPKO, OPKO Ireland Ltd. (“OPKO Ireland”, and together with OPKO, the “Company”), and Pfizer, Inc. (“Pfizer”) for the Company’s long-acting human growth hormone product (hGH-CTP) for the treatment of growth hormone deficiency (GHD) and growth failure in children born small for gestational age (“PSGA”).

Under the terms of the Amendment, effective January 1, 2020, OPKO and Pfizer have agreed to share equally all costs for the remaining development of hGH-CTP for pediatric GHD (“PGHD”), including manufacturing costs and post-marketing studies. In addition, the parties updated and amended the Development Plan and Development Budget under the Original License Agreement. The milestone payments, royalties and profit share provisions under the Original License Agreement remain unchanged.

Pursuant to the Amendment, the parties have also agreed to work together to identify an additional pediatric indication for development other than PGHD on or before December 1, 2020. Development of the additional pediatric indication is subject to subsequent mutual agreement of the parties but, if agreed, all development costs for such indication shall be shared equally by the parties.

In addition, the parties also agreed on a process whereby Pfizer may, based on subsequent feedback from the US Food & Drug Administration, and in its reasonable discretion, submit a supplemental BLA for GHD in adults following receipt of regulatory approval of a biologics license application (BLA) for PGHD.

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: May 15, 2020