

---

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))
-

### 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company dated December 15, 2014

---

**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*

---

Exhibit Index

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



## **OPKO and Pfizer Enter into Global Agreement for OPKO's Long-Acting Human Growth Hormone (hGH-CTP)**

- *hGH-CTP in global clinical development for the treatment of pediatric and adult growth hormone deficiency (GHD)*
- *hGH-CTP has potential to reduce dosing frequency of human growth hormone to single weekly injection from current standard of daily injection*
- *OPKO to receive upfront payment of \$295 million and eligible to receive up to an additional \$275 million upon achievement of regulatory milestones*
- *Upon Pfizer's commercialization of hGH-CTP, OPKO is eligible to receive royalty and/or profit sharing payments*
- *Pfizer to obtain exclusive license to commercialize hGH-CTP globally*

Miami, FL, and New York, NY, December 15, 2014 — OPKO Health, Inc. (NYSE:OPK) and Pfizer Inc. (NYSE: PFE) announced today that they have entered into a worldwide agreement for the development and commercialization of OPKO's long-acting hGH-CTP for the treatment of growth hormone deficiency (GHD) in adults and children, as well as for the treatment of growth failure in children born small for gestational age (SGA) who fail to show catch-up growth by 2 years of age. hGH-CTP has the potential to reduce the required dosing frequency of human growth hormone to a single weekly injection from the current standard of one injection per day. hGH-CTP is currently in a global phase 3 trial in adults and a global phase 2 trial in children and has orphan drug designation in the U.S. and Europe for both adults and children with GHD.

Under the terms of the agreement, OPKO will receive an upfront payment of \$295 million and is eligible to receive up to an additional \$275 million upon the achievement of certain regulatory milestones. Pfizer will receive the exclusive license to commercialize hGH-CTP worldwide.

In addition, OPKO is eligible to receive initial royalty payments associated with the commercialization of hGH-CTP for Adult GHD which is subject to regulatory approval. Upon the launch of hGH-CTP for Pediatric GHD, which is subject to regulatory approval, the royalties will transition to gross profit sharing for both hGH-CTP and Pfizer's Genotropin.

OPKO will lead the clinical activities and will be responsible for funding the development programs for the key indications, which includes Adult and Pediatric GHD and Pediatric SGA. Pfizer will be responsible for all development costs for additional indications as well as all post-marketing studies. In addition, Pfizer will fund the commercialization activities for all indications and lead the manufacturing activities covered by the global development plan.

"We believe this collaboration will help advance our commitments to patients with Adult and Pediatric Growth Hormone Deficiency as we believe Pfizer's strengths, expertise and presence in the human growth hormone space makes them the ideal partner for our hGH-CTP program. Our collaboration enables full alignment between Pfizer and OPKO to optimize development and potentially bring an innovative treatment to patients. We believe that the global growth hormone market is currently valued at more than \$3 billion, and believe that hGH-CTP has the potential to be the best in class long-acting growth hormone product. Our long acting human growth hormone is our most advanced product candidate utilizing our CTP technology to extend the half-life of a broad range of therapeutic peptides and proteins. By reducing the number of injections, our technology can improve patient compliance," said OPKO's CEO, Phillip Frost, M.D.

"This agreement strengthens Pfizer's commitment to rare diseases, and we are pleased to work with OPKO to help provide a potential next-generation therapy for patients with Adult and Pediatric Growth Hormone Deficiency," said Geno Germano, Group President, Pfizer Global Innovative Pharma (GIP). "Long-acting growth hormone is the first innovation in the GHD space in 20 years. hGH-CTP would be complementary to our existing Genotropin franchise, and could potentially provide an option that could improve patients' adherence to treatment with once weekly dosing."

The transaction is subject to customary Hart-Scott-Rodino approval and is expected to close during the first-quarter of 2015.

### **About hGH-CTP**

hGH-CTP is a novel, long-acting recombinant human growth hormone analog being developed by OPKO for the treatment of children with growth failure due to inadequate endogenous growth hormone secretion, and adults with growth hormone deficiency (GHD) of either childhood or adult-onset etiology. hGH-CTP is intended to reduce the burden of daily injection therapy by requiring only weekly injections potentially improving compliance and treatment outcomes. OPKO's proprietary technology allows the company to extend the hormone's half-life without the use of polymers, encapsulation techniques, or nanoparticles. This technology is based on a natural peptide, the C-terminal peptide (CTP) of the beta chain of human chorionic gonadotropin (hCG). OPKO has an ongoing pivotal Phase 3 clinical trial in adults for hGH-CTP and a Phase 2 clinical trial in pediatric patients. hGH-CTP has been granted orphan drug designation in the U.S. and Europe for both adults and children with growth hormone deficiency

### **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 <http://www.OPKO.com>.

### **Pfizer and Rare Diseases**

Rare diseases are among the most serious of all illnesses and impact millions of patients worldwide, representing an opportunity to apply our knowledge and expertise to help make a significant impact in addressing unmet medical needs. The Pfizer focus on rare diseases builds on more than a decade of experience and a global portfolio of 22 medicines approved worldwide that treat rare diseases in the areas of hematology, neuroscience, inherited metabolic disorders, pulmonology, and oncology.

### **About Pfizer Inc.**

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at [www.pfizer.com](http://www.pfizer.com).

**OPKO 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), 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 expected benefits of hGH-CTP, whether the collaboration with Pfizer will be successful, whether OPKO's clinical trials for adult and pediatric growth hormone deficiency will support marketing approval, whether hGH-CTP will be successfully developed or commercialized, expectations regarding the product, its efficacy, safety and market potential, whether OPKO will receive royalty and/or profit sharing payments for sales from hGH-CTP, expectations about the global growth hormone market, whether hGH-CTP has the potential to be the best in class long-acting growth hormone product, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. 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 filings with the Securities and Exchange Commission, as well as the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. 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.*

**PFIZER DISCLOSURE NOTICE:** *The information contained in this release is as of December 15, 2014. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

*This release contains forward-looking information about an agreement between Pfizer and OPKO for the development and commercialization of hGH-CTP that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Forward-looking statements include, among other things, those regarding hGH-CTP and the collaboration, including their potential benefits and market potential, as well as those about the anticipated timing of the closing of the transaction. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates as well as the possibility of unfavorable study results; whether and when biologics license applications may be filed in any jurisdictions for hGH-CTP for any indication; whether and when any such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of hGH-CTP in any such indications; risks relating to the satisfaction of conditions to closing the transaction in the anticipated timeframe or at all; and competitive developments.*

*A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2013 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).*