
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 30, 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))
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Item 8.01 Other Events.

On December 30, 2016, OPKO Health, Inc. (the “Company”), a Delaware corporation, issued a press release announcing an update on the Company’s hGH-CTP clinical programs. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

On January 3, 2017, the “Company determined that its 3.0% Convertible Senior Notes due 2033 (the “Notes”), of which \$31.9 million is outstanding, continue to be convertible by holders of such Notes through March 31, 2017. The Company has elected to satisfy its conversion obligation under the Notes in shares of the Company’s common stock. The conversion right has been extended because the closing price per share of the Company’s common stock has exceeded \$9.19, or 130% of the applicable conversion price of \$7.07, for at least 20 of 30 consecutive trading days during the quarter ended December 31, 2016. The Company had previously announced that this conversion right had been triggered at each of the quarters ended March 31, 2015 through December 31, 2016. The Notes will continue to be convertible until March 31, 2017, and may be convertible thereafter, if one or more of the conversion conditions specified in the Indenture, dated as of January 30, 2013, by and between the Company and Wells Fargo Bank N.A. (the “Indenture”), is satisfied during future measurement periods. Pursuant to the Indenture, a holder who elects to convert the Notes will receive 141.4827 shares of the Company’s Common Stock plus such number of additional shares as is applicable on the conversion date per \$1,000 principal amount of Notes based on the early conversion provisions in the Indenture. A complete explanation of the conversion rights of holders of the Notes, as well as the procedures required to convert the Notes, is set forth in the Indenture.

Wells Fargo Bank, National Association is the trustee for the holders of the Notes and the conversion agent under the Indenture. Any questions relating to the mechanics of the conversion for the Notes should be directed to Wells Fargo Bank National Association, Attn: Barry Somrock at CMESCONVERSIONS@wellsfargo.com.

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 30, 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.

January 3, 2017

By: Steven D. Rubin

Name: Steven D. Rubin

Title: Executive VP-Administration

Exhibit Index

Exhibit No.	Description
99.1	Press Release of the Company dated December 30, 2016



OPKO Health Provides Update on hGH-CTP Clinical Programs

Commenced data analysis of the Phase 3 Clinical Study of hGH-CTP in Growth Hormone Deficient Adults

Initiated Global Pediatric Phase 3 Clinical Study of hGH-CTP in Growth Hormone Deficient Children

Miami, Florida, December 30, 2016 — OPKO Health, Inc. (NASDAQ:OPK) announced it has commenced data analysis in the phase 3, double-blind, placebo-controlled study of its investigational long-acting human growth hormone product (hGH-CTP) in adults with growth hormone deficiency (GHD). The multinational, multi-center study, which utilized a 2:1 randomization between hGH-CTP and placebo, enrolled 203 subjects, 198 of whom received at least one dose of study treatment. Treatment was administered through a weekly injection.

On the primary endpoint of change in trunk fat mass from baseline to 26 weeks, there was no statistical difference between hGH-CTP and placebo. However, after unblinding the study, OPKO identified one or more outliers that may have affected the primary outcome. As a result, OPKO is undertaking further review of the study population as promptly as possible. The safety profile observed in this study was consistent with that known for growth hormone treatments. A greater percentage of subjects on hGH-CTP normalized serum concentrations of insulin-like growth factor-I compared to placebo. Additional efficacy and safety data and analyses from the study will be released once available.

In addition to completing the Phase 3 adult GHD study, OPKO announces that it has initiated a pivotal Phase 3 study this month in pre-pubertal growth hormone deficient children to evaluate weekly treatment with hGH-CTP versus daily injections of Genotropin. The hGH-CTP will be delivered in a pen device in this multi-regional study.

OPKO has a world-wide collaboration and license agreement with Pfizer Inc. for the development and commercialization of hGH-CTP. Under the agreement, OPKO is responsible for conducting the clinical program and Pfizer is responsible for registering and commercializing the product.

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 Bio-Reference Laboratories, the nation's third-largest clinical laboratory 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. Our pharmaceutical business features RAYALDEE, an FDA-approved treatment for SHPT in stage 3-4 CKD patients with vitamin D insufficiency, VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation launched by partner TESARO and IV formulation PDUFA date: January 2017), TT401, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists, and TT701, an androgen receptor modulator for androgen deficiency indications. Our biologics business includes hGH-CTP, a once-weekly human growth hormone injection (in phase 3 and partnered with Pfizer), a long-acting Factor VIIa drug for hemophilia (in phase 2a) and a long-acting oxyntomodulin for diabetes and obesity (in phase 1). 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.

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 timing for completion of data analysis for the study and release of additional safety and efficacy data, whether any outlier(s) impacted the primary outcome and secondary endpoints, whether OPKO's clinical trials for hGH-CTP in adult and pediatric GHD patients will be successful or generate data to support marketing approval, whether study results will demonstrate hGH-CTP is superior to placebo in reducing truncal fat, whether hGH-CTP will prove to be safe and effective and achieve IGF-1 normalization, whether hGH-CTP will be successfully developed or commercialized, expectations regarding the product and its market potential, 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, litigation, and the success of our collaboration on hGH-CTP with Pfizer, Inc. 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.

Company

OPKO Health, Inc.

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