
**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): September 7, 2018

OPKO Health, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-33528

(Commission
File Number)

75-2402409

(IRS Employer
Identification No.)

4400 Biscayne Blvd. Miami, Florida

(Address of Principal Executive Offices)

33137

(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))

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 7.01. Regulation FD Disclosure.

On September 11, 2018, OPKO Health, Inc. (“OPKO” or the “Company”) issued a press release regarding Nasdaq’s decision to halt trading in OPKO’s common stock in connection with the lawsuit previously reported in the Company’s Current Report on Form 8-K filed on September 10, 2018 (the “Lawsuit”). A copy of such press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated in this Item 7.01 by reference. The information included in this Item 7.01 and in Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 8.01. Other Events.

On September 7, 2018, at 14:34:38 Eastern Daylight Time, Nasdaq halted trading in the Company’s common stock pending receipt from the Company of information requested by the exchange related to the allegations contained in the Lawsuit. Nasdaq has advised the Company that trading will remain halted until the exchange is satisfied with OPKO’s response to Nasdaq’s request for information

ITEM 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company dated September 11, 2018

Exhibit List

Exhibit No.	Description
99.1	Press Release of the Company dated September 11, 2018

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: September 11, 2018

By: /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer

OPKO COMMENTS ON CONTINUED NASDAQ HALT OF TRADING OF COMMON STOCK

MIAMI, Sept. 11, 2018 -- OPKO Health, Inc. (NASDAQ: OPK) has had trading in its common stock halted by The Nasdaq Stock Market, and the exchange has advised OPKO that the halt will continue until the company responds (to Nasdaq's satisfaction) to the exchange's request for information related to the previously reported lawsuit filed by the U.S. Securities and Exchange Commission against a number of individuals and entities, including OPKO and its CEO and Chairman Phillip Frost. As noted previously, the lawsuit does not contain any allegations about OPKO's financial practices, financial statements or business practices, and OPKO is confident that once a proper investigation is completed and the facts of the case have been fully disclosed, the matter will be resolved favorably for the company. OPKO is working expeditiously to respond to Nasdaq's request for information, but it cannot currently estimate when trading will resume.

About OPKO Health, Inc.

OPKO Health is a diversified healthcare company. In diagnostics, its BioReference Laboratories is the nation's third largest clinical laboratory; GeneDx is a rapidly growing genetic testing business; the 4Kscore® prostate cancer test is used to confirm an elevated PSA to help decide about next steps such as prostate biopsy; Claros® 1 is a point of care diagnostics platform with PSA and testosterone as the most advanced in development. In our pharmaceutical pipeline, RAYALDEE is our first pharmaceutical product to be marketed. OPK88003, a once weekly oxyntomodulin for type 2 diabetes and obesity in Phase 2 clinical trials, is among a new class of GLP-1 glucagon receptor dual agonists. OPK88004, a SARM (Selective Androgen Receptor Modulator) for treating BPH (Benign Prostatic Hypertrophy), urinary incontinence and other conditions is in clinical trials. The Company's most advanced product utilizing its CTP technology, a once-weekly human growth hormone for injection, is in Phase 3 trials and is partnered with Pfizer.

OPKO has research, development, production and distribution facilities abroad. More information is available at 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 the outcome of the SEC lawsuit and the trading in OPKO's common stock, as well as other non-historical statements about our expectations, beliefs or intentions. 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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