
**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)

<u>Delaware</u> (State or Other Jurisdiction of Incorporation)	<u>001-33528</u> (Commission File Number)	<u>75-2402409</u> (IRS Employer Identification No.)
<u>4400 Biscayne Blvd. Miami, Florida</u> (Address of Principal Executive Offices)		<u>33137</u> (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 7, 2018, OPKO Health, Inc. (“OPKO” or the “Company”) issued a press release regarding the lawsuit described in Item 8.01 of this Current Report on Form 8-K; 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, the United States Securities and Exchange Commission filed a lawsuit in the United States District Court for the Southern District of New York against a number of individuals and entities, including OPKO, its CEO and Chairman, Dr. Phillip Frost, and Frost Gamma Investments Trust, an entity affiliated with Dr. Frost, alleging violations of the Securities Act, the Exchange Act and rules promulgated thereunder.

ITEM 9.01. Financial Statements and Exhibits.**(d) Exhibits**

Exhibit No.	Description
99.1	Press Release of the Company dated September 7, 2018

Exhibit List

Exhibit No.	Description
99.1	Press Release of the Company dated September 7, 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 10, 2018

By: /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer

OPKO COMMENTS ON SEC COMPLAINT

MIAMI, Sept. 07, 2018 -- OPKO Health, Inc. (NASDAQ: OPK) provided the following comment on the lawsuit filed by the U.S. Securities and Exchange Commission earlier today.

“OPKO learned today that the Securities and Exchange Commission has filed a lawsuit in the Southern District of New York against a number of individuals and entities, including OPKO and its CEO and Chairman Phillip Frost. The SEC failed to provide notice of its intent to sue prior to filing the complaint, which contains serious factual inaccuracies. Had the SEC followed its own standard procedures, OPKO and Dr. Frost would gladly have provided information that would have answered a number of the SEC’s apparent questions, and filing of this lawsuit against them could have been avoided. OPKO and Dr. Frost have always prided themselves on adhering to the highest standards of financial disclosure, and they are 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 them.”

The Company noted that the complaint does not contain any allegations about OPKO’s financial practices, financial statements or business practices.

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, 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.

CONTACT:

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