
**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): December 27, 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 December 27, 2018, OPKO Health, Inc. (the “Company”) issued a press release in connection with the settlements, subject to court approval, 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 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 Securities Exchange Act of 1934, as amended (the “Exchange Act”), except as expressly set forth by specific reference in such a filing.

ITEM 8.01. Other Events.

On December 27, 2018, the Company announced that the Company and Phillip Frost, M.D., the Company’s CEO and Chairman (“Dr. Frost”), entered into settlement agreements with the Securities and Exchange Commission (the “Commission”), subject to court approval, resolving the complaint filed by the Commission against the Company and Dr. Frost in the U.S. District Court for the Southern District of New York on September 7, 2018 (“the Complaint”). The proposed settlements include no restriction on Dr. Frost’s ability to continue to serve as the Company’s CEO and Chairman.

Pursuant to the settlement, and without admitting or denying any of the allegations of the Complaint, the Company will be enjoined from violating Section 13(d) of the Exchange Act and will pay a \$100,000 penalty. Liability under Section 13(d) can be established without any showing of wrongful intent or negligence.

The Company also agreed to, within certain stipulated time periods: (i) establish a Management Investment Committee (“MIC”) that will make recommendations to an Independent Investment Committee (“IIC”) of the Board of Directors in connection with existing and future strategic minority investments; and (ii) retain an Independent Compliance Consultant (“ICC”) to (a) advise the Company on whether filings pursuant to Section 13(d) for previous strategic investments made at the suggestion of or in tandem with Dr. Frost should be amended or made to reflect group membership with Dr. Frost and his related entities; (b) review the Company’s existing policies and procedures relating to compliance with Section 13(d) of the Exchange Act; and (c) review the independence of the MIC and IIC of the Board of Directors solely for purposes of the handling of strategic minority investments. The ICC will report its findings to the Commission within fifteen (15) days of completion of its work, and the Company will certify its compliance with these undertakings in writing.

Under the terms of the settlement between the Commission and Dr. Frost, and without admitting or denying any of the allegations in the Complaint, Dr. Frost will be enjoined from violating Sections 5(a) and (c) and 17(a)(2) of the Securities Act and Section 13(d) of the Exchange Act; will pay approximately \$5.5 million in penalty, disgorgement and pre-judgment interest; and will be prohibited, with certain exceptions, from trading in penny stocks. Liability under Exchange Act Section 13(d) and Securities Act Sections 5(a) and (c) can be established without any showing of wrongful intent or negligence, and liability under Securities Act Section 17(a)(2) can be established upon a showing of negligence.

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 27, 2018 |

Exhibit List

| <u>Exhibit No.</u> | <u>Description</u> |
|------------------------|--|
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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: December 27, 2018

By: /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer

For Immediate Release
December 27, 2018

OPKO Health and OPKO's CEO and Chairman, Dr. Phillip Frost, Announce Proposed Resolution of SEC Action

Frost to continue as CEO and Chairman of Opko

MIAMI—(PR NEWSWIRE)—Dec. 27, 2018 – In a settlement, subject to court approval, OPKO Health, Inc. (NASDAQ: OPK) and OPKO's CEO and Chairman, Dr. Phillip Frost, have agreed with the Securities and Exchange Commission to resolve the action brought against them in *SEC v. Honig et al.*, 18 Civ. 08175 (S.D.N.Y).

“We have reached agreement with the SEC that will end a potentially expensive, contentious and time-consuming litigation and I am happy that we can focus on an exciting and productive 2019 for OPKO Health,” said Dr. Frost.

Without admitting or denying the SEC's allegations, OPKO agreed to an injunction from certain violations of the Securities Exchange Act of 1934 (the “Exchange Act”); a \$100,000 penalty; and will perform certain undertakings related to the Exchange Act. Dr. Frost agreed to, without admitting or denying the SEC's allegations, injunctions from certain violations of the Securities Act of 1933 and the Exchange Act; approximately \$5.5 million in penalty, disgorgement, and prejudgment interest; and a prohibition, with certain exceptions, from trading in penny stocks.

Dr. Frost will continue to serve as OPKO's CEO and Chairman.

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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 Company’s business, 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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