
**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): July 24, 2019

OPKO Health, Inc.
(Exact Name of Registrant as Specified in its 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	OPK	NASDAQ Global Select Market

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 July 29, 2019, OPKO Health, Inc. (the "Company") and Phillip Frost, M.D., Chairman and Chief Executive Officer released a joint statement on the Company's website regarding Dr. Frost's recent hospitalization. According to the statement:

Dr. Frost informed the Company that he admitted himself into the hospital within the last few days after experiencing chest pains. Dr. Frost has undergone a successful surgery, and he is expected to make a full recovery. Dr. Frost has been in regular contact with Company management and members of the Board of Directors during his hospitalization, and the Company is continuing to operate normally. The Company will provide further details as appropriate. In the meantime, the OPKO family wishes Dr. Frost a speedy recovery.

ITEM 8.01. Other Events.

As previously announced on June 20, 2019, the Company submitted a de novo request to the U.S. Food and Drug Administration ("FDA") seeking regulatory clearance for the *4Kscore*® test. The Company plans to refile its *4Kscore*® test submission as a premarket approval ("PMA") application. A PMA submission is the review process used by the FDA to evaluate the approvability of Class III medical devices. The decision to submit the *4Kscore*® test as a PMA submission is based on FDA feedback to the Company's de novo request for this test, which has now been withdrawn. The FDA did not request any additional clinical data or any additional clinical trials in connection with a PMA submission. The Company currently anticipates submitting the PMA application in August 2019.

Forward Looking Statements

This Form 8-K 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 Dr. Frost's recovery and the PMA submission, as well as other non-historical statements about our expectations, beliefs or intentions. The forward-looking statements contained in this Form 8-K 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.

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: July 29, 2019

By: /s/ Steven D. Rubin
Name: Steven D. Rubin
Title: Executive Vice President