
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):

April 17, 2014

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 3.02 Unregistered Sale of Equity Securities.

The information required to be reported under this Item is incorporated by reference to Item 7.01 of this Current Report on Form 8-K.

Item 7.01 Regulation FD Disclosure.

On April 17, 2013, OPKO Health, Inc., a Delaware corporation (the “Company”) entered into a Stock Purchase Agreement (the “Purchase Agreement”) by and among the Company, OPKO Holdings Israel Ltd, a wholly-owned subsidiary of the Company (together with the Company, the “Buyers”), Inspiro Medical Ltd., an Israeli medical device company (“Inspiro”), and certain shareholders of Inspiro (the “Sellers”).

Pursuant to the Purchase Agreement, the Buyers will purchase from the Sellers all of the issued and outstanding shares of Inspiro for \$10 million. In connection with the transaction, the Buyers will pay to the Sellers at closing \$1 million in cash and \$9 million in shares of the Company’s common stock (the “Stock Consideration”), based on the average closing sales price per share of the Company’s Common Stock as reported by the New York Stock Exchange for the ten trading days immediately preceding the execution date of Purchase Agreement, or \$9.00 per share. Pursuant to the Purchase Agreement, \$2 million of the Stock Consideration is to be held in a separate escrow account to secure the indemnification obligations of Sellers under the Purchase Agreement. The Stock Consideration will be issued in reliance upon an exemption from the registration requirements under the Securities Act of 1933, as amended (the “Securities Act”), pursuant to Section 4(2) thereof. The above description of the Purchase Agreement does not purport to be complete and is solely intended as a summary of the material terms of the Stock Purchase Agreement. The completion of the acquisition is subject to various customary closing conditions. The transaction is expected to close during the second quarter.

On April 17, 2014, the Company issued a press release announcing that it entered into the Purchase Agreement. A copy of the press release is being filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in Item 7.01 to this Current Report on Form 8-K and Exhibit 99.1 attached hereto 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 by the Company under the Exchange Act.

This Current Report on 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 that relate to anticipated closing date of the acquisition. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements including delays in completing the acquisition, the time required to consummate the proposed acquisition, the focus of management on acquisition-related issues, the risk that certain required approvals and consents will not be obtained, the risk that the businesses will not be integrated successfully, the risk that any potential synergies from the transaction may not be fully realized or may take longer to realize than expected, new information arising out of clinical trial results, and the risk that the safety and/or efficacy results of existing clinical trials will not support continued clinical development, as well as 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 and litigation, among other factors. The forward- looking statements contained in this Current Report on Form 8-K may become outdated over time. The Company does not assume any responsibility for updating any forward-looking statements, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company, dated April 17, 2014

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.

April 22, 2014

By: Adam Logal

Name: Adam Logal

Title: Senior Vice President-Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release of the Company, dated April 17, 2014



OPKO Acquires Next Generation Dry Powder Inhaler to Treat Respiratory Disorders

Inspiromatic™ Improves Drug Delivery, Monitors Patient Inhalation and Provides Real-Time Patient Feedback

MIAMI – April 17, 2014 — OPKO Health, Inc. (NYSE:OPK) has entered into a definitive agreement to acquire Inspiro Medical Ltd. (“Inspiro”), an Israeli medical device company developing a new platform to deliver small molecule drugs such as corticosteroids and beta agonists or larger molecules to treat respiratory diseases. Inspiro’s Inspiromatic™ is a “smart” easy-to-use dry powder inhaler with several advantages over existing devices.

Inspiromatic™ offers improved drug deposition to the lower airways of patients and real time data for patient compliance monitoring. The device has an internal microcontroller and flow sensor that controls the delivery of the medication and, using micro-pump technology, dispenses the drug particles at the right speed without the need for forceful inhalation. It also provides instant feedback to the patient with a green or red flasher light to indicate proper inhalation and a beeper after the dose has been delivered. For physicians, Inspiromatic™ provides a built-in logger that stores patient use data for easy access and transmission by electronic devices such as smart phones.

In a recently completed, First In Man double blinded clinical study conducted in 30 asthmatic children comparing Inspiromatic™ to a market leading dry powder inhaler, Inspiromatic™ demonstrated superior pulmonary delivery of the active drug.

“We are pleased to add this next generation inhaler to OPKO’s growing product portfolio,” stated Phillip Frost, M.D., OPKO’s CEO and Chairman. “We expect this innovative device to play a valuable role in the improvement of therapy for asthma, chronic obstructive pulmonary disease, cystic fibrosis and other respiratory diseases. We plan to use the Inspiromatic™ device to test the inhaled form of OPKO’s new sulfated disaccharide drug against these disorders. This drug product is still undergoing pre-clinical testing prior to submission of an IND, but animal data indicates safety and efficacy for both inhaled and orally delivered forms. Of course, we believe that Inspiromatic™ can improve outcomes of treatment with other drugs, those presently available in more “standard” type inhalers, as well as new inhalation drugs being developed. This acquisition fits our strategy of developing new products that address large markets in need of more effective therapeutic solutions.”

Nimrod Kaufmann, CEO and Co-Founder of Inspiro, commented, “We are extremely proud of Inspiro’s success in bringing our smart Inspiromatic™ respiratory drug-delivery device to market. With Inspiro now a part of OPKO, we will be able to help more people faster. Inspiro joining OPKO is a big win for the shareholders of both Inspiro and OPKO, as well as good news for our patients and physicians.”

Eran Feldhay, M.D., CEO of Trendlines Medical, Inspiro’s largest shareholder, added, “The acquisition of Inspiro is our third exit in eight months, all to U.S.-based multinational corporations. This success brings continuing confirmation of the strength of the Trendlines team in fulfilling our vision of creating and developing companies to improve the human condition. We are very pleased to see OPKO take the Inspiro opportunity forward.”

About OPKO Health, Inc.

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry leading positions in large, rapidly growing markets by leveraging its discovery, development and commercialization expertise and novel and proprietary technologies.

About Inspiro Medical Ltd.

Inspiro Medical Ltd. is a medical device company dedicated to the development of a next-generation dry powder inhaler platform. The Inspiromatic™ dry powder inhaler, developed by Inspiro, is the first active dry powder inhaler (DPI) that delivers drugs effectively at extremely low inhalation flow rates, instructs the patient in real time and enables efficient physician follow-up to substantially improve medication delivery and compliance.

About Trendlines

The Trendlines Group (www.trendlines.com) invests in, incubates, and supports early-stage, high-promise medical and agricultural technology companies in Israel, a global leader in start-up ingenuity. Trendlines Medical, our investment unit for medical innovation, works in partnership with innovators and investors, in an environment that encourages curiosity and fosters collaboration. Simply stated, Trendlines creates and develops companies to improve the human condition.

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 intended acquisition of Inspiro Medical, the expected benefits of the Inspiromatic™ inhaler, whether it will offer improved drug deposition to the lower airways of patients and real time data for patient compliance monitoring, whether it will provide superior delivery of active drug over other inhalers, whether it will play a valuable role in the improvement of therapy for asthma, chronic obstructive pulmonary disease, cystic fibrosis and other respiratory diseases, whether OPKO will use the Inspiromatic™ device to test the inhaled form of OPKO’s new sulfated disaccharide drug against certain disorders, whether the Inspiromatic™ or OPKO’s new sulfated disaccharide drug product will ever be successfully developed or commercialized, whether the Inspiromatic™ can improve outcomes of treatment with other drugs, those presently available in more “standard” type inhalers, as well as new inhalation drugs being developed, that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, that the Inspiromatic™ and/or any of our compounds or products under development may fail, may not achieve the expected results or effectiveness and may not generate data that would support the approval or marketing of products for the indications being studied or for other indications, that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied, 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, that the various conditions to the closing of the transaction with Inspiro Medical may not be met, as well as 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 and litigation, 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.

OPKO Health, Inc.

Steven D. Rubin or Adam Logal, 305-575-4100