Opko Health, Inc. Form 8-K June 30, 2016

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): June 29, 2016

OPKO Health, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction

001-33528 (Commission

75-2402409 (IRS Employer

of incorporation)

File Number) 4400 Biscayne Blvd.

Identification No.)

Miami, Florida 33137

(Address of principal executive offices) (Zip Code)

(305) 575-4100

Registrant s telephone number, including area code

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))

Item 1.01. Entry into a Material Definitive Agreement.

On June 29, 2016, OPKO Health, Inc., a Delaware corporation (the Company), OPKO Global Holdings, Inc., a Cayman Islands corporation and a wholly owned subsidiary of the Company (Sub), and Transition Therapeutics Inc., an Ontario corporation (TTHI), entered into an arrangement agreement (the Arrangement Agreement). Pursuant to the Arrangement Agreement, Sub will acquire all of the equity interests of TTHI (the Arrangement) and TTHI will be Sub s wholly owned subsidiary. The Arrangement is intended to qualify as a reorganization within the meaning of the Internal Revenue Code of 1986, as amended (the Code), so that none of the Company, Sub, TTHI nor any of TTHI s stockholders generally will recognize gain or loss for U.S. federal income tax purposes in the transaction. The Arrangement will not be tax free for Canadian income tax purposes.

At the effective time of the Arrangement (the Effective Time), Sub will acquire all of the issued and outstanding common shares of TTHI, no par value per share (the TTHI Common Stock), and all of the options to purchase shares of TTHI Common Stock that are in-the-money at the Effective Time (the TTHI Options), in exchange for US\$60 million in shares of the Company s common stock, par value \$0.01 per share (the Company Common Stock), which pursuant to the Arrangement Agreement is equal to 6,430,868 shares of Company Common Stock. At the Effective Time, each issued and outstanding share of TTHI Common Stock (other than any shares of TTHI Common Stock held by the Company or any Company affiliate) will be converted and exchanged into shares of Company Common Stock using an exchange rate equal to (i) 6,430,868 divided by (ii) the number of shares of TTHI Common Stock outstanding immediately prior to the Effective Time (including shares of TTHI Common Stock deemed to have been issued as a result of the conversion of the TTHI Options, but excluding any shares of TTHI Common Stock held by the Company or any affiliate of the Company). No fractional shares of Company Common Stock will be issued in the Arrangement, and TTHI s stockholders will receive one share of Company Common Stock in lieu of any fractional shares, after taking into account all of the shares of TTHI Common Stock represented by certificates or book-entries, delivered by such stockholder. Each option to purchase shares of TTHI Common Stock that is not-in-the money at the Effective Time will be terminated at the Effective Time.

The obligations of the Company and TTHI to consummate the Arrangement are subject to customary conditions, including, but not limited to, (a) obtaining the required approvals of TTHI s stockholders, (b) obtaining an interim order (the Interim Order) and final order from the Ontario Superior Court of Justice (the Court) approving the Arrangement and the fairness of the terms and conditions of the exchange of TTHI Common Stock and the TTHI Options for Company Common Stock, (c) the absence of any injunction or similar restraint prohibiting or making illegal consummation of the Arrangement or any of the other transactions contemplated by the Arrangement Agreement, (d) the approval by the NASDAQ Stock Market with respect to the listing of the shares of Company Common Stock to be issued in the Arrangement, (e) subject to certain materiality exceptions, the accuracy of the representations and warranties of each party and (f) the performance in all material respects by each party of its obligations under the Arrangement Agreement.

Subject to the satisfaction or waiver of the foregoing conditions and the other terms and conditions contained in the Arrangement Agreement, the transaction is expected to close in the second half of 2016.

The Arrangement Agreement contains certain termination rights for both the Company and TTHI in certain circumstances, including: (a) by mutual written agreement of the parties; (b) by either party if the Arrangement is not consummated on or before November 30, 2016, provided that such date will be extended by an additional 30 days under certain circumstances, and provided further that such failure is not principally caused by any breach of the Arrangement Agreement by the party proposing to terminate; (c) by either party upon a final and nonappealable injunction or similar restraint permanently restraining, enjoining or otherwise prohibiting consummation of the transactions contemplated by the Arrangement Agreement; (d) by either party if TTHI s stockholders fail to approve the transactions contemplated by the Arrangement Agreement; (e) by either party if the Interim Order from the Court has not been obtained on or before October 31, 2016 or the final order from the Court has not been obtained on or

before November 25, 2016, provided that, in each case, the right to terminate is not available to a party if such party is not in material compliance with its obligations under the Arrangement Agreement; (f) by the Company, if (i) TTHI breaches or fails to perform its representations and warranties or covenants in the Arrangement Agreement and such breach (A) is not capable of being cured or is not cured within 15 business days following receipt by TTHI of the Company s written notice and (B) would result in the failure of a condition to closing being satisfied, (ii) the Board of Directors of TTHI fails to recommend that TTHI s stockholders approve the Arrangement Agreement, (iii)

there is a Change of Recommendation (as defined in the Arrangement Agreement), (iv) there is a publicly announced Company Acquisition Proposal (as defined in the Arrangement Agreement), after the public announcement, the TTHI stockholders do not approve the Arrangement, the Arrangement is not submitted for their approval or the Arrangement is not otherwise completed, and within 12 months of such public announcement, an agreement relating to any Company Acquisition Proposal is entered into or the Company Acquisition Proposal is consummated, (v) TTHI enters into a written agreement with respect to a Company Acquisition Agreement (as defined in the Arrangement Agreement), or (vi) TTHI enters into an agreement with respect to a Superior Proposal (as defined in the Arrangement Agreement); or (g) by TTHI if (i) the Company breaches or fails to perform its representations and warranties or covenants in the Arrangement Agreement and such breach (A) is not capable of being cured or is not cured within 15 business days following receipt by the Company of TTHI s written notice and (B) would result in the failure of a condition to closing being satisfied, (ii) there is a Change in Recommendation, or (iii) TTHI enters into a written agreement with respect to a Superior Proposal.

If the Arrangement Agreement is terminated under certain circumstances specified in the Arrangement Agreement, TTHI will be required to pay the Company a termination fee of \$3,000,000 (the Termination Fee); however, if the Arrangement Agreement is terminated by (a) either party due to TTHI s stockholders not approving the Arrangement at a special meeting (the Special Meeting), TTHI will be required to pay the Company a termination fee of \$1,800,000 in lieu of the Termination Fee and (b) the Company due to TTHI s breaches of its representations and warranties under the Arrangement Agreement, TTHI will be required to pay the Company \$500,000 in lieu of the Termination Fee. Additionally, if the Company terminates the Arrangement Agreement due to TTHI s breaches of its representations and warranties, and within 12 months after such termination, the Company would otherwise be entitled to the Termination Fee, then TTHI will pay the Company an additional \$2,500,000.

TTHI has made customary representations and warranties regarding, among other things: organization, standing and corporate power; authority; capitalization; TSX and SEC filings; governmental approvals; absence of undisclosed liabilities; absence of certain changes; tax matters; intellectual property; environmental matters; compliance with laws; labor relations; regulatory matters; U.S. export and import controls; employee benefit plans; material contracts; legal proceedings; and insurance.

The Company and Sub have made customary representations and warranties regarding, among other things: organization, standing and corporate power; authority; capitalization; SEC filings; absence of undisclosed liabilities; absence of certain changes or events; intellectual property; compliance with laws; and legal proceedings.

The Arrangement Agreement contains customary covenants of each of TTHI, the Company and Sub, including, among other things, that (i) TTHI will, as soon as practicable after the execution of the Arrangement Agreement, and in any event before July 29, 2016, apply to the Court for the Interim Order, (ii) TTHI will hold the Special Meeting as soon as reasonably practicable after the Interim Order has been obtained, and in any event before August 31, 2016, (iii) TTHI will prepare, file and distribute a circular relating to the Special Meeting and such other documents as may be necessary or desirable to permit the TTHI stockholders to vote on the Arrangement and (iv) each party will cooperate with each other and use their respective reasonable best efforts to obtain all governmental consents, approvals and authorizations that are necessary to consummate the transactions contemplated by the Arrangement Agreement.

Prior to the approval of the Arrangement Agreement by TTHI s stockholders, its Board of Directors may, upon receipt of a Superior Proposal and in certain other circumstances, change its recommendation that TTHI s stockholders approve the Arrangement Agreement, subject to complying with notice and other specified conditions, including giving the Company the opportunity to propose changes to the Arrangement Agreement in response to such Superior Proposal or other circumstances.

Each of TTHI and the Company have additionally agreed, subject to certain exceptions, to conduct its business in the ordinary course consistent with past practice between the execution of the Arrangement Agreement and the Effective Time and not to take certain actions during such period.

This summary and the copy of the Arrangement Agreement attached hereto as Exhibit 2.1 are included solely to provide investors with information regarding the terms of the Arrangement Agreement. They are not

intended to provide factual information about the parties or any of their respective subsidiaries or affiliates. Investors are cautioned that the representations, warranties and covenants included in the Arrangement Agreement were made by TTHI, the Company and Sub to each other. These representations, warranties and covenants were made as of specific dates and only for purposes of the Arrangement Agreement and are subject to important exceptions and limitations, including a contractual standard of materiality that may be different from that generally relevant to investors, and are qualified by information disclosed in the Company s and TTHI s public filings as well as in confidential disclosure schedules that the parties exchanged in connection with the execution of the Arrangement Agreement. In addition, the representations and warranties may have been included in the Arrangement Agreement for the purpose of allocating risk between TTHI, the Company and Sub rather than to establish matters as facts. The representations and warranties contained in the Arrangement Agreement are solely for the benefit of the parties to the Arrangement Agreement. Investors are not third-party beneficiaries under the Arrangement Agreement and in reviewing the representations, warranties and covenants contained in the Arrangement Agreement or any descriptions thereof in this summary, it is important to bear in mind that such representations, warranties and covenants or any descriptions were not intended by the parties to the Arrangement Agreement to be characterizations of the actual state of facts or condition of TTHI, the Company or any of their respective subsidiaries or affiliates. Moreover, information concerning the subject matter of the representations, warranties and covenants may change after the date of the Arrangement Agreement, which subsequent information may or may not be fully reflected in TTHI s or the Company s public disclosures. For the foregoing reasons, the representations, warranties and covenants or any descriptions of those provisions should not be read alone and should instead be read in conjunction with the other information contained in the reports, statements and filings that TTHI publicly files with the Ontario Securities Commission or the SEC and that the Company publicly files with the SEC.

The foregoing description of the Arrangement Agreement and the transactions contemplated thereby does not purport to be complete and is qualified in its entirety by reference to the Arrangement Agreement, which is filed as Exhibit 2.1 to this Current Report on Form 8-K and incorporated by reference herein.

Additional Information and Where to Find It

Further information regarding the transaction will be contained in an information circular that Transition Therapeutics will prepare and mail to its stockholders in connection with the Transition Therapeutics stockholders meeting. Transition Therapeutics stockholders are urged to read the information circular once it becomes available, as it will contain important information concerning the proposed transaction. Transition Therapeutics stockholders may obtain a copy of the arrangement agreement, information circular and other meeting materials when they become available at www.sec.gov and www.sedar.com.

This 8-K is for informational purposes only. It does not constitute an offer to purchase shares of Transition Therapeutics or OPKO or a solicitation or recommendation statement under the rules and regulations of the Canadian securities regulators, the United States Securities and Exchange Commission or other applicable laws.

Cautionary Statement Regarding Forward-Looking Statements

Certain statements in this communication regarding the proposed acquisition of Transition Therapeutics by OPKO, including any statements regarding the expected timetable for completing the proposed transaction, synergies, benefits and opportunities of the proposed transaction, future opportunities for the combined company and products, future financial performance, the potential for Transition Therapeutics products, whether TT701 will serve an important need in patients who can benefit from its anabolic effects without risks associated with testosterone products, whether TT701 can be used in conjunction with our Claros®1 products, and any other statements regarding OPKO s and Transition Therapeutics future expectations, beliefs, plans, product candidates, objectives, financial conditions, assumptions or future events or performance that are not historical facts are forward-looking statements made within the meaning of Canadian Securities Laws, of Section 27A of the Securities Act of 1933, as amended (the Securities

Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). The words anticipate, probable, expect, intend, project, believe, ensure, if, estimate, forecasts, predict, outlook, may, anticipate, strategy, and similar expressions, an would, potential, might, likely plan, positioned, thereof, are intended to identify forward-looking statements.

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All forward-looking information are subject to numerous risks and uncertainties, many of which are beyond the control of OPKO and Transition Therapeutics, that could cause actual results to differ materially from the results expressed or implied by the statements. These risks and uncertainties include, but are not limited to: failure to obtain the required vote of Transition Therapeutics stockholders; the timing to consummate the proposed transaction; the risk that a condition to closing of the proposed transaction may not be satisfied or that the closing of the proposed transaction might otherwise not occur; the risk that a regulatory approval that may be required for the proposed transaction is not obtained or is obtained subject to conditions that are not anticipated; the diversion of management time on transaction-related issues; ability to successfully integrate the businesses; 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 communication may become outdated over time. OPKO and Transition Therapeutics do not assume any responsibility for updating any forward-looking statements. Additional information concerning these and other factors can be found in OPKO s and Transition Therapeutics respective filings with the SEC, available through the SEC s Electronic Data Gathering and Analysis Retrieval system at www.sec.gov, and Transition Therapeutics filings with the Ontario Securities Commission, available at www.sedar.com. The foregoing list of important factors is not exclusive. OPKO and Transition Therapeutics assume no obligation to update or revise any forward-looking statements as a result of new information, future events or otherwise, except as may be required by law. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof.

Item 3.02 Unregistered Sales of Equity Securities.

The information disclosed under Item 1.01 is incorporated into this Item 3.02 in its entirety. The Company Common Stock to be issued in connection with the Arrangement is expected to be issued in reliance upon an exemption from registration under U.S. federal securities laws provided by Section 3(a)(10) of the Securities Act for the issuance of securities in an exchange where the terms and conditions of such issuance and exchange are approved after a hearing upon the fairness of such terms and conditions at which all persons to whom it is proposed to issue securities in such exchange shall have the right to appear. The Arrangement will be subject to approval by the Ontario Superior Court of Justice. The Company anticipates that, if the Arrangement becomes effective under the terms and conditions set forth in the Arrangement Agreement (including receipt of the final order from the Ontario Superior Court of Justice), the Company Common Stock to be issued pursuant to the Arrangement Agreement will be exempt from the registration requirements of the Securities Act pursuant to Section 3(a)(10) thereof.

Item 7.01 Regulation FD Disclosure.

On June 30, 2016, the Company and TTHI issued a joint press release announcing the execution of the Arrangement Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

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 OPKO under the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit

Description

2.1 Arrangement Agreement by and among the Company, OPKO Global Holdings, Inc. and Transition Therapeutics Inc. dated as of June 29, 2016.⁽¹⁾

Joint Press Release of the Company and Transition Therapeutics Inc., dated June 30, 2016.

(1) The exhibits to the Arrangement Agreement have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish copies of any such schedules and exhibits to the U.S. Securities and Exchange Commission upon request.

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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.

Dated: June 30, 2016 By: /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President Chief Financial Officer

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EXHIBIT INDEX

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Joint Press Release of the Company and Transition Therapeutics Inc., dated June 30, 2016.

(1) The exhibits to the Arrangement Agreement have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish copies of any such schedules and exhibits to the U.S. Securities and Exchange Commission upon request.