# **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 23, 2013

# **OPKO** Health, Inc.

(Exact Name of Registrant as Specified in Charter)

001-33528

75-2402409

Delaware

| (State or Other |  | (Commission                      | (IRS Employer                                    |
|-----------------|--|----------------------------------|--|
|                 | Jurisdiction of  | File Number)                     | Identification No.)                              |
|                 | Incorporation)   |                                  |  |
|                 | 4400 Biscayne Blvd.  |                                  |  |
|                 | Miami, Florida   |                                  | 33137  |
|                 | (Address of Principal Executive Offices)   |                                  | (Zip Code)                                       |
| Reg             | istrant's telephone number, including area code: (305)   | 575-4100                         |  |
|                 | ck the appropriate box below if the Form 8-K filing is of the following provisions:                    | intended to simultaneously satis | fy the filing obligation of the registrant under |
| X               | Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)                  |                                  |  |
| X               | 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 April 23, 2013, OPKO Health, Inc., a Delaware corporation ("OPKO") and PROLOR Biotech, Inc. ("PROLOR") entered into an Agreement and Plan of Merger (the "Merger Agreement"). The Merger Agreement provides that, upon the terms and subject to the conditions set forth in the Merger Agreement, a newly formed, wholly-owned subsidiary of OPKO will merge with and into PROLOR, with PROLOR continuing as the surviving corporation and a wholly-owned subsidiary of OPKO (the "Merger").

At the effective time of the Merger (the "Effective Time"), each share of common stock of PROLOR, par value \$0.00001 per share, issued and outstanding at the Effective Time will be cancelled and converted into the right to receive 0.9951 shares of OPKO common stock, par value \$0.01 per share.

The Merger Agreement contains customary representations, warranties and obligations of the parties. The completion of the Merger is subject to various closing conditions, including obtaining the required approvals of OPKO's and PROLOR's stockholders, receiving certain regulatory and antitrust approvals (including under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended), receiving certain clearances or approvals by the Israeli Securities Authority, the SEC's declaration of effectiveness of the registration statement in connection with the issuance of OPKO common stock in the merger and the non-existence of any stop order or similar proceeding by the SEC in respect of the registration statement or the joint proxy statement/prospectus and the approval by the New York Stock Exchange with respect to the listing of the shares of OPKO common stock to be issued in the Merger. The Merger is intended to qualify as a reorganization for federal income tax purposes. The transaction is expected to close during the second half of 2013.

The Merger Agreement contains certain termination rights for both OPKO and PROLOR. If the Merger Agreement is terminated under certain circumstances specified in the Merger Agreement, OPKO or PROLOR, as the case may be will be required to pay the other a termination fee of \$9,600,000 and in certain circumstances PROLOR will be required to pay OPKO a termination fee of \$14,400,000. The Merger Agreement also contains a "go shop" provision pursuant to which PROLOR has the right to solicit and engage in discussions and negotiations with respect to competing proposals through June 2, 2013. After that date, PROLOR may continue discussions until June 22, 2013 with any party that has submitted a competing proposal that the Board of Directors and Strategic Alternatives Committee of PROLOR determines in good faith would reasonably be expected to result in a superior proposal as defined in the Merger Agreement.

Certain of OPKO's directors, executive officers and stockholders are directors and stockholders of PROLOR. Specifically, Phillip Frost, M.D., OPKO's Chairman and Chief Executive Officer, and a greater than 5% stockholder of OPKO is PROLOR's Chairman of the Board and a greater than 5% stockholder of PROLOR. Jane H. Hsiao, Ph.D., M.B.A., OPKO's Vice Chairman of the Board and Chief Technical Officer, and a greater than 5% stockholder of OPKO, and Steven D. Rubin, OPKO's Executive Vice President – Administration and a Director, and a less than 5% stockholder of OPKO are both directors of PROLOR and less than 5% stockholders of PROLOR. The Board of Directors of each of OPKO and PROLOR (with the directors noted above abstaining) has approved the Merger and the Merger Agreement. The transaction was also approved by PROLOR's Strategic Alternatives Committee.

#### Additional Information About the Transaction and Where to Find It

This communication is being made in respect of the proposed business combination involving OPKO and PROLOR. This communication may be deemed to be solicitation material in respect of the proposed business combination involving OPKO and PROLOR. In connection with the proposed transaction, OPKO will file with the SEC a registration statement on Form S-4 that will include a joint proxy statement of OPKO and PROLOR and that will also constitute a prospectus of OPKO. The definitive joint proxy statement/prospectus will be mailed to stockholders of OPKO and PROLOR. STOCKHOLDERS OF OPKO AND PROLOR ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS WHEN THEY BECOME AVAILABLE AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THOSE DOCUMENTS, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and security holders will be able to obtain free copies of the registration statement and the definitive joint proxy statement/prospectus (when available) and other documents filed with the SEC by OPKO and PROLOR through the website maintained by the SEC at www.sec.gov. Free copies of the registration statement and the definitive joint proxy statement/prospectus (when available) and other documents filed with the SEC can also be obtained by directing a request to:

OPKO CONTACT:

PROLOR CONTACT:

Steve D. Rubin, Executive Vice President – Administration Juan F. Rodriguez, Chief Financial Officer OPKO Heath, Inc.
Tel: +1 305-575-4100

Barbara Lindheim BLL Partners, LLC Tel: +1 212 584-2276 blindheim@bllbiopartners.com

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

#### **Certain Information Regarding Participants**

OPKO, PROLOR and their respective directors and executive officers and other persons may be deemed to be participants in the solicitation of proxies in respect of the proposed transaction. Information regarding OPKO's directors and executive officers is available in its proxy statement for its 2012 annual meeting of stockholders, which was filed with the SEC on April 27, 2012. Information regarding PROLOR's directors and executive officers is available in its proxy statement for its 2012 annual meeting of stockholders, which was filed with the SEC on April 24, 2012. Other information regarding the participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the definitive Joint Proxy Statement/Prospectus and other relevant materials to be filed with the SEC when they become available.

### Item 7.01 Regulation FD Disclosure.

On April 24, 2013, OPKO and PROLOR issued a press release regarding the Merger. A copy of the press release is being furnished 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 OPKO under the Exchange Act.

## Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. 99.1 <u>Description</u>
Press release of OPKO and PROLOR, dated April 24, 2013.

## **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: April 24, 2013 By: /s/ Juan F. Rodriguez

Name: Juan F. Rodriguez

Title: Senior Vice PresidentChief Financial Officer

# EXHIBIT INDEX

Exhibit No. 99.1 <u>Description</u>
Press release of OPKO and PROLOR, dated April 24, 2013.





#### OPKO HEALTH TO ACQUIRE PROLOR BIOTECH

—Acquisition Adds Promising Late Stage Product hGH-CTP Targeting Growth Hormone Deficiency and Preclinical Products Targeting Hemophilia, Obesity & Diabetes—

—Complementary Drug Development Technologies Strengthen OPKO's Innovation Leadership—

—PROLOR to Host Conference Call at 8:30 A.M. EDT Thursday, April 25 to Discuss Transaction—

Miami, U.S. and Nes-Ziona, Israel, April 24, 2013 — OPKO Health, Inc. (NYSE: OPK) and PROLOR Biotech, Inc. (NYSE MKT: PBTH) today announced that the companies have signed a definitive merger agreement under which OPKO will acquire PROLOR, a biopharmaceutical company focused on developing and commercializing longer-acting proprietary versions of already approved therapeutic proteins, in an all-stock transaction. Under the terms of the agreement, which has been approved by the boards of directors of both companies, holders of PROLOR common stock will receive 0.9951 shares of OPKO common stock for each share of PROLOR common stock. Based on a price of \$7.03 per share of OPKO common stock, the transaction is valued at approximately \$480 million, or \$7.00 per share of PROLOR common stock. The companies expect the transaction to be completed during the second half of 2013. Closing of the transaction is subject to certain conditions including, the approval of OPKO's and PROLOR's stockholders and other customary closing conditions.

PROLOR's long-acting version of human growth hormone, hGH-CTP, has successfully completed four clinical trials, including a Phase II trial in adults with growth hormone deficiency (GHD). The trials showed that hGH-CTP has the potential to reduce the required dosing frequency of human growth hormone from the current standard of one injection per day to a single weekly injection. hGH-CTP demonstrated a good safety and tolerability profile in these clinical trials. A Phase II trial in children with GHD is currently ongoing, and a Phase III trial in adults with GHD is planned to begin in the second quarter of 2013. Recombinant human growth hormone (hGH) is used for the long-term treatment of children and adults with GHD due to inadequate secretion of endogenous growth hormone. hGH-CTP has been awarded orphan drug designation in the U.S. and Europe for both adults and children with GHD.

PROLOR's long-acting version of human growth hormone and long-acting clotting factors in preclinical development for hemophilia are based on the company's proprietary CTP technology. When attached to a therapeutic protein, CTP significantly extends the length of time the protein remains active in the body. Clinical and preclinical studies show that the CTP technology appears to be safe and effective in extending the duration of all proteins tested to date. CTP was identified at Washington University in St. Louis and is exclusively licensed to PROLOR for all proteins and peptides, except for four endocrine proteins that are licensed to Merck. One of these, the long-acting fertility drug Elonva®, is already marketed by Merck & Co. in Europe.

"This transaction is consistent with OPKO's stated objective of broadening our portfolio of market-transforming therapies in selected specialty markets," commented Dr. Phillip Frost, OPKO's Chairman and Chief Executive Officer. "With the inclusion of PROLOR's pipeline, OPKO will have four significant products in Phase III clinical development and a robust pipeline of important therapeutic and unique diagnostic products in various stages of development. PROLOR's drug-product candidates for growth hormone deficiency, hemophilia, obesity and diabetes, along with its broadly applicable technology platforms and efficient research and development center are highly valuable assets that will complement OPKO's strategy."

"We believe this transaction recognizes the value we have created at PROLOR and provides our shareholders with attractive economic terms, as well as the opportunity to continue to share in the success of the combined company," commented Shai Novik, President of PROLOR. "We believe that OPKO's track record of commitment to innovation and growth, along with its diversified portfolio of innovative therapeutic and diagnostic products, growing international presence, ongoing investments in commercial infrastructure and highly experienced management team make this combination an excellent fit for PROLOR."

"Leveraging the combined resources of both companies not only strengthens our various development programs, but also underscores our commitment to providing patients with next-generation therapies that may improve their health and quality of life," added Dr. Abraham Havron, Chief Executive Officer of PROLOR.

Barrington Research Associates, Inc., acted as the financial advisor to OPKO Health. Jefferies LLC acted as financial advisor to PROLOR Biotech and the Strategic Alternatives Committee on the transaction, and Oppenheimer & Co provided a fairness opinion to the Strategic Alternatives Committee. Akerman Senterfitt acted as legal advisor to OPKO Health. DLA Piper LLP (US) acted as legal advisor to the Strategic Alternatives Committee and Greenberg Traurig, P.A. acted as legal advisor to PROLOR Biotech.

#### CONFERENCE CALL AND WEBCAST INFORMATION

PROLOR will host a live teleconference and webcast with senior management and a representative of OPKO management to discuss the acquisition on Thursday, April 25, 2013 at 8:30 a.m. EDT. To participate in the conference call, please dial toll-free at 1-866-652-5200 (U.S.), 1-855-669-9657 (Canada), 1-80-9213284 (Israel) or at 1-412-317-6060 for other countries. After placing the call, please tell the operator you wish to join the PROLOR investor conference call. A replay of the conference call will be available through May 1, 2013 at: 1-877-344-7529 (U.S.) and 1-412-317-0088 (international). Ask for conference number 10028297.

Alternatively, the live webcast of the conference call and slide presentation can be accessed via PROLOR's website at <a href="https://www.prolor-biotech.com">www.prolor-biotech.com</a>. Windows Media or Real Player will be needed to access the webcast. The webcast will be available on PROLOR's website for at least 90 days.

### 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. For more information, visit http://www.opko.com.

## ABOUT PROLOR BIOTECH, INC.

PROLOR Biotech, Inc. is a clinical stage biopharmaceutical company applying unique technologies, including patented CTP technology, primarily to develop longer-acting proprietary versions of already approved therapeutic proteins that currently generate billions of dollars in annual global sales. The CTP technology is applicable to virtually all proteins. In addition to its long-acting version of human growth

hormone, which successfully completed a Phase II clinical trial, PROLOR is also developing long-acting versions of Factor VIIa and Factor IX for hemophilia and a GLP-1/Glucagon dual receptor agonist peptide for diabetes and obesity. For more information, visit <a href="www.prolor-biotech.com">www.prolor-biotech.com</a>

#### ADDITIONAL INFORMATION AND WHERE TO FIND IT

This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. In connection with the proposed merger between PROLOR and OPKO, OPKO will file with the Securities and Exchange Commission (the "SEC") a Registration Statement on Form S-4 that will include a proxy statement of OPKO and PROLOR and a prospectus of OPKO. Stockholders of OPKO and PROLOR are urged to read the joint proxy statement/prospectus regarding the proposed transaction when it becomes available, as well as other documents filed with the SEC, because they will contain important information. Stockholders of OPKO and PROLOR will be able to obtain a copy of the joint proxy statement/prospectus, as well as other filings containing information about PROLOR and OPKO, without charge, at the SEC's website (www.sec.gov). Stockholders of OPKO and PROLOR may also obtain copies of all documents filed with the SEC, without charge, by directing a request to Shachar Shlosberger, PROLOR Biotech, Inc., 7 Golda Meir Street, Weizmann Science Park, Nes-Ziona, Israel 74140, telephone (+972) 8-930-0051, or Steven D. Rubin or Juan F. Rodriguez, OPKO Health, Inc., 4400 Biscayne Blvd., Miami, Florida, telephone (305) 575-4100.

#### SAFE HARBOR STATEMENT

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 benefits resulting from the acquisition of PROLOR, including whether the Phase 3 clinical trials for hGH-CTP will be commenced or completed on a timely basis or at all, that earlier clinical results may not be reproducible or indicative of future results, that hGH-CTP and/or any of PROLOR's compounds 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 products, as well as products under development by others, may prove to be as or more effective than PROLOR's 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 OPKO's and PROLOR's filings with the Securities and Exchange Commission, the ability to obtain regulatory approvals for the transaction on the proposed terms and schedule; the failure of OPKO's or PROLOR's stockholders to approve the transaction; the risk that a condition to closing of the merger may not be satisfied; the time required to consummate the proposed merger; the focus of management on merger-related issues; 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 press release may become outdated over time. OPKO and PROLOR do not assume any responsibility for updating any forward-looking statements.

You may obtain copies of all documents filed with the SEC regarding this transaction, free of charge, at the SEC's website (<a href="www.sec.gov">www.sec.gov</a>). You may also obtain these documents, free of charge, from OPKO's website (<a href="www.opko.com">www.opko.com</a>). You may also obtain these documents, free of charge, from PROLOR's website (<a href="www.prolor-biotech.com">www.prolor-biotech.com</a>).

PARTICIPANTS IN THE MERGER SOLICITATION PROLOR, OPKO and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of PROLOR and OPKO in connection with the proposed transaction. Information about PROLOR's directors and executive officers is set forth in its proxy statement for its 2012 Annual Meeting of Stockholders, which was filed with the SEC on April 24, 2012, and its Annual Report on Form 10-K for the year ended December 31, 2012, filed on March 15, 2013. These documents are available free of charge at the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a>, or by going to PROLOR's Investor Relations page on its corporate website at <a href="https://www.sec.gov">www.sec.gov</a>, or by going to OPKO's directors and executive officers is set forth in its proxy statement for its 2012 Annual Meeting of Stockholders, which was filed with the SEC on April 27, 2012, and its Annual Report on Form 10-K for the year ended December 31, 2012, filed on March 18, 2013. These documents are available free of charge at the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a>, or by going to OPKO's Investor Relations page on its corporate website at <a href="https://www.sec.gov">www.sec.gov</a>, or by going to OPKO's Investor Relations page on its corporate website at <a href="https://www.sec.gov">www.sec.gov</a>, or by going to OPKO's Investor Relations page on its corporate website at <a href="https://www.sec.gov">www.sec.gov</a>, or by going to OPKO's Investor Relations page on its corporate website at <a href="https://www.sec.gov">www.sec.gov</a>, or by going to OPKO's Investor Relations page on its corporate website at <a href="https://www.sec.gov">www.sec.gov</a>, or by going to OPKO's Investor Relations page on its corporate website at <a href="https://www.sec.gov">www.sec.gov</a>, or by going to OPKO's Investor Relations of proxies in connection with the transaction will be included in the joint proxy statement/prospe

OPKO CONTACT:

Steve D. Rubin, Executive Vice President – Administration

Juan F. Rodrigez, Chief Financial Officer

OPKO Heath, Inc.

Tel: +1 305 575-4100

PROLOR CONTACT:

Barbara Lindheim
BLL Partners, LLC

+1 212 584-2276

blindheim@bllbiopartners.com