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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):

December 10, 2010

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 1.01 Entry into a Material Definitive Agreement.**

On December 10, 2010, OPKO Health, Inc. and TESARO, Inc. entered into a definitive agreement granting TESARO exclusive rights to the development, manufacture, commercialization and distribution of rolapitant and a related compound. Under the terms of the agreement, OPKO is eligible for payments of up to \$121 million, including an up-front payment of \$6 million, and additional payments based upon achievement of specified regulatory and commercialization milestones. In addition, TESARO will pay to OPKO double digit tiered royalties on sales of licensed product. TESARO and OPKO will share future profits from the commercialization of licensed products in Japan and OPKO will have an option to market the products in Latin America. In addition, OPKO will acquire a 10% equity position in TESARO.

**Item 9.01 Financial Statements and Exhibits.**

99.1 Press Release

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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.

*December 14, 2010*

*By: Adam Logal*

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*Name: Adam Logal*

*Title: Executive Director of Finance, Chief Accounting  
Officer and Treasurer*

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Exhibit Index

Exhibit No.	Description
99.1	Press Release



December 14, 2010

## **TESARO AND OPKO HEALTH SIGN EXCLUSIVE LICENSE AGREEMENT FOR ROLAPITANT**

- *Rolapitant is a Phase III-ready neurokinin-1 (NK-1) receptor antagonist in development for chemotherapy induced nausea and vomiting (CINV)*
- *TESARO will be responsible for worldwide development and commercialization*

**Boston & Miami** – (BUSINESS WIRE)– TESARO, Inc. and OPKO Health, Inc. (NYSE Amex:OPK) today announced that they have signed a definitive agreement granting TESARO exclusive rights for the development, manufacture, commercialization and distribution of rolapitant and a related compound. Rolapitant, a Phase III-ready, oncology supportive-care product candidate, is a potent and selective neurokinin-1 (NK-1) receptor antagonist with an extended plasma half-life that has the potential to improve the management of nausea and vomiting experienced by cancer patients undergoing treatment with emetogenic chemotherapy. Phase II clinical testing of rolapitant for the prevention of nausea and vomiting in cancer patients treated with highly emetogenic chemotherapy demonstrated promising five-day activity following the administration of a single dose.

Under the terms of the agreement OPKO is eligible for payments of up to \$121 million, including an up-front payment and additional payments based upon achievement of specified regulatory and commercialization milestones; and will receive double digit tiered-royalties on sales. TESARO and OPKO will share future profits from the commercialization of licensed products in Japan and OPKO will have an option to market the products in Latin America. In addition, OPKO will acquire a 10% equity position in TESARO.

“TESARO is very pleased to announce this agreement with OPKO and to advance the development of rolapitant, an important supportive care product candidate,” said Lonnie Moulder, Chief Executive Officer of TESARO. “Having successfully commercialized the present market-leading therapy in the U.S. for CINV prevention while building MGI PHARMA, our leadership team has a deep understanding of the unmet patient needs and market dynamics that exist in this area of oncology supportive care. We believe that rolapitant may be differentiated from other agents in this class and has great potential to help cancer patients undergoing chemotherapy. In addition, this first transaction will greatly accelerate our plans to build a leading oncology-focused biopharma company.”

TESARO was co-founded by former executives of MGI PHARMA, an oncology and acute-care focused biopharmaceutical company that Eisai Co., Ltd. acquired in 2008 for \$3.9 billion. While at MGI PHARMA, TESARO executives led the development and commercialization of numerous oncology products, including the successful U.S. commercialization of Aloxi<sup>®</sup> (palonosetron HCl), the leading product in the 5-HT<sub>3</sub> receptor antagonist class for prevention of CINV.

“We are pleased to complete this important transaction and look forward to seeing rolapitant progress towards registration in key markets throughout the world,” said Phillip Frost, M.D., OPKO’s Chairman and Chief Executive Officer. “The TESARO team’s special expertise and successful experience with the development and commercialization of oncology products will be of enormous benefit in making rolapitant a meaningful product for cancer patients and a commercial success.”

“There is a continued need for unique agents to prevent nausea and vomiting associated with emetogenic chemotherapy regimens,” said Steven Grunberg, M.D., Professor of Medicine and Pharmacology, University of Vermont. “The successful results of the randomized, controlled Phase II clinical trial of rolapitant in patients receiving an anticancer regimen with high potential to produce nausea and vomiting are encouraging for this potentially differentiated agent.”

### **About Rolapitant**

Rolapitant, a potent and selective neurokinin-1 (NK-1) receptor antagonist with an extended plasma half-life, has completed Phase II clinical testing for prevention of chemotherapy induced nausea and vomiting (CINV), post-operative nausea and vomiting (PONV), and chronic cough. The safety and tolerability of single and repeat doses of rolapitant has been assessed in over 1000 healthy volunteers and patients. NK-1 receptors are highly concentrated in the brain and bind the neurokinin substance P. Activation of NK-1 receptors plays a central role in nausea and vomiting induced by emetogenic stimuli, including certain cancer chemotherapies. NK-1 receptor antagonists have been demonstrated to improve the management of nausea and vomiting experienced by cancer patients undergoing

chemotherapy.

#### **About Chemotherapy Induced Nausea and Vomiting (CINV)**

CINV is estimated to afflict over 70% of cancer patients undergoing chemotherapy and, if not prevented, may possibly result in a delay or even discontinuation of chemotherapy treatment. Prolonged nausea and vomiting may result in unwanted weight loss, dehydration and malnutrition as well as hospitalization.

#### **About OPKO Health, Inc.**

Miami-based OPKO is a specialty healthcare company involved in the discovery, development, and commercialization of proprietary pharmaceutical products, medical devices, vaccines, diagnostic technologies and imaging systems. Initially focused on the treatment and management of ophthalmic diseases, OPKO has since expanded into other areas of major unmet medical need. For more information, visit [www.opko.com](http://www.opko.com).

#### **About TESARO, Inc.**

Founded in 2010, TESARO is a privately held oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients by acquiring, developing and commercializing safer and more effective therapeutics. Earlier this year, TESARO secured \$60 million in start-up funding from New Enterprise Associates (NEA) and the TESARO founders. TESARO is headquartered in Boston, Massachusetts. For more information, visit [www.tesarobio.com](http://www.tesarobio.com).

#### **For Further Information Contact:**

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*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 product development efforts, including the ability to develop and commercialize rolapitant for chemotherapy-induced nausea and vomiting, the ability to obtain registration for rolapitant in key markets and the timing thereof, and the potential for rolapitant to help cancer patients undergoing chemotherapy, as well as other non-historical statements about expectations, beliefs or intentions regarding business, technologies and products, financial condition, strategies or prospects. These forward-looking statements are not guarantees of OPKO’s or TESARO’s future performance and involve a number of risks and uncertainties that may cause actual results to differ materially from the results discussed in these statements. Many factors could cause either Company’s actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include, an inability to successfully develop and commercialize rolapitant and the NK-1 program assets, that rolapitant may not achieve the expected results or effectiveness and may not generate data that would support the approval or marketing of this product, that others may develop products, including other NK-1 receptor antagonists, which are superior to rolapitant, and that the acquired compounds may not have advantages over presently marketed products. In addition, forward-looking statements may also be adversely affected by risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, 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 OPKO and TESARO do not undertake any obligation to update forward-looking statements. The Companies’ intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.*

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