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): November 7, 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 2.02 Results of Operations and Financial Condition.

On November 7, 2014, OPKO Health, Inc., a Delaware corporation (the "Company") issued a press release announcing operating and financial highlights for the quarter ended September 30, 2014. A copy of the press release is attached hereto as Exhibit 99.1.

The information included herein and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 ("Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company dated November 7, 2014

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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.

November 7, 2014

By: /s/ Adam Logal

Name: Adam Logal
Title: Senior Vice President-Chief Financial Officer

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Exhibit Index

Exhibit No.	Description
99.1	Press Release of the Company dated November 7, 2014

OPKO Announces Third Quarter Operating and Financial Results

- **Rayaldee™ Meets Primary Endpoints in Both Pivotal Phase 3 Trials; NDA Submission Planned for Q4 2014**
- **Rayaldee Results to be Presented at American Society of Nephrologists Meeting**
- **Clinical Trial Start for Rayaldee as Adjunctive Cancer Therapy to Begin in Q4 2014**
- **European Marketing Commenced for 4Kscore™ Blood Test to Identify Risk of Aggressive Prostate Cancer; Latin America Rollout Planned for Fourth Quarter 2014**
- **Rolapitant™ NDA Submitted by OPKO Licensee Tesaro and Accepted for Review by FDA**
- **Cash and Cash Equivalents of $118.3 Million Providing Adequate Liquidity To Fund Development Programs**
- **hGH-CTP Development Program Continues to Progress Rapidly**
- **Long Acting Factor VII for Hemophilia and Long Acting Oxyntomodulin for Obesity and Diabetes Clinical Trials to Begin During 2015**

MIAMI—November 7, 2014 — OPKO Health, Inc. (NYSE:OPK), a multi-national biopharmaceutical and diagnostics company, today reported operating and financial results for its third quarter ended September 30, 2014.

Business Highlights

- **Rayaldee Meets Primary Endpoints in Both Pivotal Phase 3 Trials; NDA Submission planned for Q4 2014:** OPKO announced successful top-line results from both of its pivotal Phase 3 trials with Rayaldee. These trials were identical randomized, double-blind, placebo-controlled, multi-site studies intended to establish the safety and efficacy of Rayaldee as a new treatment for secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency. OPKO plans to submit a New Drug Application (NDA) with the United States (U.S.) Food and Drug Administration (FDA) in the fourth quarter of 2014.
- **Rayaldee Results to be Presented at Upcoming American Society of Nephrologists Meeting:** Rayaldee Phase 3 trial data will be unveiled in a late-breaking clinical presentation entitled “Safety and Efficacy of Modified-release Calcifediol for Secondary Hyperparathyroidism in Patients with Stage 3 or 4 CKD and Vitamin D Insufficiency “ on November 15, 2014 during the American Society of Nephrology meeting in Philadelphia, PA.
- **Clinical Trial Start for Rayaldee as Adjunctive Cancer Therapy Anticipated For Q4 2014:** OPKO intends to initiate a clinical trial to evaluate Rayaldee as an adjunctive therapy for the prevention of skeletal-related events (SREs) in breast and prostate cancer patients with bone metastases undergoing anti-resorptive therapy during the fourth quarter of 2014.
- **hGH-CTP Development Program Continues to Progress Rapidly:** OPKO’s hGH-CTP development programs for long acting growth hormone continue to make significant progress during the first nine months of 2014. Enrollment of our ongoing Phase 3 clinical trial in adults continues to advance and interim data for our pediatric Phase 2 clinical trials were presented at the European Society of Pediatric Endocrinology Conference in September.
- **Long Acting Factor VII for Hemophilia and Long Acting Oxyntomodulin for Obesity and Diabetes Clinical Trials to Begin During 2015:** OPKO’s development programs for long acting Factor VII and long acting oxyntomodulin continue to progress toward entering clinical trials during 2015.
- **European Launch for the 4Kscore Test Commenced; Adoption of 4Kscore Test Continues to Grow:** During September, OPKO launched the 4Kscore Test in Europe through its wholly owned subsidiary, OPKO Health Spain. Earlier this year, OPKO completed a validation study and launched the 4Kscore Test in the U.S. through its CLIA accredited OPKO Lab. OPKO also expects to launch the 4Kscore Test in Latin America through its Chilean and Mexican subsidiaries in late 2014 and elsewhere shortly thereafter. OPKO is working to obtain reimbursement for the 4Kscore Test by payers in the U.S. and abroad and expects adoption to rapidly increase once reimbursement is received. The presentation, “The 4Kscore Test as a Predictor of High-Grade Prostate Cancer on Biopsy,” was presented at meetings of the New England Section and Western Section of the American Urological Association in October 2014.
- **Rolapitant NDA Filing Submitted in September and Accepted for Review by FDA in November:** OPKO’s partner, TESARO, submitted a NDA to the FDA for approval of oral rolapitant, an investigational neurokinin-1 (NK-1) receptor

antagonist in development for the prevention of chemotherapy-induced nausea and vomiting (CINV). The NDA is supported by data from four controlled studies covering a spectrum of patients receiving chemotherapy that commonly causes nausea and vomiting. The top-line results of three of the Phase 3 studies were previously announced by TESARO and were presented in detail at the American Society for Clinical Oncology (ASCO) annual meeting in June 2014. On November 5, 2014, Tesaro announced the FDA accepted its NDA filing for rolapitant which triggered a milestone payment to OPKO under its license agreement with TESARO.

"We made significant progress during the third quarter, successfully completing our two Phase 3 trials for Rayaldee with positive efficacy and safety results, and successfully launching our 4Kscore Test in Europe," said Phillip Frost, M.D., Chairman and CEO. "We continue to see the 4Kscore Test being increasingly adopted by Urologists in the U.S. and abroad and expect to launch it in Mexico and Chile in the coming months," Dr. Frost continued. "We also aggressively pursued our Factor VII product for hemophilia and oxyntomodulin for overweight and obesity and hope to begin clinical trials in mid-2015."

Financial Highlights

At September 30, 2014, OPKO had cash and cash equivalents of $118.3 million providing OPKO with adequate liquidity to continue the development of its product candidates. During the nine months ended September 30, 2014, OPKO continued to increase its investment in research and development programs, utilizing $65.6 million of cash from operations. The principal use of cash from operations include investments in clinical trials for Rayaldee and hGH-CTP, a clinical validation study for the 4Kscore Test which was completed in March 2014, and the continued development of OPKO's Claros 1™ Analyzer point of care platform system, as well as OPKO's earlier stage development programs.

Pharmaceutical product revenue for the three months ended September 30, 2014 increased to $17.3 million compared to $16.6 million for the 2013 period. This increase was principally the result of increased revenue from OPKO's active pharmaceutical ingredient business at FineTech. Total revenue for the three months ended September 30, 2014 was $19.8 million compared to $20.6 million for the 2013 period. The decrease in total revenue was the result of the 2013 period including non-recurring revenue of $1.3 million related to OPKO's transaction with Pharmsynthez, partially offset by increased pharmaceutical product revenue.

Net loss for the three months ended September 30, 2014 was $48.7 million, compared to $60.0 million in the comparable period of 2013. As a result of the successful achievement of the primary efficacy and safety endpoints for the Rayaldee Phase 3 clinical trials, the valuation for contingent consideration payable to the sellers of Cytochroma increased significantly during the three months ended September 30, 2014 resulting in $17.7 million of increased contingent consideration expense. Further, OPKO continued to increase its investment in research and development activities during the three months ended September 30, 2014 related to its ongoing Phase 3 programs for Rayaldee and hGH-CTP. As a result, OPKO's spending on research and development increased $9.4 million to $20.5 million for the three months ended September 30, 2014 from $11.1 million for the three months ended September 30, 2013. These increases were partially offset during the three months ended September 30, 2014 by a decrease in non-cash expense of $40.8 million from the change in fair value of our derivative instruments, principally related to our Senior 2033 Notes.

For the nine months ended September 30, 2014, pharmaceutical product revenue increased approximately 15% to $58.5 million compared to $50.7 million for the 2013 period. The increase in pharmaceutical product revenue was principally the result of increased revenue from FineTech, OPKO Health Europe and OPKO Mexico. Total revenue for the nine months ended September 30, 2014 was $65.6 million compared to $75.8 million for the 2013 period. Total revenue for the nine months ended September 30, 2013 included non-cash, non-recurring revenue of $12.5 million and $3.2 million of non-recurring revenue related to OPKO's transactions with RXi and Pharmsynthez, respectively, which was partially offset by increased product revenue.

Net loss for the nine months ended September 30, 2014 was $118.7 million compared to $98.0 million for the first nine months of 2013. OPKO continued to increase its investment in research and development activities related to its Phase 3 programs for Rayaldee and hGH-CTP, as well as incurred costs associated with the clinical validation study for the 4Kscore, the Claros 1 Analyzer point of care diagnostic platform and earlier stage development programs. As a result, OPKO's investment in research and development increased $27.2 million to $57.7 million for the nine months ended September 30, 2014 from $30.6 million for the nine months ended September 30, 2013. In addition, net loss for the nine months ended September 30, 2014 included a non-recurring in-process research and development expense of $10.1 million due to a write-off of in-process research and development expense in connection with the acquisition of Inspiro. Further, as a result of the successful achievement of the primary efficacy and safety endpoints for Rayaldee, the valuation of the contingent consideration payable to the sellers of Cytochroma increased significantly during the period resulting in $19.0 million of increased contingent consideration expense. The nine month period ended September 30, 2013 included $12.5 million of non-cash income related to the RXi transaction and a $10.8 million gain realized from the successful exit of a strategic investment. These reductions were partially offset during the nine months ended September 30, 2014 by a decrease in non-cash expense of $52.1 million from the change in fair value of our derivative instruments, principally related to our Senior 2033 Notes of which we retired $70 million during June 2014.

About OPKO Health, Inc.

We are a multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies.

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 expected financial performance, continued revenue growth and our ability to build a profitable business, whether we have sufficient liquidity to fund development of our product candidates and operations, our product development effort and the expected benefits of our products, including whether our ongoing and future Phase 3 clinical trials will be completed on a timely basis or at all and whether the data from any of our trials will support approval, validation and/or reimbursement for our products, the expected timing for launch of our products in development, including Rayaldee and hGH-CTP, the expected timing of our clinical trials, enrollment in clinical trials, and disclosure of results for the trials, our ability to market and sell any of our products in development, including Rayaldee, the 4Kscore, and hGH-CTP, our ability to launch sales of the 4Kscore Test in Latin America and through our other subsidiaries, increased adoption rates for the 4Kscore by Urologists in the U.S. and abroad, the timing for submission of a NDA by us for Rayaldee, whether the 4Kscore will provide substantial benefits to patients and doctors by informing them of the risk of a patient having a high-grade cancer and clarify the decision making process, whether the 4Kscore will reduce unnecessary biopsies, 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 Annual Reports on Form 10-K filed and to be filed with the Securities and Exchange Commission and in our other filings with the Securities and Exchange Commission, as well as the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, that the 4Kscore, Rayaldee, Rolapitant, hGH-CTP, and/or any of our compounds or diagnostic 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. 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.
Les Funtleyder (305) 575-6013

OPKO Health, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(unaudited)
(in millions)

	As of	
	September 30, 2014	December 31, 2013
Assets:		
Cash and cash equivalents	$ 118.3	$ 185.8
Other current assets	44.8	56.9
Total Current Assets	163.1	242.7
In-process Research and Development and Goodwill	1,018.0	1,019.7
Other assets	114.1	129.1
Total Assets	$ 1,295.2	$ 1,391.5
Liabilities and Equity:		
Current liabilities	$ 76.8	$ 91.8
2033 Senior Notes, net	114.9	211.9
Other long-term liabilities	216.2	214.8
Total Liabilities	407.9	518.5
Equity	887.3	873.0
Total Liabilities and Equity	$ 1,295.2	$ 1,391.5

OPKO Health, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(unaudited)
(in millions, except per share data)

	For the three months ended	
	September 30, 2014	2013
Revenues	$ 19.8	$ 20.6
Costs and expenses	68.0	39.7
Operating loss	(48.2)	(19.0)
Other income and (expense), net	(1.5)	(38.9)
Loss before income taxes and investment losses	(49.7)	(57.9)
Benefit from (provision for) income taxes	(0.3)	(1.3)
Loss before investment losses	(50.0)	(59.2)
Loss from investments in investees	(0.0)	(1.6)
Net loss	(50.0)	(60.8)
Less: Net loss attributable to non-controlling interests	(1.3)	(0.8)
Preferred stock dividend	—	—

Net loss attributable to common shareholders	$ (48.7)	$ (60.4)
Basic and diluted loss per share	$ (0.11)	$ (0.17)

	For the nine months ended September 30,	
	2014	2013
Revenues	$ 65.6	$ 75.8
Costs and expenses	179.0	119.6
Operating loss	(113.4)	(43.8)
Other income and (expense), net	(4.3)	(46.0)
Loss before income taxes and investment losses	(117.7)	(89.8)
Benefit from (provision for) income taxes	(1.0)	(2.3)
Loss before investment losses	(118.7)	(92.1)
Loss from investments in investees	(2.5)	(7.8)
Net loss	(121.2)	(99.9)
Less: Net loss attributable to non-controlling interests	(2.5)	(2.3)
Preferred stock dividend	—	(0.4)
Net loss attributable to common shareholders	$ (118.7)	$ (98.0)
Basic and diluted loss per share	$ (0.28)	$ (0.29)

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