UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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, 2016

OPKO Health, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-33528**	**75-2402409**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS 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

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 (see General Instruction A.2. below):

☐ 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 2.02. Results of Operations and Financial Condition.

On November 7, 2016, OPKO Health, Inc., a Delaware corporation (the "Company"), issued a press release announcing operating and financial highlights for the quarter ended September 30, 2016. 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, 2016

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.

Date: November 7, 2016

OPKO Health, Inc.

By /s/ Adam Logal

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

Exhibit List

Exhibit No.	Description
99.1	Press Release of the Company dated November 7, 2016

Exhibit 99.1

OPKO Health Reports Financial Third Quarter Operating Results

- **Consolidated revenue increased to $298.0 million for the three months ended September 30, 2016 from $143.0 million for the comparable period of 2015. Consolidated revenue for the nine months ended September 30, 2016 increased to $946.2 million from $215.5 million for the comparable period of 2015.**
- **Net loss was $15.0 million for the three months ended September 30, 2016 compared to net income of $128.2 million for the comparable period of 2015. For the nine months ended September 30, 2016, net loss was $11.4 million compared to net loss of $31.6 million for the comparable period of 2015**
- **U.S. commercial launch of *RAYALDEE*® planned for late November 2016; full marketing and sales team now in place**
- **Completed acquisition of Transition Therapeutics; Phase 2 clinical trial protocols for two important products being developed**
- ***4Kscore* test utilization continues to grow; many payors now in place, negotiations with others continue**
- **Topline data for three long acting biologic products to be presented**
    - **Long acting hGH-CTP topline Phase 3 data in adults in 4Q 2016**
    - **Long acting Factor VIIa-CTP safety data from the first in human Phase 2a trial in early 2017**
    - **Long acting oxyntomodulin first in human Phase 1 safety data expected early 2017**
- **Clinical trials for Claros point of care (POC) PSA test to begin in late 2016; PMA filing anticipated in 1H 2017; Claros POC testosterone test clinical trials and 510(k) filing to follow in 2017**

MIAMI (November 7, 2016) – OPKO Health, Inc. (NASDAQ:OPK), reports financial and operating results for the three months ended September 30, 2016.

Financial Highlights

- Consolidated revenues for the three months ended September 30, 2016 increased to $298.0 million from $143.0 million for the comparable period 2015. The 2016 period includes revenue from BioReference, acquired in August 2015.

- Net loss for the three months ended September 30, 2016 was $15.0 million compared with net income of $128.2 million for the 2015 period. Net (loss) income during the three month periods include significant non-recurring and non-cash activities:
    - The 2015 period includes a non recurring income tax benefit related to the release of a valuation allowance against our deferred tax assets as a result of the BioReference acquisition; and
    - Other income and (expense) was ($10.5) million and $47.0 million in the 2016 and 2015 periods, respectively, primarily related to the change in fair value of derivative instruments. The change in fair value is principally related to an embedded derivative in OPKO's January 2013 convertible senior notes due in 2033. The 2015 period also includes a non-recurring gain of $17.3 million related to our deconsolidation of SciVac Therapeutics Ltd. The three months ended September 30, 2016 includes $3.9 million of other than temporary impairment expense for two of our strategic investments as a result of a decrease in share price.
- Cash, cash equivalents and marketable securities were $144.6 million as of September 30, 2016.

Business Highlights

- ***RAYALDEE* launch scheduled for late November 2016:** The U.S. Food and Drug Administration (FDA) approved *RAYALDEE* for the treatment of secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. *RAYALDEE* is a patented product containing 30 mcg of a prohormone called calcifediol (25-hydroxyvitamin D3). OPKO has now completed hiring and training a highly specialized marketing and sales team, which is ready for the November 2016 launch.
- **Transition Therapeutics:** The acquisition of Transition Therapeutics Inc., a Toronto based biotechnology company, closed in August 2016. Transition Therapeutics has two drugs in mid-stage clinical development; TT401, a long acting GLP-1/glucagon dual agonist for the treatment of type 2 diabetes and obesity, and TT701, an orally administered selective androgen receptor modulator (SARM) being developed for the treatment of patients who will benefit from its effects on increasing muscle and bone strength and decreasing body fat mass.
- ***4Kscore* test utilization continues to grow; reimbursement in place with many payors, coverage negotiations continue with others:** Reimbursement of the *4Kscore* test is progressing; pricing agreements are already in place with several payors, and the Company is working to obtain positive coverage by its local Medicare administrator. During the quarter ended September 30, 2016, approximately 16,000 *4Kscore* tests were performed, a 9% increase from the quarter ended June 30, 2016 and a 365% increase over the comparable period of 2015.
- **Top-line data for three long acting biologic programs anticipated**
    - **Long acting hGH-CTP topline Phase 3 data in adults in 4Q 2016:** OPKO expects to report top-line results from its Phase 3 trial evaluating the safety and efficacy of once weekly injections of hGH-CTP with a primary endpoint of superiority compared to placebo in decreasing fat mass in adults with growth hormone deficiency (GHD) in the fourth quarter of 2016. The trial is a randomized, double-blind, placebo controlled, multicenter, global study in adults with GHD.

- **Long acting Factor VIIa-CTP safety data from the first in human Phase 2a trial expected in early 2017:** This is a dose escalation study to determine safety for OPKO's long-acting version of coagulation Factor VIIa (Factor VIIa-CTP) for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX.
- **Long acting oxyntomodulin first in human Phase 1 safety data expected early 2017:** OPKO's Phase 1 single dose escalation study to evaluate the safety and pharmacokinetics of our long acting oxyntomodulin (MOD-6031) in healthy subjects was successful in determining the maximum tolerable dose, indicating activity, as expected.

- **Clinical trials for Claros point of care (POC) PSA test to begin in late 2016; PMA filing anticipated in 1H 2017; Claros POC testosterone test clinical trials and 510(k) filing to follow in 2017:** OPKO intends to commence a multi-center clinical study of OPKO's POC diagnostic test for prostate specific antigen (PSA) utilizing its proprietary diagnostic platform in late 2016. OPKO intends to submit its application to the FDA for approval of the assay in mid-2017. OPKO expects to commence an additional multi-center clinical study for its POC testosterone test in 2017 followed by a 510(k) submission in late 2017.

"We are finalizing the details of our commercial launch of *RAYALDEE* and have completed the selection and hiring of a very talented commercial team, all of whom bring deep relationships in the nephrology and specialty pharmaceutical sales market," stated Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "*RAYALDEE* will be an important medicine for a large number of chronic kidney disease patients suffering from SHPT and vitamin D insufficiency. We are working closely with the Vifor Fresnius Medical Care Renal Pharma team to bring *RAYALDEE* to market outside the U.S. and are presently planning the start of a Phase 3 trial in dialysis patients which represents the first potential line extension for *RAYALDEE* in addition to its currently approved indication."

"With the Transition Therapeutics acquisition, we now have two additional important drugs in Phase 2 development; one for patients who could benefit from its effects on increasing bone and muscle strength while decreasing fat mass; the other for type 2 diabetes and obesity. Each drug has already been studied and shown to be safe in approximately 400 patients. We are also very pleased to now have the benefit of an experienced Transition Therapeutics team led by its CEO, Tony Cruz. "Our BioReference Laboratories and its GeneDx unit continue to grow and the utilization of our innovative *4Kscore* test for predicting the probability of aggressive prostate cancer remains strong. Last, we have made great progress on our Claros point of care diagnostic system and anticipate starting clinical trials for our PSA and testosterone tests in the coming months," continued Dr. Frost.

CONFERENCE CALL & WEBCAST INFORMATION:

OPKO's senior management will provide a business update and discuss results in greater detail in a conference call and live audio webcast at 4:30 p.m. Eastern time today.

The conference call dial in information is listed below. To access the webcast, please log on to the OPKO website at www.opko.com.

WHEN: Monday, November 7, 2016, 4:30 p.m. ET
DOMESTIC DIAL-IN: (866) 634-2258
INTERNATIONAL DIAL-IN: (330) 863-3454
PASSCODE: 12830677

For those unable to participate in the conference call or webcast, a replay will be available beginning November 7, 2016 at 7:30 p.m. ET for a period of time. To access the replay, dial (855) 859-2056 or (404) 537-3406. The replay passcode is: 12830677.

The replay can also be accessed for a period of time on OPKO's website at www.opko.com.

About OPKO Health, Inc.

OPKO Health is a diversified healthcare company that seeks to establish industry-leading positions in large, rapidly growing markets. Our diagnostics business includes Bio-Reference Laboratories, the nation's third-largest clinical laboratory with a core genetic testing business and a 420-person sales force to drive growth and leverage new products, including the 4Kscore® prostate cancer test and the Claros® 1 in-office immunoassay platform. Our pharmaceutical business features RAYALDEE, an FDA-approved treatment for SHPT in stage 3-4 CKD patients with vitamin D insufficiency, VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation launched by partner TESARO and IV formulation PDUFA date: January 2017), TT401, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists, and TT701, an androgen receptor modulator for androgen deficiency indications. Our biologics business includes hGH-CTP, a once-weekly human growth hormone injection (in phase 3 and partnered with Pfizer), a long-acting Factor VIIa drug for hemophilia (in phase 2a) and a long-acting oxyntomodulin for diabetes and obesity (in phase 1). We also have production and distribution assets worldwide, multiple strategic investments and an active business development strategy. More information is available at www.opko.com.

Cautionary Statement Regarding Forward-Looking Statements

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, our product development efforts and the expected benefits of our products, including whether our ongoing and future 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, the expected timing of commencing and concluding our clinical trials, enrollment in clinical trials, and disclosure of results for the trials, the timing of our regulatory submissions, our ability to market and sell any of our products in development, expectations about developing RAYALDEE for dialysis patients, our ability to obtain broad reimbursement coverage for the 4Kscore test, increased adoption rates for the 4Kscore, our expectations about the

Transition Therapeutics products in development, 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 integration challenges for Bio-Reference, EirGen, Transition, and other acquired businesses, 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, Varubi™, 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.

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

	As of	
	September 30, 2016	December 31, 2015
Assets:		
Cash, cash equivalents and marketable securities	$ 144.6	$ 193.6
Other current assets	357.4	260.5
Total Current Assets	502.0	454.1
In-process Research and Development and Goodwill	1,347.5	1,535.6
Other assets	950.5	809.5
Total Assets	$ 2,800.0	$ 2,799.2
Liabilities and Equity:		
Current liabilities	$ 254.5	$ 251.9
2033 Senior Notes, net	51.5	49.0
Deferred tax liabilities	184.5	226.0
Other long-term liabilities, principally deferred revenue and contingent consideration	204.1	292.5
Total Liabilities	694.6	819.4
Equity	2,105.4	1,979.8
Total Liabilities and Equity	$ 2,800.0	$ 2,799.2

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	2015	2016	2015
Revenues				
Revenue from services	$ 259.0	$ 103.9	$ 777.6	$ 107.9
Revenue from products	20.6	20.8	63.3	59.1
Revenue from transfer of intellectual property	18.4	18.3	105.3	48.5
Total revenues	298.0	143.0	946.2	215.5
Costs and expenses				
Cost of revenues	151.2	67.3	452.2	92.1
Selling, general and administrative	124.9	55.3	370.3	93.6
Research and development	24.4	18.9	83.6	74.0
Contingent consideration	3.1	1.6	15.6	6.5
Amortization of intangible assets	18.1	8.1	47.3	14.0
Grant repayment	—	—	—	25.9
Total Costs and expenses	321.7	151.2	969.0	306.1
Operating (loss) income	(23.7)	(8.2)	(22.8)	(90.6)
Other income and (expense), net	(10.5)	47.0	(8.1)	(23.6)
(Loss) income before income taxes and investment losses	(34.2)	38.8	(30.9)	(114.2)
(Provision for) benefit from income taxes	20.0	93.0	24.6	87.2
(Loss) income before investment losses	(14.2)	131.8	(6.3)	(27.0)
Loss from investments in investees	(0.8)	(3.6)	(5.1)	(6.0)
Net (loss) income	(15.0)	128.2	(11.4)	(33.0)
Less: Net loss attributable to non-controlling interests	—	—	—	(1.4)
Net (loss) income attributable to common shareholders	$ (15.0)	$ 128.2	$ (11.4)	$ (31.6)
Basic income (loss) per share	$ (0.03)	$ 0.26	$ (0.02)	$ (0.07)
Diluted income (loss) per share	$ (0.03)	$ 0.18	$ (0.02)	$ (0.07)