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 8, 2018

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

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

ITEM 1.01. Entry into a Material Definitive Agreement.

Private Placements of Common Stock

On November 8, 2018, OPKO Health, Inc. ("OPKO" or the "Company") entered into stock purchase agreements with certain investors pursuant to which the Company agreed to sell to such investors in private placements (the "Private Placements") an aggregate of approximately 26.5 million shares of the Company's Common Stock (the "Shares") at a purchase price of $3.49 per share, which was the closing bid price of the Company's Common Stock on the NASDAQ Global Select Market ("NASDAQ") on such date, for an aggregate purchase price of $92.5 million. The closing of the private placements is subject to obtaining requisite approval from NASDAQ for the listing of the Shares. The investors in the private placements include an affiliate of Dr. Phillip Frost, the Company's Chairman and Chief Executive Officer ($70 million), and Dr. Jane Hsiao, the Company's Vice Chairman and Chief Technical Officer ($2 million).

The Company intends to use the proceeds from the private placements for general corporate purposes.

The private placements are being conducted in reliance on the exemption of the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), pursuant to Section 4(a)(2) of the Securities Act, based upon the representations made by the investors that they are "accredited investors" and that they are purchasing the Shares without a present view toward a distribution of the Shares. In addition, there was no general advertisement conducted by the Company in connection with the sale of the Shares.

Credit Agreement

On November 8, 2018, the Company entered into a credit agreement (the "Credit Agreement") with an affiliate of Dr. Frost pursuant to which the lender committed to provide the Company with an unsecured line of credit in the amount of $60 million. Borrowings under the line of credit will bear interest at a rate of 10% per annum and may be repaid and reborrowed at any time. The credit agreement includes various customary remedies for the lender following an event of default, including the acceleration of repayment of outstanding amounts under line of credit. The line of credit matures on November 8, 2023.

ITEM 2.02. Results of Operations and Financial Condition.

On November 9, 2018, the Company, issued a press release announcing operating and financial highlights for the quarter ended September 30, 2018. 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 as amended ("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 as amended ("Securities Act") or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

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The information regarding the Credit Agreement set forth in Item 1.01 of this Current Report on Form 8-K under the heading "Credit Agreement" is incorporated in this Item 2.03 by reference.

ITEM 3.02. Unregistered Sales of Equity Securities.

The information regarding the private placements set forth in Item 1.01 of this Current Report on Form 8-K under the heading "Private Placements of Common Stock" is incorporated in this Item 3.02 by reference.

ITEM 7.01. Regulation FD Disclosure.

On November 8, 2018, the Company issued a press release announcing that it will hold a conference call to provide a business update and discuss its third quarter financial and operating results, as well as provide guidance on expected revenues and operating expenses for the fourth quarter of fiscal year 2018. A copy of the press release is attached hereto as Exhibit 99.2.

The information included herein and in Exhibit 99.2 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 under the Securities Act 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 9, 2018
99.2	Press Release of the Company dated November 8, 2018

Exhibit List

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99.1	Press Release of the Company dated November 9, 2018
99.2	Press Release of the Company dated November 8, 2018

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.

By: /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer

Date: November 9, 2018

Exhibit 99.1

OPKO Health Reports Third Quarter 2018 Financial Results

Conference Call begins today at 4:15 p.m. Eastern Time

MIAMI (November 9, 2018) – OPKO Health, Inc. (NASDAQ: OPK)reports financial results and business highlights for the three months ended September 30, 2018.

Financial Highlights

- Net loss for the three months ended September 30, 2018 decreased by 23% to $27.7 million or $0.05 a share compared to net loss of $35.9 million or $0.06 per share for the comparable 2017 period. Total revenues improved to $249.8 million during the three months ended September 30, 2018 compared to $246.0 million for the comparable period of 2017.
- Revenues from products during the three months ended September 30, 2018 include $5.8 million from*RAYALDEE* and revenues from services were $202.8 million for the 2018 period compared with $200.9 million for the corresponding 2017 period.
- During the three months ended September 30, 2018, costs of revenue and selling, general and administrative expenses decreased by approximately 8%, or $19.5 million, compared to the 2017 period. Research and Development expenses were $30.2 million compared to $32.5 million for the corresponding 2017 period.
- On November 8, 2018, OPKO secured approximately $150 million of additional capital, consisting of a private placement of common stock resulting in proceeds of $92.5 million, and an unsecured credit line of $60 million.

Business Highlights

- ***RAYALDEE* total prescriptions reported by IMS for Q3 2018 increased 222% compared with Q3 2017 and 18% compared with Q2 2018**: As of November 1, 2018, approximatley 79% of patients have access to *RAYALDEE* under their insurance plans.
- **Initiated the Phase 2 clinical trial to study the safety and efficacy of*RAYALDEE* as a new treatment for secondary hyperparathyroidism (SHPT) in adults with vitamin D insufficiency and stage 5 chronic kidney disease (CKD) requiring hemodialysis.** The trial will be conducted at multiple dialysis centers in the U.S. in two sequential cohorts. The first cohort of approximately 44 patients will be treated for 26 weeks in a randomized, open-label fashion with

either *RAYALDEE* or placebo to identify the appropriate dosing to be studied in the second cohort. Data readout for this first cohort is expected in 2019. The second cohort of more than 200 patients will be treated for 26 weeks in a randomized, double-blind fashion with one of three different doses of *RAYALDEE* or placebo. The primary efficacy endpoint will be correction of vitamin D insufficiency and control of SHPT. Patients will then be treated with *RAYALDEE* for another 26 weeks in an open-label extension.

- **4Kscore utilization in Q3 2018 was approximately 18,700 tests compared to 18,900 during Q3 2017**. Utilization of the 4Kscore remains strong while we continue to work with our Medicare administrator, Novitas, on their proposed local coverage determination. During this process, Novitas has continued to provide coverage of the 4Kscore to Medicare beneficiaries.

- **Completed the enrollment of a Global Phase 3 study of somatrogon (hGH-CTP) in Growth Hormone Deficient Children:** The somatrogon Phase 3 trial is a randomized, open-label study comparing once-weekly somatrogon to once daily Genotropin®. This study has enrolled 228 treatment naïve children with growth hormone deficiency (GHD) in 21 countries. The primary endpoint of the trial is height velocity at 52 weeks. Secondary endpoints are safety and pharmacodynamics.

- **Enrollment in Japanese Phase 3 registration trial of somatrogon in growth hormone deficient children expected to complete by year end:** The global and Japanese pediatric studies utilize the multiple dose pen device that will be launched commercially upon approval.

- **Completed the enrollment of a Phase 2b clinical trial for our once-weekly oxyntomodulin dual GLP1-Glucagon agonist to treat type 2 diabetes and obesity**: In a previous Phase 2 trial in 420 overweight patients with type 2 diabetes, the drug was shown to be safe and effective. The current trial is to study a new dosing schedule to achieve even greater weight loss and topline results are anticipated during 1Q 2019.

- **Advanced the Phase 2b trial for our SARM (selective androgen receptor modulator) to treat benign prostatic hyperplasia (BPH)**: Enrollment of approximately 110-120 patients in this dose ranging study of our orally administered SARM is expected to be completed by the end of this year.

- **Premarket Approval (PMA) application for Claros® point-of-care PSA test under review by FDA; decision anticipated during 1H 2019**: OPKO has completed a PMA submission to FDA for Sangia, our point of care PSA test utilizing the Claros 1 immunoassay analyzer. This is the first test on our proprietary diagnostic platform that can provide rapid, quantitative blood test results in the physician's office with only a finger stick drop of whole blood. Several biomarkers and biological meaningful chemistry tests such as testosterone and Vitamin D utilizing the Claros platform are advancing toward a 510(k) submission to the FDA.

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 4:15 p.m. Eastern time today. The conference call dial-in and webcast information is as follows:

WHEN: Friday, November 9, 2018 at 4:15 p.m. Eastern time
DOMESTIC DIAL-IN: (866) 634-2258
INTERNATIONAL DIAL-IN: (330) 863-3454
PASSCODE: 3487296
WEBCAST: www.investor.opko.com/events

For those unable to participate in the live conference call or webcast, a replay will be available beginning November 9, 2018 two hours after the close of the conference call. To access the replay, dial (855) 859-2056 or (404) 537-3406. The replay passcode is: 3487296. The replay can be accessed for a period of time on OPKO's website at www.investor.opko.com/events.

About OPKO Health, Inc.

OPKO Health is a diversified healthcare company. In diagnostics, its BioReference Laboratories is the nation's third largest clinical laboratory; GeneDx is a rapidly growing genetic testing business; the 4Kscore® prostate cancer test is used to confirm an elevated PSA to help decide about next steps such as prostate biopsy; Claros® 1 is a point of care diagnostics platform with PSA and testosterone as the most advanced in development. In our pharmaceutical pipeline, RAYALDEE is our first pharmaceutical product to be marketed. OPK88003, a once weekly oxyntomodulin for type 2 diabetes and obesity in Phase 2 clinical trials, is among a new class of GLP-1 – glucagon receptor dual agonists. OPK88004, a SARM (Selective Androgen Receptor Modulator) for treating BPH (Benign Prostatic Hypertrophy), urinary incontinence, and other conditions, is in clinical trials. The Company's most advanced product utilizing its CTP technology, a once weekly human growth hormone for injection, is in Phase 3 trials, and is partnered with Pfizer. OPKO has research, development, production and distribution facilities abroad. 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 and expectations regarding the market for and sales of our products, our product development efforts and the expected benefits of our products, including whether our ongoing and future clinical trials will be successfully enrolled or completed on a timely basis or at all and whether the data from any of our trials will support submission or approval, validation and/or reimbursement for our products, whether Novitas will continue to provide coverage of the 4kscore test for Medicare beneficiaries, whether OPK88004 will improve the symptoms of BPH by reducing prostate size and increase muscle mass and bone strength and decrease body fat, whether OP88003 will be shown to be safe and effective and achieve even greater weight loss, the expected timing for launch of our products in development, the expected timing of commencing and concluding our clinical trials, expected enrollment in clinical trials, the timing of our regulatory submissions, our ability to market and sell any of our products in development, and expectations about developing RAYALDEE for dialysis patients, 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 success of our relationship with Pfizer and our other partners, integration challenges for Bio-Reference, EirGen, Transition, and other acquired businesses, liquidity issues and 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, hGH-CTP, OPK88003, OPK88004, 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.

CONTACTS:

Investors
LHA Investor Relations
Miriam W. Miller, 212-838-3777
MMiller@lhai.com
or
Bruce Voss, 310-691-7100
bvoss@lhai.com

—Tables to Follow—

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

	As of	
	September 30, 2018	December 31, 2017
Assets:		
Cash, cash equivalents and marketable securities	$ 43.7	$ 91.5
Other current assets	246.1	257.4
Total Current Assets	289.8	348.9
In-process Research and Development and Goodwill	1,360.0	1,364.4
Other assets	831.2	876.7
Total Assets	$ 2,481.0	$ 2,590.0
Liabilities and Equity:		
Current liabilities	$ 286.9	$ 316.5
2033 Senior Notes and 5% Convertible Notes	87.6	29.2
Deferred tax liabilities	134.1	148.7
Other long-term liabilities, principally deferred revenue, contingent consideration and lines of credit	183.8	240.0
Total Liabilities	692.4	734.4
Equity	1,788.6	1,855.6
Total Liabilities and Equity	$ 2,481.0	$ 2,590.0

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2018	2017	2018	2017
Revenues				
Revenue from services	$ 202.8	$200.9	$630.2	$ 663.3
Revenue from products	25.4	22.8	81.8	74.0
Revenue from transfer of intellectual property	21.6	22.3	56.4	67.7
Total revenues	249.8	246.0	768.4	805.0
Costs and expenses				
Cost of revenues	150.9	151.3	455.1	463.5
Selling, general and administrative	84.1	103.2	263.2	318.7
Research and development	30.2	32.5	92.3	92.2
Contingent consideration	1.2	(11.20)	(12.40)	(4.50)
Amortization of intangible assets	16.9	18.0	51.4	53.9
Total Costs and expenses	283.3	293.8	849.6	923.8
Operating loss	(33.50)	(47.80)	(81.20)	(118.80)
Other income and (expense), net	(3.90)	(8.50)	5.4	1.0
Loss before income taxes and investment losses	(37.40)	(56.30)	(75.80)	(117.80)
Income tax benefit (provision)	11.6	24.4	10.4	42.3
Income (loss) before investment losses	(25.80)	(31.90)	(65.40)	(75.50)
Loss from investments in investees	(1.90)	(4.00)	(11.60)	(11.80)
Net loss	$ (27.70)	$ (35.90)	$ (77.00)	$ (87.30)
Loss per share, basic and diluted	$ (0.050)	$ (0.060)	$ (0.140)	$ (0.160)

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Exhibit 99.2

OPKO Health to Announce Third Quarter 2018 Financial Results on November 9, 2018

MIAMI (November 8, 2018) – OPKO Health, Inc. (NASDAQ: OPK) plans to announce its operating and financial results for the three and nine months ended September 30, 2018 after the close of the U.S. financial markets on Friday, November 9, 2018.

OPKO's senior management will provide a business update and discuss its financial results for the quarter ended September 30, 2018, as well as provide guidance on expected revenues and operating expenses for the fourth quarter 2018 in a live conference call and audio webcast beginning at 4:15 p.m. Eastern time on Friday, November 9, 2018.

Conference Call & Webcast Information

WHEN: Friday, November 9, 2018 at 4:15 p.m. Eastern time
DOMESTIC DIAL-IN: (866) 634-2258
INTERNATIONAL DIAL-IN: (330) 863-3454
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OPKO has research, development, production and distribution facilities abroad. More information is available at www.opko.com.

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Investors
LHA Investor Relations
Miriam Weber Miller, 212-838-3777
MMiller@lhai.com
or
Bruce Voss, 310-691-7100
bvoss@lhai.com

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