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): August 2, 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 2.02. Results of Operations and Financial Condition.

On August 7, 2018, OPKO Health, Inc., a Delaware corporation (the "Company"), issued a press release announcing operating and financial highlights for the quarter ended June 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 7.01. Regulation FD Disclosure.

On August 2, 2018, the Company issued a press release announcing that it will hold a conference call to provide a business update and discuss its second quarter financial and operating results. 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 August 7, 2018
99.2	Press Release of the Company dated August 2, 2018

Exhibit List

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99.1	Press Release of the Company dated August 7, 2018
99.2	Press Release of the Company dated August 2, 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

Date: August 7, 2018

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer

OPKO Health Reports Second Quarter 2018 Financial Results

Conference Call begins today at 4:30 p.m. Eastern Time

MIAMI (August 7, 2018) – OPKO Health, Inc. (NASDAQ: OPK)reports financial results and business highlights for the three months ended June 30, 2018.

Financial Highlights

- Net loss for the quarter decreased by 63% to $6.2 million or $0.01 a share on revenues of $263.7 million during the three months ended June 30, 2018, compared to net loss of $16.9 million or $0.03 per share on revenues of $292.6 million for the comparable period of 2017.
- Revenues from products during the three months ended June 30, 2018 include $4.8 million from*RAYALDEE* and revenues from services were $216.1 million for the 2018 period compared with $233.9 million for the corresponding 2017 period.
- Revenue and net loss for the three months ended June 30, 2017 benefited from a non-recurring $10 million milestone payment for VARUBI while net loss for the three months ended June 30, 2018 benefited from the reduction of contingent consideration expense of $15.4 million attributable to changes in assumptions regarding the timing of milestone payments.
- During the three months ended June 30, 2018, costs of revenue and selling, general and administrative expenses decreased by approximately 9%, or $26.0 million, compared to the 2017 period. Research and Development expenses were $29.2 million compared to $33.1 million for the corresponding 2017 period.

Business Highlights

- ***RAYALDEE* total prescriptions reported by IMS for Q2 2018 increased 467% compared with Q2 2017 and 36% compared with Q1 2018**: As of August 1, 2018, more than 83% of patients have access to *RAYALDEE* under their insurance plans. Fresenius Medical Care Renal Pharma (Vifor Fresenius) received approval from Health Canada to market *RAYALDEE* in Canada for the treatment of secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency.
- **4Kscore utilization in Q2 2018 increased 10% compared with Q2 2017**. Utilization of the 4Kscore continues to improve with nearly 20,500 4Kscore tests performed during the three

months ended June 30, 2018 compared to 18,600 tests performed during the second quarter of 2017.

- **Geoff Monk Appointed as General Manager, BioReference Laboratories:** Mr. Monk has more than 20 years of management experience in the diagnostic laboratory business and was previously Managing Director of the New York and New Jersey unit of Quest Diagnostics.

- **Advanced the Phase 2b trial for our SARM (selective androgen receptor modulator) to treat benign prostatic hyperplasia (BPH)**: Enrollment is ongoing in this dose ranging study for our orally administered SARM. This medicine is expected to improve symptoms of BPH by reducing prostate size and, on the basis of data from a previous trial in 350 men, increase muscle mass and bone strength and decrease body fat. BPH affects approximately 50 million men in the U.S.

- **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, active-controlled study taking place in over 30 countries. This study enrolled approximately 225 treatment naïve children with growth hormone deficiency (GHD) who were randomized 1:1 into two arms: once-weekly somatrogon vs once-daily Genotropin®. The primary endpoint of the trial is height velocity at 52 weeks. Secondary endpoints are safety and pharmacodynamic endpoints.

- **Japanese Phase 3 registration trial of somatrogon in growth hormone deficient children continues to enroll patients:** 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.

- **Premarket Approval (PMA) application for Claros® point-of-care PSA test under review by FDA**: OPKO has submitted a PMA for a PSA test utilizing the Claros 1 immunoassay analyzer, a novel diagnostic instrument that can provide rapid, quantitative blood test results in 10 minutes in the physician's office with only a finger stick drop of whole blood. A second product utilizing the Claros platform to measure testosterone is advancing toward a 510(k) submission to the FDA.

- **Initiation of two additional Phase 2 clinical trials anticipated in 2018**:

    - ***RAYALDEE* in dialysis patients with SHPT**: Together with our partners, Vifor Fresenius and Japan Tobacco, OPKO is developing *RAYALDEE* for Stage 5 CKD patients with SHPT undergoing dialysis and anticipates initiating a global Phase 2 trial during Q3 of this year.

    - **OPKO's NK-1 antagonist to treat pruritus (itching) in Stage 5 CKD patients undergoing dialysis**: An Investigational New Drug application was submitted to the FDA and a single-dose Phase 2a trial is commencing. Pruritus is often a problem for renal dialysis patients.

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 and webcast information is as follows:

WHEN: Tuesday, August 7, 2018 at 4:30 p.m. Eastern time.
DOMESTIC DIAL-IN: (866) 634-2258
INTERNATIONAL DIAL-IN: (330) 863-3454
PASSCODE: 9243717
WEBCAST: investor.opko.com/events

For those unable to participate in the live conference call or webcast, a replay will be available beginning August 7, 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: 9243717. The replay can be accessed for a period of time on OPKO's website at http://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 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:

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—Tables to Follow—

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

	As of	
	June 30, 2018	December 31, 2017
Assets:		
Cash, cash equivalents and marketable securities	$ 80.4	$ 91.5
Other current assets	241.2	257.4
Total Current Assets	321.6	348.9
In-process Research and Development and Goodwill	1,359.9	1,364.4
Other assets	849.4	876.7
Total Assets	$ 2,530.9	$ 2,590.0
Liabilities and Equity:		
Current liabilities	$ 276.5	$ 316.5
2033 Senior Notes and 5% Convertible Notes	86.2	29.2
Deferred tax liabilities	148.3	148.7
Other long-term liabilities, principally deferred revenue, contingent consideration and lines of credit	209.4	240.0
Total Liabilities	720.4	734.4
Equity	1,810.5	1,855.6
Total Liabilities and Equity	$ 2,530.9	$ 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 June 30,		For the six months ended June 30,	
	2018	2017	2018	2017
Revenues				
Revenue from services	$ 216.1	$ 233.9	$ 427.4	$ 462.5
Revenue from products	28.5	29.0	56.4	51.2
Revenue from transfer of intellectual property	19.1	29.7	34.8	45.3
Total revenues	263.7	292.6	518.6	559.0
Costs and expenses				
Cost of revenues	150.1	157.4	304.1	312.2
Selling, general and administrative	87.7	105.5	179.2	215.5
Research and development	29.2	33.1	62.1	59.7
Contingent consideration	(15.40)	4.4	(13.60)	6.7
Amortization of intangible assets	17.2	18.0	34.5	35.9
Total Costs and expenses	268.8	318.4	566.3	630.0
Operating loss	(5.10)	(25.80)	(47.70)	(71.00)
Other income and (expense), net	8.1	3.5	9.2	9.4
Income (loss) before income taxes and investment losses	3.0	(22.30)	(38.50)	(61.60)
Income tax benefit (provision)	(2.00)	11.0	(1.10)	17.9
Income (loss) before investment losses	1.0	(11.30)	(39.60)	(43.70)
Loss from investments in investees	(7.20)	(5.60)	(9.70)	(7.70)
Net loss	$ (6.20)	$ (16.90)	$ (49.30)	$ (51.40)
Basic loss per share	$ (0.010)	$ (0.030)	$ (0.090)	$ (0.090)
Diluted loss per share	$ (0.010)	$ (0.040)	$ (0.090)	$ (0.110)

# # #

OPKO Health to Announce Second Quarter 2018 Financial Results on August 7, 2018

MIAMI (August 2, 2018) – OPKO Health, Inc. (NASDAQ: OPK) plans to announce its operating and financial results for the three and six months ended June 30, 2018 after the close of the U.S. financial markets on Tuesday, August 7, 2018.

OPKO's senior management will provide a business update and discuss its financial results in a live conference call and audio webcast beginning at 4:30 p.m. Eastern time on Tuesday, August 7, 2018.

Conference Call & Webcast Information

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