
**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): July 29, 2021

OPKO Health, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-33528

(Commission
File Number)

75-2402409

(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)
- Precommencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Precommencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	OPK	NASDAQ Global Select Market

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 July 29, 2021, OPKO Health, Inc. (the “Company”) issued a press release announcing operating and financial highlights for the quarter ended June 30, 2021. In the press release, the Company also provided information about its conference call during which it will provide a business update and discuss its second quarter ended June 30, 2021 financial and operating results, as well as provide financial guidance. 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company dated July 29, 2021
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company dated July 29, 2021

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.

Date: July 29, 2021

By: /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer



OPKO Health Reports 2021 Second Quarter Business Highlights and Financial Results

Conference call begins at 4:30 p.m. Eastern time today

MIAMI (July 29, 2021) – OPKO Health, Inc. (NASDAQ: OPK) reports business highlights and financial results for the three months ended June 30, 2021.

Business Highlights

- **BioReference Laboratories (BRL) test volume increased 32% compared with the second quarter of 2020.** During the second quarter of 2021, BRL processed approximately 2.8 million COVID-19 PCR tests and has current capacity to process more than 100,000 PCR tests per day. In addition, during the quarter BRL performed approximately 132,000 COVID-19 serology tests to measure SARS-CoV-2 antibody levels and currently has significant additional capacity.

In June 2021, BRL announced a COVID-19 custom testing program for U.S.-based crew and guests who cruise with Royal Caribbean Group, helping provide a safe environment for travelers and crew members. In April 2021, BRL announced a COVID-19 testing agreement for players and staff, stadium employees and league staff for the 2021 Major League Baseball season and the renewal of a similar agreement for the 2021 Major League Soccer season and 2021-2022 National Football League season.

Also, BRL announced the appointment of Katherine Stueland as President and Chief Executive Officer of GeneDx, Inc., its global genomics subsidiary. Ms. Stueland joined GeneDx from Invitae Corporation, where she served most recently as Chief Commercial Officer.

- **Executed agreement with Nicoya Therapeutics for the development and commercialization of RAYALDEE® in Greater China.** OPKO entered into an agreement with Nicoya Macau Limited, an affiliate of Nicoya Therapeutics (Nicoya), for the development and commercialization in Greater China including mainland China, Hong Kong, Macau and Taiwan of RAYALDEE for the treatment of secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD). OPKO received an upfront payment of \$5 million and is entitled to receive an additional \$5 million payment upon the earlier of the 12-month anniversary of the agreement or Nicoya achieving a certain predetermined development milestone. In addition, OPKO will be eligible to receive up to \$115 million upon the achievement of certain development, regulatory and sales-based milestones. Nicoya will pay OPKO tiered, double-digit royalties on product sales and will be responsible for regulatory approvals and commercial activities pertaining to RAYALDEE in their territory.

- **Executed exclusive worldwide agreement with CAMP4 Therapeutics Corporation (CAMP4) for the development, manufacture and commercialization of therapeutics utilizing the AntagoNAT technology.** The AntagoNAT technology is an oligonucleotide platform developed under OPKO CURNA. CAMP4 has prioritized OPKO's lead AntagoNAT compound to progress into clinical trials for the treatment of Dravet syndrome. Under the terms of the agreement, OPKO received an upfront cash payment and shares of privately held CAMP4. In addition, OPKO will be eligible to receive up to \$93.5 million and additional shares upon the achievement of certain development and sales milestones for products developed from this technology and associated intellectual property. CAMP4 will also pay OPKO double-digit royalties on product sales.
- **Sale of sterile fill-and-finish manufacturing facility in Ireland.** OPKO sold one of its facilities in Waterford, Ireland to Horizon Therapeutics plc for \$65 million less certain assumed and accrued liabilities relating to transferred employees. The facility previously housed EirGen's sterile fill-and-finish business.

Second Quarter Financial Results

- **Diagnostics:** Revenue from services in the second quarter of 2021 increased to \$397.2 million from \$251.0 million in the prior-year period, primarily due to an increase in volume of COVID-19, clinical and genomic testing. Total costs and expenses were \$367.2 million in the second quarter of 2021 compared with \$216.2 million in the second quarter of 2020, resulting in operating income of \$30.0 million compared with \$40.9 million in the 2020 period. The decrease in operating income is primarily due to non-recurring benefits in the second quarter of 2020 including \$10.9 million of revenue from the successful 4Kscore Medicare appeal and a \$6.2 million grant received under the CARES Act.
- **Pharmaceuticals:** Revenue from products in the second quarter of 2021 was \$35.7 million compared with \$29.3 million in the second quarter of 2020, primarily attributable to accelerating growth within OPKO's international pharmaceutical businesses partially offset by a decline in sales of RAYALDEE. Total prescriptions for RAYALDEE in the second quarter of 2021 decreased to approximately 11,700 from approximately 18,400 in the second quarter of 2020. Revenue from sales of RAYALDEE in the second quarter of 2021 and 2020 was \$5.0 million and \$8.6 million, respectively. Revenue from the transfer of intellectual property was \$9.5 million in the second quarter of 2021 compared with \$14.7 million in the 2020 period, reflecting a decrease in the amortization of payments received from Pfizer with respect to somatrogon. The second quarter of 2021 included a \$5.0 million upfront payment under the license agreement with Nicoya. Total costs and expenses were \$58.9 million in the second quarter of 2021 compared with \$50.0 million in the prior year period, primarily due to the growth of OPKO's international pharmaceutical operations. Operating loss was \$13.7 million in the second quarter of 2021 compared with an operating loss of \$6.0 million in the second quarter of 2020.
- **Consolidated:** Consolidated total revenues for the second quarter of 2021 were \$442.4 million compared with \$301.2 million for the comparable period of 2020. Operating income for the second quarter of 2021 was \$5.6 million compared with operating income of \$27.2 million for the comparable period of 2020. Net loss for the second quarter of 2021, which included an \$11.1 million non-cash, non-recurring loss as a result of the issuance of shares in connection with the \$55.4 million convertible notes exchange, was \$16.2 million, or \$0.03 per share, compared with net income of \$33.7 million, or \$0.05 per diluted share, for the comparable period of 2020.

- **Cash and equivalents:** Cash, cash equivalents and marketable securities were \$65.8 million as of June 30, 2021. The Company has availability under its present line of credit with JP Morgan of \$64.3 million. Also, in July 2021 OPKO received gross proceeds of \$65.0 million from the sale of its fill-and-finish manufacturing facility in Ireland.
- **Convertible notes:** In May 2021, certain noteholders of the Company's 4.50% Convertible Senior Notes due 2025 agreed to exchange \$55.4 million of the outstanding notes for shares of the Company's common stock, plus a cash payment equal to the accrued and unpaid interest on the exchanged notes.

CONFERENCE CALL & WEBCAST INFORMATION

OPKO's senior management will provide a business update, discuss second quarter financial results and answer questions during a conference call and live audio webcast beginning at 4:30 p.m. Eastern time today, July 29, 2021. Participants are requested to pre-register for the conference call using the link [here](#). Upon pre-registering, participants will receive dial-in numbers, an event passcode and a unique registrant ID to gain immediate access to the call and bypass the live operator. Participants may pre-register at any time, including up to and after the start of the call. Alternatively, please dial (888) 869-1189 or (706) 643-5902 and use conference ID 7028169

To access the live call via webcast, please click on the link [OPKO 2Q21 Results Conference Call](#). Individual investors and investment community professionals who do not plan to ask a question during the call's Q&A session are encouraged to listen to the call via the webcast.

For those unable to listen to the live conference call, a replay can be accessed for a period of time on OPKO's website at [OPKO 2Q21 Results Conference Call](#). A telephone replay will be available beginning approximately two hours after the completion of the conference call. To access the replay, please dial (855) 859-2056 or (404) 537-3406, and use conference ID 7028169.

About OPKO Health

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development, and commercialization expertise and novel and proprietary technologies. For more information, visit 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, expectations about COVID-19 testing, the demand for testing, our capacity for testing, the impact of COVID-19 on all of our businesses, positively and negatively, our ability to expand our capacity should there be additional demand, our product development efforts and the expected benefits of our products, whether our products in development will

be commercialized, whether the relationship with our business partners will be successful, our ability to market and sell any of our 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 under the heading "Risk Factors" in our other filings with the Securities and Exchange Commission, as well as the ongoing effects of the COVID-19 pandemic, the continuation and success of our relationship with our commercial partners, liquidity issues and the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. 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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—Tables to Follow—

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

	As of June 30, 2021	December 31, 2020
	<u> </u>	<u> </u>
Assets:		
Cash and cash equivalents	\$ 65.8	\$ 72.2
Other current assets	481.2	451.0
Total current assets	<u>547.0</u>	<u>523.2</u>
In-process research and development and goodwill	1,267.6	1,270.8
Other assets	<u>607.1</u>	<u>679.1</u>
Total Assets	<u><u>\$ 2,421.7</u></u>	<u><u>\$ 2,473.1</u></u>
 Liabilities and Equity:		
Current liabilities	\$ 304.0	\$ 375.5
Convertible notes	183.2	222.0
Deferred tax liabilities, net	136.4	137.2
Other long-term liabilities, principally contract liabilities, leases, contingent consideration and lines of credit	<u>55.5</u>	<u>66.8</u>
Total Liabilities	<u>679.1</u>	<u>801.5</u>
Equity	<u>1,742.6</u>	<u>1,671.6</u>
Total Liabilities and Equity	<u><u>\$ 2,421.7</u></u>	<u><u>\$ 2,473.1</u></u>

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

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Revenues				
Revenue from services	\$ 397.2	\$ 251.0	\$ 904.2	\$ 421.8
Revenue from products	35.7	29.3	69.6	60.4
Revenue from transfer of intellectual property and other	9.5	20.9	13.8	30.5
Total revenues	<u>442.4</u>	<u>301.2</u>	<u>987.6</u>	<u>512.7</u>
Costs and expenses				
Cost of revenues	292.9	162.7	656.5	302.9
Selling, general and administrative	113.2	77.7	225.5	153.8
Research and development	18.2	17.6	37.5	39.4
Contingent consideration	(0.1)	1.1	(1.1)	0.3
Amortization of intangible assets	12.6	14.9	25.2	29.9
Total costs and expenses	<u>436.8</u>	<u>274.0</u>	<u>943.6</u>	<u>526.3</u>
Operating income (loss)	5.6	27.2	44.0	(13.6)
Other income and (expense), net	<u>(16.9)</u>	<u>12.7</u>	<u>(23.7)</u>	<u>(4.3)</u>
Income (loss) before income taxes and investment losses	(11.3)	39.9	20.3	(17.9)
Income tax provision	<u>(4.8)</u>	<u>(6.0)</u>	<u>(5.3)</u>	<u>(7.2)</u>
Income (loss) before investment losses	(16.1)	33.9	15.0	(25.1)
Loss from investments in investees	<u>(0.1)</u>	<u>(0.2)</u>	<u>(0.1)</u>	<u>(0.3)</u>
Net income (loss)	<u>\$ (16.2)</u>	<u>\$ 33.7</u>	<u>\$ 14.9</u>	<u>\$ (25.4)</u>
Income (loss) per share, basic and diluted	<u>\$ (0.03)</u>	<u>\$ 0.05</u>	<u>\$ 0.02</u>	<u>\$ (0.04)</u>
Weighted average common shares outstanding, basic and diluted	646,996,891	640,578,794	644,001,280	640,578,794

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