
**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): April 28, 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)
 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))

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 April 28, 2021, OPKO Health, Inc. (the “Company”) issued a press release announcing operating and financial highlights for the quarter ended March 31, 2021. 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 April 22, 2021, the Company issued a press release announcing that it will hold a conference call to provide a business update and discuss its first quarter ended March 31, 2021 financial and operating results, as well as discuss financial guidance. 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

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press Release of the Company dated April 28, 2021 |
| 99.2 | Press Release of the Company dated April 22, 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 April 28, 2021 |
| 99.2 | Press Release of the Company dated April 22, 2021 |



OPKO Health Reports 2021 First Quarter Business Highlights and Financial Results

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

MIAMI (April 28, 2021) – OPKO Health, Inc. (NASDAQ: OPKO) reports business highlights and financial results for the three months ended March 31, 2021.

Business Highlights

- **BioReference Laboratories test volume increased 158% compared with the first quarter of 2020** During the first quarter of 2021, BioReference Laboratories (BRL) processed approximately 4.3 million COVID-19 tests and has current capacity to process more than 100,000 PCR tests per day. In addition, during the quarter, BRL performed approximately 200,000 COVID-19 serology tests to measure SARS-CoV-2 antibody levels and currently has significant additional capacity.

BRL continues to provide COVID-19 solutions to meet the testing needs of physicians, health systems, long-term care facilities, governments, schools, employers, professional sports leagues and entertainment venues, as well as the general public through relationships with retail pharmacy chains including Rite-Aid and CVS. 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.

In March 2021, BRL announced expansion of its COVID-19 school testing program to support return to in-person classroom instruction across the country. For two of the nation's largest school systems, BRL provides testing services to nearly 200 schools every day and has tested nearly 500,000 public school students, teachers and principals.

- **Topline results reported from first cohort of Phase 2 trial with RAYADEE in patients with stage 5 chronic kidney disease (CKD) on dialysis.** Cohort 1 of the Phase 2 clinical trial explored the safety and efficacy of a high-strength formulation of RAYALDEE (calcifediol) as a new treatment for secondary hyperparathyroidism (SHPT) in adults with vitamin D insufficiency and stage 5 CKD who require hemodialysis. Topline results from 44 subjects (33 RAYALDEE; 11 placebo) demonstrated that the prohormone RAYALDEE was well tolerated at a dose of 900 mcg/week, decreased intact parathyroid hormone (iPTH) versus placebo, and was activated to calcitriol (the active hormone) despite the lack of functional kidneys. A full analysis of the data is underway and will be reviewed with both FDA and OPKO's development partners.
 - **Regulatory submission for somatrogen by Pfizer, OPKO's commercial partner, accepted by the European Medicines Agency (EMA)** In February 2021, the EMA validated for review the Marketing Authorization Application (MAA) for somatrogen, a long-acting recombinant human growth hormone intended to be administered once-weekly to treat pediatric patients with
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growth hormone deficiency (GHD). Pfizer expects a decision from the European Commission in 2022. In January 2021, the FDA accepted for filing the initial Biologics License Application for somatrogen with a target Prescription Drug User Fee Act action date in October 2021. Pfizer also submitted a New Drug Application for somatrogen to the Pharmaceuticals and Medical Devices Agency in Japan.

- **Multiple presentations highlighting somatrogen clinical data were presented at two endocrinology conferences**Data from OPKO's somatrogen clinical studies were presented virtually at ENDO 2021, the Endocrine Society's 2021 Annual Meeting held March 20-23, 2021, and at ICE 2021, the 19th International Congress of Endocrinology Annual Meeting held February 24-28, 2021. Utilizing OPKO's proprietary long-acting technology, somatrogen represents a significant advancement to increase patient adherence and improve quality of life compared with daily injections. Posters and abstracts from the endocrinology conferences can be viewed on the Company's website in the [Investors](#) section. In addition, OPKO will be participating in the 2021 Pediatric Endocrine Society Virtual Annual Meeting to be held today through May 3, 2021.
- **Phase 2 trial with RAYADEE in COVID-19 outpatients is 71% enrolled and ongoing at 10 U.S. sites**The trial is a randomized, double-blind, placebo-controlled study and is expected to enroll approximately 160 outpatients, including some with stage 3 or 4 CKD who are at higher risk for developing more severe illness. The qualified outpatients are being randomized one-to-one to four weeks of daily treatment with either RAYADEE or placebo, and then monitored for another two weeks. Topline data from this trial are expected in the third quarter and, if sufficiently positive, will form the basis for an immediate request to FDA for an Emergency Use Authorization.

First Quarter Financial Results

- Consolidated revenues for the first quarter of 2021 were \$545.2 million compared with \$211.5 million for the comparable period of 2020. Net income for the first quarter of 2021 was \$31.1 million, or \$0.05 per diluted share, compared with a net loss of \$59.1 million, or \$0.09 per share, for the comparable period of 2020.
 - **Diagnostics:** Revenue from services in the first quarter of 2021 increased to \$507.0 million from \$170.8 million in the prior-year period, primarily due to COVID-19 testing, partially offset by lower revenue in our base testing business reflecting the negative impact of the COVID-19 pandemic. Total costs and expenses were \$439.9 million in the first quarter of 2021 compared with \$189.0 million in the first quarter of 2020, resulting in operating income of \$67.0 million compared with an operating loss of \$18.1 million in the 2020 period. The increase in operating income of \$85.1 million reflects the increased demand for COVID-19 PCR testing.
 - **Pharmaceuticals:** Revenue from products in the first quarter of 2021 was \$33.9 million compared with \$31.1 million in the first quarter of 2020, primarily attributable to an increase in sales at OPKO Chile and FineTech, partially offset by a decline in sales of RAYADEE, which were negatively impacted by the COVID-19 pandemic. Total prescriptions of RAYADEE for the first quarter of 2021 decreased to approximately 12,300 from approximately 18,300 for the first quarter of 2020. Revenue from the transfer of intellectual property was \$4.3 million in the first quarter of 2021 compared with \$9.6 million in the first quarter of 2020, reflecting a decrease in the amortization of payments received from Pfizer with respect to somatrogen. Total costs and
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expenses were \$57.4 million in the first quarter of 2021 compared with \$54.8 million in the prior-year period, primarily due to increased sales and an inventory reserve for RAYADEE. The operating loss was \$19.2 million in the first quarter of 2021 compared with \$14.1 million in the first quarter of 2020.

- **Cash and equivalents:** Cash, cash equivalents and marketable securities were \$89.5 million as of March 31, 2021. In addition, the Company has availability under its present line of credit with JP Morgan of \$64.7 million and an unutilized \$100 million credit facility that provides access to incremental capital on a non-dilutive basis.

CONFERENCE CALL & WEBCAST INFORMATION

OPKO's senior management will provide a business update, discuss first quarter financial results and answer questions during a conference call and live audio webcast beginning at 4:30 p.m. Eastern time today, April 28, 2021. Participants are requested to pre-register for the conference call using the link [here](#), or dialing (888) 869-1189 or (706) 643-5902 and using conference ID 9993698. Upon 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.

To access the live call via webcast, please click on the link [OPKO 1Q21 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 1Q21 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 9993698.

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, the availability of resources, including labor, equipment and supplies, to meet demand for testing and the potential impact on us should these resources be constrained, our product development efforts and the expected benefits of our products, whether our products in development will be commercialized, the possibility of further analyses of existing clinical data, the risk that clinical trial data are subject to

differing interpretations and assessments by regulatory authorities, whether regulatory authorities will be satisfied with the design of and results from our clinical studies, whether RAYALDEE prescriptions will increase, 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 Pfizer, Vifor and our other partners, 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 somatrogon, RAYALDEE, 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 proposed or for other indications, that enrollment for our Phase 2 trial with RAYALDEE in COVID-19 may not complete and topline data may not be available when anticipated and may not, in any event, be positive such that an Emergency Use Authorization could be sought, that regulatory approvals for our products, particularly somatrogon, may not be received when anticipated or at all, 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:

LHA Investor Relations

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—Tables to Follow—

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

| | As of | |
|--|-------------------|----------------------|
| | March 31, 2021 | December 31, 2020 |
| Assets: | | |
| Cash, cash equivalents and marketable securities | \$ 89.5 | \$ 72.2 |
| Other current assets | 509.5 | 451.0 |
| Total Current Assets | 599.0 | 523.2 |
| In-process Research and Development and Goodwill | 1,266.4 | 1,270.8 |
| Other assets | 654.2 | 679.1 |
| Total Assets | \$ 2,519.6 | \$ 2,473.1 |
| Liabilities and Equity: | | |
| Current liabilities | \$ 403.9 | \$ 375.5 |
| Convertible Notes | 224.8 | 222.0 |
| Deferred tax liabilities, net | 135.2 | 137.2 |
| Other long-term liabilities, principally contract liabilities, leases, contingent consideration and lines of credit | 59.2 | 66.8 |
| Total Liabilities | 823.1 | 801.5 |
| Equity | 1,696.5 | 1,671.6 |
| Total Liabilities and Equity | \$ 2,519.6 | \$ 2,473.1 |

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

| | For the three months ended March 31, | |
|---|---|-------------|
| | 2021 | 2020 |
| Revenues | | |
| Revenue from services | \$ 507.0 | \$ 170.8 |
| Revenue from products | 33.9 | 31.1 |
| Revenue from transfer of intellectual property | 4.3 | 9.6 |
| Total revenues | 545.2 | 211.5 |
| Costs and expenses | | |
| Cost of revenues | 363.5 | 140.3 |
| Selling, general and administrative | 112.3 | 76.1 |
| Research and development | 19.3 | 21.8 |
| Contingent consideration | (1.0) | (0.9) |
| Amortization of intangible assets | 12.6 | 14.9 |
| Total Costs and expenses | 506.7 | 252.2 |
| Operating income (loss) | 38.5 | (40.7) |
| Other income and (expense), net | (6.8) | (17.1) |
| Income (loss) before income taxes and investment losses | 31.7 | (57.8) |
| Income tax provision | (0.6) | (1.2) |
| Net income (loss) before investment losses | 31.1 | (59.0) |
| Loss from investments in investees | 0.0 | (0.1) |
| Net income (loss) | \$ 31.1 | \$ (59.1) |
| Income (loss) per share, basic and diluted | \$ 0.05 | \$ (0.09) |
| Weighted average common shares outstanding, basic and diluted | 640,853,200 | 640,578,794 |

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OPKO Health to Report First Quarter 2021 Financial Results on April 28, 2021

MIAMI (April 22, 2021) – OPKO Health, Inc. (NASDAQ: OPKO) plans to report operating and financial results for the three months ended March 31, 2021, as well as discuss financial guidance, after the close of the U.S. financial markets on Wednesday, April 28, 2021. OPKO's senior management will provide a business update and discuss results in greater detail during a conference call and live audio webcast on April 28th beginning at 4:30 p.m. Eastern time.

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