
**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): February 18, 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 February 18, 2021, OPKO Health, Inc. (the “Company”) issued a press release announcing operating and financial highlights for the quarter ended December 31, 2020. In the press release, the Company also provided information with respect to the conference call it is hosting to provide a business update and discuss its financial and operating results for the fourth quarter and full year ended December 31, 2020, as well as discuss 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 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 February 18, 2021
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document

Exhibit Index

Exhibit No.	Description
99.1	Press Release of the Company dated February 18, 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.

By: /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer

Date: February 18, 2021



OPKO Health Reports 2020 Fourth Quarter Business Highlights and Financial Results

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

MIAMI (February 18, 2021) – OPKO Health, Inc. (NASDAQ: OPKO) Reports business highlights and financial results for the three months ended December 31, 2020.

Business Highlights

- **BioReference Laboratories' volume in the fourth quarter of 2020 increased 170% compared to 2019. COVID-19 PCR testing volume increased 24% over the third quarter of 2020.** During the fourth quarter of 2020, BioReference Laboratories (BRL) processed approximately 4.3 million COVID-19 PCR tests and currently has the capacity to process more than 100,000 PCR tests per day. In addition, BRL performed approximately 220,000 COVID-19 serology tests to measure SARS-CoV-2 antibody levels and currently has significant additional capacity.

BRL continues to provide innovative solutions to the COVID-19 testing needs of physicians, health systems, long-term care facilities, governments, schools, employers, professional sports teams, entertainment venues, and the general public through relationships with Rite-Aid and CVS. In January 2021, BRL announced COVID-19 testing agreements for players and officials, as well as team and league staff for the 2020-2021 seasons for the National Basketball Association (NBA) and National Hockey League. BRL is also supporting the COVID-19 testing needs of the Winter X Games in Aspen, U.S. Soccer's Women's and Men's National Teams and the NBA G League in Orlando.

- **BRL introduced Scarlet Health™ to expand digital health access.** In January 2021, BRL launched Scarlet Health, an in-home, fully integrated digital platform providing access to on-demand diagnostic services. Backed by BRL's national presence and infrastructure, with laboratory facilities and professionals across the country, Scarlet Health delivers an innovative, flexible, mobile alternative to traditional patient service centers or other draw locations when phlebotomy and other specimen collection services are needed.
 - **GeneDx added repeat expansion analysis genetic tests.** GeneDx launched several new genetic tests, including repeat expansion analysis for spinocerebellar ataxia, Friedreich ataxia and other forms of hereditary ataxias. With these additions, GeneDx has created a comprehensive and affordable offering that covers the vast majority of genes involved with pediatric-onset and adult-onset ataxias.
 - **Regulatory submission from OPKO's commercial partner, Pfizer, accepted in the U.S. and filed in Japan for somatrogon to treat pediatric patients with growth hormone deficiency.** The U.S. Food and Drug Administration (FDA) accepted for filing the initial Biologics License Application for somatrogon, a long-acting human growth hormone intended to be administered once-
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weekly for the treatment of pediatric patients with growth hormone deficiency. The target Prescription Drug User Fee Act action date for decision by the FDA is October 2021. In addition, a New Drug Application was submitted to the Ministry of Health, Labour, and Welfare in Japan for somatrogen. Pfizer remains on schedule with respect to its regulatory submission for marketing approval of somatrogen in Europe in the first quarter of this year.

- **RAYALDEE has received marketing authorizations in 11 European countries.** Vifor Fresenius Medical Care Renal Pharma, OPKO's commercial partner for RAYALDEE in Europe, has received marketing authorizations for RAYALDEE for the treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease and vitamin D insufficiency in 11 European countries, adding Spain, Portugal, Italy and Switzerland to previously announced approvals in the United Kingdom, Germany, Sweden, Norway, Ireland, Denmark and the Netherlands. Market launch of RAYALDEE in authorized countries is expected later this year.

Fourth Quarter Financial Results

- Net income for the fourth quarter of 2020 was \$32.3 million, or \$0.05 per diluted share, compared with a net loss of \$112.4 million, or \$0.18 per share, for the comparable period of 2019. Consolidated revenues for the fourth quarter of 2020 were \$494.6 million compared with \$224.3 million for the comparable period of 2019.
 - **Diagnostics:** Revenue from services in the fourth quarter of 2020 increased to \$457.9 million from \$177.9 million in the prior-year period, due to COVID-19 testing volume, partially offset by lower clinical test volume reflecting the negative impact of the pandemic and by reduced clinical and genomic test reimbursement. Total costs and expenses were \$388.0 million in the fourth quarter of 2020 compared with \$223.4 million in the fourth quarter of 2019, resulting in operating income of \$69.9 million compared with an operating loss of \$45.4 million in the 2019 period. The increase in operating income of \$115.3 million reflects increased volumes as a result of COVID-19 testing and a non-cash impairment charge of \$38.7 included in the 2019 period for goodwill and intangible assets related to the acquisition of Claros.
 - **Pharmaceuticals:** Revenue from products in the fourth quarter of 2020 was \$30.8 million compared with \$32.0 million in the fourth quarter of 2019, primarily attributable to a decline in sales of Rayaldee, which were negatively impacted by challenges in onboarding new patients due to the intensified COVID-19 pandemic, offset by an increase in sales from OPKO Chile. Total prescriptions of Rayaldee for the fourth quarter of 2020 decreased to approximately 15,000, compared with approximately 17,900 for the fourth quarter of 2019. Revenue from the transfer of intellectual property was \$5.9 million in the fourth quarter of 2020 compared with \$14.4 million in the fourth quarter of 2019, reflecting a decrease in the amortization of payments received from Pfizer with respect to somatrogen. Total costs and expenses were \$45.7 million in the fourth quarter of 2020 compared with \$103.2 million in the prior-year period, which included a non-cash impairment charge of \$53.1 million for goodwill and intangible assets related to the acquisitions of CURNA and Transition Therapeutics. The operating loss was \$9.0 million in the fourth quarter of 2020 compared with \$56.8 million in the fourth quarter of 2019.
 - **Cash and equivalents:** Cash, cash equivalents and marketable securities were \$72.2 million as of December 31, 2020. In addition, the Company has availability under its present line of credit
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with JP Morgan of \$57.6 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 fourth quarter financial results and answer questions during a conference call and live audio webcast at 4:30 p.m. Eastern time today, February 18, 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 8597848. 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 4Q20 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 4Q20 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 8597848.

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, GeneDx's test offerings and the effectiveness and utility of its ataxias tests, BioReference's Scarlet Health mobile service, the availability of and demand for the service, whether the service and the integrated platform will function or perform as designed, the role and value of the service to patients and healthcare providers and whether the demand for at home health care will continue or increase as anticipated, 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 somatrogen, 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 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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—Tables to Follow—

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

	As of	
	December 31, 2020	December 31, 2019
Assets:		
Cash, cash equivalents and marketable securities	\$ 72.2	\$ 85.5
Other current assets	451.0	238.5
Total Current Assets	523.2	324.0
In-process Research and Development and Goodwill	1,270.8	1,262.1
Other assets	679.1	723.2
Total Assets	<u>\$ 2,473.1</u>	<u>\$ 2,309.3</u>
Liabilities and Equity:		
Current liabilities	\$ 375.5	\$ 249.1
Convertible Notes	222.0	211.2
Deferred tax liabilities, net	137.2	118.7
Other long-term liabilities, principally contract liabilities, leases, contingent consideration and lines of credit	66.8	115.5
Total Liabilities	801.5	694.5
Equity	1,671.6	1,614.8
Total Liabilities and Equity	<u>\$ 2,473.1</u>	<u>\$ 2,309.3</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 December 31,		For the year ended December 31,	
	2020	2019	2020	2019
Revenues				
Revenue from services	\$ 457.9	\$ 177.9	\$ 1,262.2	\$ 716.4
Revenue from products	30.8	32.0	120.0	112.2
Revenue from transfer of intellectual property	5.9	14.4	53.2	73.3
Total revenues	494.6	224.3	1,435.4	901.9
Costs and expenses				
Cost of revenues	318.7	142.3	894.4	572.5
Selling, general and administrative	101.8	79.1	355.6	343.3
Research and development	17.5	23.0	75.3	117.9
Contingent consideration	(5.3)	(14.8)	(4.0)	(14.9)
Amortization of intangible assets	12.6	15.4	56.4	64.8
Asset impairment charges	0.0	91.8	0.0	92.4
Total Costs and expenses	445.3	336.8	1,377.7	1,176.0
Operating Income (loss)	49.3	(112.5)	57.7	(274.1)
Other income and (expense), net	(3.4)	4.0	(9.0)	(30.8)
Income loss before income taxes and investment losses	45.9	(108.5)	48.7	(304.9)
Income tax provision	(13.6)	(3.4)	(17.6)	(7.1)
Income (loss) before investment losses	32.3	(111.9)	31.1	(312.0)
Loss from investments in investees	(0.0)	(0.5)	(0.5)	(2.9)
Net Income (loss)	\$ 32.3	\$ (112.4)	\$ 30.6	\$ (314.9)
Loss per share, basic and diluted	\$ 0.05	\$ (0.18)	\$ 0.05	\$ (0.53)
Weighted average common shares outstanding, basic and diluted	640,590,427	622,474,281	640,655,290	595,454,394

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