
**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): May 9, 2022

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 May 9, 2022, OPKO Health, Inc. (the “Company”) issued a press release announcing operating and financial highlights for the quarter ended March 31, 2022. The press release also contains information on how to access the conference call the Company is hosting to provide a business update and discuss its financial and operating results for the first quarter ended March 31, 2022n, 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 May 9, 2022
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 May 9, 2022

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: May 9, 2022

By: /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer



OPKO Health Reports 2022 First Quarter Business Highlights and Financial Results

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

MIAMI (May 9, 2022) – OPKO Health, Inc. (NASDAQ: OPKO) reports business highlights and financial results for the three months ended March 31, 2022.

Business Highlights

Business highlights for the first quarter of 2022 and subsequent weeks include the following:

- **Acquired ModeX Therapeutics, Inc. (ModeX), gains proprietary immunotherapy technology, new executives and Directors.** ModeX is a privately held biotechnology company focused on developing innovative multi-specific immune therapies for cancer and infectious diseases. In connection with the acquisition, Dr. Elias Zerhouni joins OPKO as President and Vice Chairman of the Board of Directors, Dr. Gary Nabel joins as Chief Innovation Officer and a member of OPKO's Board of Directors, and Alexis Borisy joins OPKO's Board. OPKO acquired ModeX for \$300 million in OPKO common stock.
- **Completed sale of GeneDx LLC (formerly GeneDx, Inc.) to Sema4 Holdings Corp. (Sema4).** Sema4 acquired GeneDx for an upfront payment of \$150 million in cash, subject to adjustments, plus 80 million shares of Sema4 Class A common stock, with up to an additional \$150 million in revenue-based milestones over the next two years (payable in cash or Sema4 shares at Sema4's discretion). Based on the closing price of Sema4's Class A common stock on April 29, 2022, the date the transaction closed, the total upfront consideration is approximately \$322 million and the total aggregate consideration including potential milestones is approximately \$472 million.
- **Pfizer launched NGENLA® (Somatrogen) injection in Germany, Japan and additional markets.** NGENLA was granted marketing authorization by the Ministry of Health, Labour and Welfare in Japan and by the European Commission in January and February of this year, respectively. With the achievement of these milestones, OPKO earned an aggregate of \$85 million in milestone payments. NGENLA is a once-weekly injection to treat pediatric patients with growth disturbance due to insufficient secretion of growth hormone. NGENLA provides pediatric patients, their caregivers and healthcare providers with a new treatment option for growth hormone deficiency that reduces the frequency of required injections from once-daily to once-weekly. Pfizer is OPKO's global commercial partner for Somatrogen.
- **Vifor Fresenius Medical Care Renal Pharma (VFMCRP) launched RAYALDEE® in Germany, and subsequently in Switzerland.** VFMCRP initiated the commercial launch of RAYALDEE (extended-release calcifediol) in Germany, the first launch of RAYALDEE outside the U.S. VFMCRP is OPKO's commercial partner for RAYALDEE in Europe and selected markets outside the U.S. VFMCRP has received marketing authorizations for RAYALDEE in 11 European countries and expects to launch the product in additional markets.

First Quarter Financial Results

- **Diagnostics:** Revenue from services in the first quarter of 2022 was \$286.6 million compared with \$507.0 million in the prior-year period, with the decrease primarily due to lower COVID-19 testing volume and related reimbursement, partially offset by an improvement in genomic test reimbursement and an increase in clinical and genomic test volumes. BioReference processed approximately 2.0 million COVID-19 PCR tests in the first quarter of 2022 versus 4.1 million in

the first quarter of 2021. Total costs and expenses were \$330.1 million in the first quarter of 2022 compared with \$439.9 million in the first quarter of 2021, resulting in an operating loss of \$43.5 million compared with operating income of \$67.0 million in the 2021 period. Operating income decreased primarily due to a decline in the volume of COVID-19 tests.

- **Pharmaceuticals:** Revenue from products in the first quarter of 2022 increased to \$36.6 million from \$33.9 million in the first quarter of 2021, with the increase primarily attributable to accelerating growth of OPKO's international pharmaceutical businesses. Revenue from sales of RAYALDEE in the first quarter of 2022 was \$5.1 million compared with \$5.8 million in the prior-year period. Revenue from the transfer of intellectual property was \$6.0 million in the first quarter of 2022 compared with \$4.3 million in the 2021 period. During the first quarter of 2022, OPKO recognized a \$3.0 million sales milestone from VFMC RP triggered by the first commercial sales in Europe. Total costs and expenses were \$60.7 million in the first quarter of 2022 compared with \$57.4 million in the prior-year period. The increase was driven by the amortization of NGENLA, which received approval in Europe and Japan during the first quarter of 2022, offset by a reduction in inventory reserve, legal expenses and selling expenses related to RAYALDEE. In addition, research and development expenses decreased reflecting reduced spending on the NGENLA development program. The operating loss was \$18.1 million in the first quarter of 2022 compared with an operating loss of \$19.2 million in the first quarter of 2021.
- **Consolidated:** Consolidated total revenues for the first quarter of 2022 were \$329.2 million compared with \$545.2 million for the comparable period of 2021. Operating loss for the first quarter of 2022 was \$72.4 million compared with operating income of \$38.5 million for the 2021 quarter. Net loss for the first quarter of 2022 was \$55.4 million, or \$0.08 per share, compared with net income of \$31.1 million, or \$0.05 per diluted share, for the 2021 quarter.
- **Cash and equivalents:** Cash and cash equivalents were \$102.3 million as of March 31, 2022. In addition, OPKO has \$64.8 million available under its line of credit with JP Morgan. Subsequent to the close of the quarter, OPKO received \$150 million gross proceeds from the sale of GeneDx to Sema4. Also, OPKO expects to receive \$85 million in milestone payments from Pfizer during the second quarter of 2022.

CONFERENCE CALL & WEBCAST INFORMATION

OPKO's senior management will provide a business update, discuss first quarter financial results and the ModeX acquisition, and answer questions during a conference call and live audio webcast today beginning at 4:30 p.m. Eastern time. Participants are encouraged to pre-register for the conference call using this [link](#). Callers who pre-register will be given a unique PIN to gain immediate access to the call and bypass the live operator. Those unable to pre-register may participate by dialing (866) 777-2509 (U.S.) or (412) 317-5413 (International). A webcast of the call may also be accessed at OPKO's Investor Relations [page](#) and [here](#).

A telephone replay will be available until May 16, 2022 by dialing (877) 344-7529 (U.S.) or (412) 317-0088 (International) and providing the passcode 6587528. A webcast replay will be available beginning approximately one hour after the completion of the live conference call [here](#).

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, whether the acquisition of ModeX, including the expansion of the executive management team, will positively impact the Company, whether expectations after completion of the merger will be met, whether we will receive milestone payments under the Sema4 transaction, the benefits of NGENLA, the risk of downturns and a changing regulatory landscape in the highly competitive healthcare industry, whether our products will launch in all the territories in which they have been approved for sale, the timing of such launches, the ability to get beneficial pricing approvals, whether RAYALDEE prescriptions will increase, 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, whether our business partners will be able to commercialize our products and successfully utilize our technologies, 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 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

	March 31, 2022	As of December 31, 2021
Assets:		
Cash and cash equivalents	\$ 102.3	\$ 134.7
Assets held for sale	316.4	315.0
Other current assets	335.4	373.3
Total current assets	754.1	823.0
In-process research and development and goodwill	519.1	1,110.8
Other assets	1,033.7	465.9
Total Assets	<u>\$ 2306.9</u>	<u>\$ 2399.7</u>
Liabilities and Equity:		
Current liabilities	\$ 280.7	\$ 301.8
Liabilities associated with assets held for sale	28.5	28.2
Convertible notes	210.5	187.9
Deferred tax liabilities, net	125.0	148.5
Other long-term liabilities, principally contract liabilities, leases, contingent consideration and lines of credit	47.3	48.2
Total Liabilities	692.0	714.6
Equity	1,614.9	1,685.1
Total Liabilities and Equity	<u>\$ 2306.9</u>	<u>\$ 2399.7</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 March 31,	
	2022	2021
Revenues		
Revenue from services	\$ 286.6	\$ 507.0
Revenue from products	36.6	33.9
Revenue from transfer of intellectual property	6.0	4.3
Total revenues	329.2	545.2
Costs and expenses		
Cost of revenues	243.9	363.5
Selling, general and administrative	117.5	112.3
Research and development	18.3	19.3
Contingent consideration	(0.1)	(1.0)
Amortization of intangible assets	22.0	12.6
Total Costs and expenses	401.6	506.7
Operating income (loss)	(72.4)	38.5
Other income and (expense), net	(4.2)	(6.8)
Income (loss) before income taxes and investment losses	(76.6)	31.7
Income tax benefit (provision)	21.3	(0.6)
Net income (loss) before investment losses	(55.3)	31.1
Loss from investments in investees	(0.1)	(0.0)
Net income (loss)	\$ (55.4)	\$ 31.1
Income (loss) per share, basic and diluted	\$ (0.08)	\$ 0.05
Weighted average common shares outstanding, basic and diluted	660,302,426	640,853,200

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